federal register

FRIDAY, MARCH 21, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 56

Pages 12763–12984

PART I

HIGHLIGHTS OF THIS ISSUE

This listing does not affect the legal status of any document published in this issue. Detailed table of contents appears inside.

(Continued Inside)

March 21, 1975—Pages 12763–12984

reminders

(The items in this list were editorially compiled as an aid to FEDERAL REGISTER users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

Rules Going Into Effect Today

NRC—Financial protection requirements and indemnity agreements; miscellaneous amendments..... 7081; 2–19–75

Daily List of Public Laws

NOTE: No acts approved by the President were received by the Office of the Federal Register for inclusion in today's LIST OF PUBLIC LAWS.

ATTENTION: Questions, corrections, or requests for information regarding the contents of this issue only may be made by dialing 202–523–5266. For information on obtaining extra copies, please call 202–523–5240. To obtain advance information from recorded highlights of selected documents to appear in the next issue, dial 202–523–5022.

federal register

Area Code 202 Phone 523–5240

Published daily, Monday through Friday (no publication on Saturdays, Sundays, or on official Federal holidays), by the Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C., Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The FEDERAL REGISTER provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive orders and Federal agency documents having general applicability and legal effect, documents required to be published by Act of Congress and other Federal agency documents of public interest.

The FEDERAL REGISTER will be furnished by mail to subscribers, free of postage, for $5.00 per month or $45 per year, payable in advance. The charge for individual copies is 75 cents for each issue, or 75 cents for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

contents

list of cfr parts affected

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, follows beginning with the second issue of the month.

A cumulative guide is published separately at the end of each month. The guide lists the parts and sections affected by documents published since January 1, 1974, and specifies how they are affected.

CUMULATIVE LIST OF PARTS AFFECTED—MARCH

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during March.

1 CFR

301 ... 10441
302 ... 10442
304 ... 10442

2 CFR

101 ... 12764
102 ... 12766
201 ... 12767
202 ... 12767

3 CFR

PROCLAMATIONS:

3279 (Amended by Proc. 4355) ... 10437
4313 (Amended by Proc. 4353) ... 8931, 10433
4345 (Amended by Proc. 4353) ... 8931, 10433
4353 ... 8931, 10433
4354 ... 10435
4355 ... 10437

EXECUTIVE ORDERS:

Dec. 9, 1920 (Revoked in part by PLO 5491) ... 11727
10973 (Amended by E.O. 11841) ... 8933
11803 (Amended by E.O. 11842) ... 8935
11837 (Amended by E.O. 11842) ... 8935
11841 ... 8933
11842 ... 8935
11843 ... 12639

5 CFR

180 ... 12251
213 ... 8937, 10655, 11705, 11859, 12251, 12767
752 ... 12251
2401 ... 10951

7 CFR

2 ... 12798,
20 ... 11345
53 ... 11535
68 ... 10472
106 ... 11860
271 ... 8937, 10165
272 ... 8937
301 ... 8763, 11705, 12469
354 ... 12646
401 ... 8770, 8771
612 ... 12067
620 ... 12472
621 ... 12473
622 ... 12475
623 ... 12480
624 ... 12480
650 ... 10951
905 ... 11345, 12646
907 ... 10474, 11706, 12647
908 ... 8772, 12648
910 ... 10655, 11860, 12799
944 ... 11346
966 ... 10953
971 ... 10165
982 ... 8773
984 ... 12481
1207 ... 11860
1421 ... 12799, 12802
1801 ... 10953
1806 ... 10953
1813 ... 11707

7 CFR—Continued

PROPOSED RULES:

25 ... 8824
25A ... 8824
29 ... 10190
52 ... 12092
102 ... 11728
210 ... 10192
220 ... 11729
271 ... 10481, 12806
275 ... 12806
908 ... 11587
911 ... 11876
915 ... 11876
916 ... 11729
917 ... 11729
959 ... 10996
1094 ... 11878, 12660
1096 ... 11879
1464 ... 10192, 12670
1701 ... 10192, 11357

8 CFR

PROPOSED RULES:

242 ... 12514

9 CFR

72 ... 12768
73 ... 8938, 12768
74 ... 12768
78 ... 8773
82 ... 11861, 12768
97 ... 11346
91 ... 10443
113 ... 8774, 11587
304 ... 11346
305 ... 11346
317 ... 11346, 11347
381 ... 11347

PROPOSED RULES:

11 ... 12514
112 ... 11879
113 ... 11587, 11879
317 ... 10191
381 ... 10191

10 CFR

Ch. I ... 8774
202 ... 11707
211 ... 10165, 10444
212 ... 10444
661 ... 10953
Ch. III ... 8794

RULINGS:

1975-2 ... 10655

PROPOSED RULES:

2 ... 8832
21 ... 8832
31 ... 8832
35 ... 8832
40 ... 8832
210 ... 10195, 11363
212 ... 12287
213 ... 12287

12 CFR

22 ... 12068
Ch. II ... 10660
217 ... 12251

12 CFR—Continued

225 ... 11710
250 ... 12252
270 ... 10661
272 ... 10661
309 ... 11547
329 ... 11711
545 ... 8795, 11548, 11711
556 ... 12482
563 ... 12483
564 ... 10449
584 ... 11712
602 ... 10450
701 ... 8938
708 ... 10167
720 ... 10450

PROPOSED RULES:

11 ... 10602
205 ... 11739
206 ... 10322
335 ... 10376
531 ... 11363
541 ... 12113
544 ... 12113, 12121
545 ... 12113, 12121
552 ... 12113
701 ... 8967
706 ... 12124
707 ... 12125
745 ... 8967

13 CFR

114 ... 10661
301 ... 12769
305 ... 12483
314 ... 12484

PROPOSED RULES:

107 ... 11740
121 ... 10486, 12125

14 CFR

39 ... 8795, 8796, 8937, 10450, 10661, 10662, 10951, 11549, 11550, 11861, 11862, 12068, 12252, 12484, 12771–12773
71 ... 8796, 8797, 10169–10172, 10662, 10663, 10951, 11550, 11551, 11712, 11862, 11863, 12110, 12252, 12253, 12485, 12649, 12774
73 ... 8940, 10663, 12110
91 ... 10451, 12253
95 ... 12485
97 ... 10451, 11712, 12649
121 ... 10173
139 ... 11713
288 ... 10174, 10663
302 ... 10967
310 ... 10663
311 ... 10664

PROPOSED RULES:

21 ... 10802
23 ... 10802
25 ... 10802
27 ... 10802, 12518
29 ... 10802, 12518
31 ... 10802
33 ... 10802
35 ... 10802
37 ... 11002
39 ... 11003, 11596, 12809

FEDERAL REGISTER PAGES AND DATES—MARCH

Pages	*Date*
8764–8929	Mar. 3
8931–10163	4
10165–10432	5
10433–10654	6
10655–10950	7
10951–11344	10
11345–11534	11
11535–11704	12
11705–11858	13
11859–12066	14
12067–12250	17
12251–12468	18
12469–12638	19
12639–12762	20
12763–12984	21

rules and regulations

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

Title 2—Clemency

CHAPTER I—PRESIDENTIAL CLEMENCY BOARD

ADMINISTRATIVE PROCEDURES AND SUBSTANTIVE STANDARDS

The Presidential Clemency Board published its proposed administrative procedures and substantive standards on November 27, 1974 (39 FR 41351). Since that time, the Board has considered the first military cases before it, and has had the benefit of more than 40 comments on its proposed regulations. With the benefit of this additional experience and these comments, the Board publishes the final regulations setting out its procedures and standards.

It is the intent of the Board to provide notice to the public of the standards it uses to make recommendations to the President concerning individual applications for clemency. The Board also wishes to ensure equity and consistency for applicants under the President's clemency program.

Because it is a temporary organization within the White House Office, the sole function of which is to advise the President with respect to the exercise of his constitutional power of executive clemency, the Board does not consider itself formally bound by the Administrative Procedure Act. Nonetheless, within the time and resource constraints governing it, the Board wishes to adhere as closely as possible to the principles of procedural due process. The administrative procedures established in these regulations reflect this decision.

The Board may publish changes in individual sections as it deems necessary. The Board welcomes continuing comment on problems which may arise in the application of particular sections of these procedures and invites recommendations on how best these problems may be resolved.

Several dozen technical changes have been made in these regulations in response to new circumstances that were presented to the Board. Some clarify significantly the rights and procedures available to applicants. The following is an explanation of those changes which seem to the Board to be most significant:

Jurisdiction. Section 101.3 has been added in order to incorporate the criteria for determining whether or not a person is eligible for consideration by the Presidential Clemency Board. It restates the criteria established in Proclamation 4313 (Announcing a Program for the Return of Vietnam Era Draft Evaders and Military Deserters) and repeated in Executive Order 11803 (Establishing a Clemency Board * * *).

Remedies. Section 101.4 has been added to explain the remedies available from the Presidential Clemency Board. It states the authority with which the Board is vested by Executive Order 11803, issued pursuant to Proclamation 4313.

A Presidential pardon restores those federal civil rights lost as a result of a felony conviction. State law recognizes Presidential pardons as a matter of comity, usually restoring the right to vote in federal and state elections, to hold public office, and to obtain licenses for trades and professions from which convicted felons are barred under state law. Since conviction by military court-martial is treated as a felony conviction by many states, and since an Undesirable Discharge may have the same consequences as a court-martial conviction, the benefits of a pardon apply to former servicemen as well as to civilian draft evaders.

A Clemency Discharge neither entitles its recipient to veterans benefits nor bars his receiving those benefits to which he is otherwise entitled. The Veterans Administration and other agencies may extend veterans' benefits to some holders of a Clemency Discharge, but it is contemplated that most will not receive veterans benefits.

Availability of files to applicant and his representative. Section 101.7(c) clarifies which files an applicant and his representative have a right to see. At the offices of the Board, information collected by the Board independently of any other government agency is readily available to an applicant or his representative. All files obtained from other agencies are available to the extent not barred by the rules of the agency owning the file. For example, the Selective Service System file is available to him and his representative. Files from another agency are cited in a summary when they are used as the basis of statements in that summary. Reason for denial of access to any of these files is stated in writing upon request.

This subsection is in response to comments that §§ 201.5(b) and 201.6(c), read together, were either unclear or overbroad.

Completed case summary. The completed case summary consists of the initial case summary, amendments as described in the §§ 101.8 (c) and (e), and the materials submitted by the applicant and his representative as described in § 101.8(b). Where, in the opinion of the Board, there is a conflict of fact, false statement, or omission material to the Board's consideration of an aggravating or mitigating circumstance, as specified in §§ 102.3 and 102.4, the case is tabled. The action attorney is instructed to obtain additional facts.

This is in response to comments from the private bar.

Hearing before the Board. Subsection 101.9(c) provides for a personal appearance as a matter of right if an applicant can show that an oral presentation is necessary to the Board's understanding of a mitigating circumstance or an aggravating circumstance which applies to his case. The Board has provided a right to personal appearance in response to several comments.

Reconsideration. Subsection 101.11(b) has been amended in order to add standards which must be met if the Board is to consider an applicant's petition for reconsideration. In the proposed regulations, consideration of such petition by the Board was a matter of discretion. This amendment limits the circumstances under which reconsideration will be granted, but provides that when an applicant shows that any of those circumstances are present, reconsideration will be granted as a matter of right.

Transmittal to other agencies of Presidential decisions. Section 101.12 provides that grants of immediate pardon by the President are transmitted formally to other government agencies, as appropriate. Pending completion of the alternative service requirement, grants of conditional clemency are communicated to another federal agency only to the extent this information is necessary for the agency to perform its functions under the clemency program or for other necessary action respecting the applicant. Upon completion of alternative service, notification of the pardon is forwarded to all appropriate agencies. Denials of clemency by the President are held confidential by the Board.

The intent of this section, adopted here in response to several comments is that a person who applies for clemency should not be prejudiced in his pursuit of other remedies through the military services' discharge review processes or elsewhere.

Other remedies available to applicant. Section 101.15(b) requires that Board staff inform both applicants to the Board and persons who inquire about the clemency program, but are clearly not under the Board's jurisdiction, of the remedies available to them under military discharge review processes and through the judiciary. Applicants to the Board or to one of the other agencies administering part of the clemency program may pursue such other remedies simultaneously or subsequently to, or instead of their remedies under the clemency program. The Board's staff informs them of their other options.

Aggravating and mitigating circumstances. Sections 102.3 and 102.4 contain new aggravating and mitigating circumstances which the Board deems material to its decisions.

The Board notes that it has seen a number of cases of persons who behaved with valor during combat, but then committed AWOL offenses because of mental stress caused by combat. The Board calls attention to this mitigating circumstance as one which it considers particularly important in some cases.

A number of comments from the private bar have suggested that the Board should add as a mitigating circumstance "evidence that an applicant would probably have obtained a Selective Service status or military discharge or reassignment beneficial to him, but failed to apply due to lack of knowledge or confusion." Mitigating circumstances #1, 8, and 9, in conjunction, are adequate to meet this problem.

Calculation of length of alternative service. Subsection 102.5(c) has been added in order to make clear the Board's decision that the initial baseline period of alternative service for applicants with Undesirable Discharges is three (3) months.

Eligibility of clemency recipients for military discharge review remedies. The Presidential Clemency Board notes, although the matter is not one for inclusion in its regulations, that it has received numerous comments which assume that a recipient of executive clemency under the President's clemency program is ineligible for consideration under the military services' discharge review processes.

This is incorrect. Any applicant to the Board for executive clemency may also seek review of his discharge through one of the military services' discharge review boards or boards for the correction of military records. Applying to the Board does not exclude a former serviceman from the jurisdiction of the military services' boards, nor does it preclude the remedies which are available from those boards.

The Presidential Clemency Board notes that a veteran who receives a Clemency Discharge through the Board may subsequently seek, according to the Department of Defense, an upgrading of that discharge through the military services' normal discharge review processes.

This chapter will become effective immediately.

Issued in Washington, D.C. on March 18, 1975.

CHARLES E. GOODELL,
Chairman, Presidential Clemency Board, The White House.

1. Part 101 is added to read as follows:

PART 101—ADMINISTRATIVE PROCEDURES

Sec.

AUTHORITY: Executive Order 11803, 39 FR 33297, as amended.

§ 101.1 Purpose and scope.

This part establishes the procedures of the Presidential Clemency Board. Certain other matters are also treated, such as the assistance to be given to individuals requesting determinations of jurisdiction, or requesting information respecting those parts of the Presidential Clemency Program which are administered by the Department of Defense and the Department of Justice under Presidential Proclamation 4313 (39 FR 33293).

§ 101.2 General definitions.

"Action attorney" means an attorney on the staff of the Board who is assigned an applicant's case.

"Applicant" means an individual who invokes the jurisdiction of the Board, and who has submitted an initial filing.

"Board" means the Presidential Clemency Board as created by Executive Order 11803 (39 FR 33297) or any duly authorized panel of that Board.

§ 101.3 Jurisdiction.

Jurisdiction lies with the Board with respect to a particular person if such person applies to the Board not later than March 31, 1975 and:

(a) He has been convicted for failure under the Military Selective Service Act (50 App. U.S.C. 462) or any rule or regulation promulgated thereunder to register or register on time; to keep the local board informed of his current address, to report for or submit to preinduction or induction examination, to report for or submit to induction itself, or to report for or submit to, or complete (alternative) service under section 6(j) of the Act for offenses committed during the period from August 4, 1964 to March 28, 1973, inclusive; or

(b) He has received a punitive or undesirable discharge as a consequence of offenses under Article 85 (desertion), 86 (AWOL), or 87 (missing movement) of the Uniform Code of Military Justice (10 U.S.C. 885, 886, 887) that occurred between August 4, 1964 and March 28, 1973, inclusive, or is serving a sentence of confinement for such violation.

(c) Jurisdiction will not lie with respect to an individual precluded from re-entering the United States under 8 U.S.C. 1182(a)(22) or other law.

§ 101.4 Remedies.

(a) The Board is empowered only to make recommendations to the President on clemency applications. The Board has no final authority of its own. The Board may recommend to the President that he take one or more of the following actions:

(1) Grant an unconditional pardon without a requirement of alternative service;

(2) Grant an unconditional pardon upon the satisfactory completion of a specified period of alternative service not to exceed 24 months;

(3) Grant a clemency discharge in substitution for a Dishonorable, Bad Conduct, or Undesirable Discharge;

(4) Commute the sentence; or

(5) Deny clemency.

(b) In unusual circumstances and as authorized by Executive Order 11803, the Board may make other recommendations as to the form that clemency should take. This shall only be done in order to give full effect to the intent and purposes of the Presidential Clemency program.

§ 101.5 Initial filing.

(a) In order to comply with the requirements of Executive Order 11803, as amended, an individual must make an initial filing to the Board not later than March 31, 1975. The Board considers sufficient as an initial filing any written communication postmarked not later than March 31, 1975, and received by the Board, the Department of Justice, the Department of Defense, the Department of Transportation, or the Selective Service System. In the communication an individual or his representative must request consideration of the individual's case or raise questions which evidence a serious interest in applying for the program. Oral applications made not later than March 31, 1975 are considered sufficient if reduced to writing, and postmarked not later than May 31, 1975.

(b) If an initial filing is made by a representative, the case is not considered by the Board unless and until the applicant submits a written confirmation of his clemency application. This confirmation by the applicant may be sent either directly or through a representative, but it must be mailed not later than May 31, 1975. A statement by an attorney that he is acting on behalf of an applicant is sufficient. Applications by a representative on behalf of an applicant may be considered by the Board where good cause is shown why the applicant is unable to apply.

§ 101.6 Application form.

(a) Upon receipt of an initial filing, a member of the Board's staff makes a determination of probable jurisdiction. Persons who are clearly beyond the Board's jurisdiction are so notified in writing. A person who questions this determination should promptly write the General Counsel, Presidential Clemency Board, The White House, Washington, D.C. 20500, stating his reasons for questioning the determination. The General Counsel of the Board makes the final determination of probable jurisdiction and

so notifies the applicant or his representative in writing stating the reasons why. In doubtful cases, a final determination of jurisdiction is made by the Board.

(b) A person who has been notified that jurisdiction does not lie in his case is considered as having made a timely filing if the final determination is that the Board has jurisdiction over his case.

(c) A person who is within the jurisdiction of the Board is sent an application form, information about the Presidential clemency program, instructions for the preparation of the application form, a statement describing the Board's procedures and method of determining cases, and a list of volunteer counseling services.

(d) The person is urged to return the completed application form to the Board as soon as possible. Completed application forms must be postmarked within sixty (60) days of the time they were mailed by the Board, in order to qualify for the Board's consideration as a matter of right.

§ 101.7 Assignment of Action Attorney, case number, and determination of jurisdiction.

(a) Upon receipt by the Board of the completed application form or of information sufficient for the Board to request the records and files specified in paragraph (b) of this section, the applicant's case is reviewed for preliminary determination of the Board's jurisdiction. If it appears that the Board has jurisdiction over the case, a file is opened and a case number assigned. The Board will then request from all appropriate government agencies the relevant records and files pertaining to the applicant's case.

(b) In normal circumstances, the relevant records and files for civilian cases are the applicant's files from the Bureau of Prisons and information that he has sent to the Board. For military cases, they will include the applicant's military personnel records, military clemency folder, record of court martial, if any, and information that the applicant has sent to the Board. Applicants and their representatives have the right to request that the Board consider other pertinent files. The Board will attempt to comply with these requests.

(c) At the offices of the Board, information collected by the Board independently of any other agency is readily available to an applicant or his representative. All files obtained from other agencies are available to the extent not barred by the rules of the agency owning the file. Files from another agency are cited in a summary when they are used as the basis of statements in that summary. Reason for denial of access to any of these files is stated in writing upon request.

(d) Where the initial filing contains adequate information, the Board staff may assign a case number and request records and files prior to receipt of the completed application form.

(e) If the Action Attorney determines that the Board does not have jurisdiction in a particular case, he promptly notifies the applicant or his representative in writing, stating the reasons for such a determination.

(f) An applicant or his representative who questions this adverse determination of jurisdiction should write the General Counsel of the Board in accordance with the provisions of § 101.6(a).

§ 101.8 Initial case summary.

(a) Upon receipt of the necessary records and files, the Action Attorney prepares an initial case summary of the applicant's case. The files, records, and any additional sources used in preparing the initial case summary are listed. No other material is used. The initial case summary includes the name and business telephone number of the Action Attorney who may be contacted by the applicant or his representative.

(b) The initial case summary is sent by certified mail to the applicant or his representative. The summary is accompanied by an instruction sheet describing the method by which the summary was prepared and by a copy of the guidelines used by the Board for the determination of cases. Applicants are encouraged to review the initial case summary for accuracy and completeness and advised of their right to submit additional sworn or unsworn material. Additional material may be submitted in any length. Nothing over three (3) single-spaced, typewritten, letter-sized pages in length is read verbatim to the Board. Where necessary, therefore, an applicant should summarize his additional material to comply with this verbatim presentation requirement. If this is not done, the Action Attorney does so.

(c) At any time before Board consideration of his case, an applicant may submit evidence of inaccurate, incomplete, or misleading information in the complete Board file or other files. This information is incorporated in applicant's Board file.

(d) An applicant's case is ready for final consideration by the Board not sooner than thirty (30) days after the initial case summary is mailed to the applicant. Material which amends or supplements the applicant's initial case summary must be postmarked within this thirty (30) day period to ensure that it is considered. An applicant's request that this thirty (30) day period be extended is liberally granted by the Action Attorney, if the request is received prior to Board action and is reasonable.

(e) Upon receipt of the applicant's response to the initial summary, the Action Attorney notes all such amendments, supplements, or corrections on the initial summary submitted by the applicant or his representative. All such amendments are attached to the initial case summary with notation by the Action Attorney of any discrepancies of fact which in his opinion remain unresolved. The complete case summary consists of the initial summary, amendments as described in paragraph (c) and this section, and the materials submitted by the applicant and his representative as described in paragraph (b) of this section.

(f) Where, in the opinion of the Board, there is a conflict of fact, false statement, or omission material to the Board's consideration of an aggravating or mitigating circumstance, as specified in §§ 102.3 and 102.4, the case is tabled. The Action Attorney is then instructed to obtain additional facts.

§ 101.9 Consideration before the Board.

(a) At a regularly scheduled meeting of the Board, an applicant's case is considered. The Board may provide by rule, however, that cases will be initially considered by panels of not less than three Board members. Any case may be brought before a majority of the full Board for consideration at the request of a panel member. Panel recommendations will be considered and approved by a majority of the full Board.

(b) The Action Attorney presents to the Board a brief statement of the completed case summary and, as provided in § 101.8(b), the material submitted by the applicant.

(c) The Board grants a personal appearance to an applicant and his representative if they can show in a written statement that such an appearance is necessary to the Board's understanding of the applicant's case. The Board considers each request for an oral presentation at a regular meeting and informs the applicant and his representative whether or not his request has been granted.

(d) Any oral presentation granted by the Board shall not exceed a reasonable period of time. Neither applicant nor his representative may be present when the Board begins deliberations, but should remain available for further consultation immediately thereafter.

(e) After due deliberation the Board decides upon its recommendation to the President listing the factors it considered in making its recommendation.

§ 101.10 Recommendations to the President.

(a) At appropriate intervals, the Chairman of the Board submits to the President certain master warrants listing the names of applicants recommended for executive clemency and a list of the names of applicants considered by the Board but not recommended for clemency. The Chairman will also submit such terms and conditions for executive clemency, if any, that have been recommended in each case by the Board.

(b) Following action by the President, the Board sends notice of such action in writing to all applicants whose names were submitted to the President. Each applicant is sent a list of the mitigating and aggravating circumstances decided by the Board to be applicable in his case.

§ 101.11 Reconsideration.

(a) An applicant may ask the Board for reconsideration of his case. Petitions for reconsideration, including any supplementary material, must be postmarked within thirty (30) days of Board mailing specified in § 101.10(b).

(b) At a regularly scheduled Board meeting, a majority of the Board being present, it will reconsider the applicant's case if the applicant's petition shows one or more of the following:

(1) New fact, material to the disposition of his case, which the Board had not previously considered, provided that the applicant explains to the Board's satisfaction why such facts were not submitted earlier. New facts are, for purposes of this section, considered material only if they relate to presence or absence of an aggravating circumstance under § 102.3 or of a mitigating circumstance under § 102.4, or to calculation of length of alternative service under § 102.5.

(2) Factual error, in the complete case summary or other document considered by the Board that was material to the Board's disposition of his case and detrimental to him; or

(3) Procedural error that was material to the Board disposition of his case and detrimental to him.

(c) The Board may at its discretion permit an applicant or his representative a reasonable period of time to present before the Board an oral statement. The provisions of § 101.9 apply to any request for a personal appearance.

(d) After due deliberation, the Board may:

(1) Leave unchanged its original recommendation;

(2) Where executive clemency was not granted, recommended to the President that he grant it in accordance with such terms and conditions as may be appropriate;

(3) Where executive clemency was granted, recommend to the President that he diminish the length of alternative service on which the grant of clemency has been conditioned or immediately grant a full and unconditional pardon.

(e) Applicants requesting reconsideration are so notified in writing of the Board's decision, together with the reasons.

§ 101.12 Transmittal to other agencies of clemency decisions.

(a) The Chairman of the Board may forward for further action to the Secretaries of the Army, Navy, and Air Force, the Secretary of Transportation, the Director of the Selective Service System, and the Attorney General, as appropriate, only such information about the President's decision as is necessary in the Board's judgment for the agency to perform its functions under the President's clemency program or for other necessary action respecting the applicant.

(b) A decision by the President to deny executive clemency to a person who has fully discharged his obligations under the law for his offense is not transmitted by the Board to any other agency of the United States Government or to any other person, public or private, except the applicant or his representative.

§ 101.13 Confidentiality of communications.

(a) In order to have his case considered by the Board, an applicant need submit only information sufficient for a determination of jurisdiction and for the retrieval of necessary official records and files. The application form requires the applicant's name, date of birth, selective service number, military branch and service number, if applicable, information concerning the draft evasion offense or absence-related military offense, and the disposition thereof, and the mailing address and telephone number of either the applicant or his representative.

(b) The Board takes all steps in its power to protect the privacy of applicants and potential applicants to the Presidential clemency program. No personal information concerning an applicant or potential applicant is released by the Board unless disclosure is necessary for the proper functioning of the Board (e.g., to the Selective Service System so that alternative service may be performed) or unless required by law.

(1) Information which reveals commission of a serious crime, unrelated to any offense subject to the jurisdiction of the Presidential clemency program is forwarded to the appropriate authorities.

(2) As required by law, the name (but only the name) of a recipient of clemency is released to the public.

(c) All personal information obtained by the Board in the course of reviewing an applicant's case, except information obtained from other agencies, is sealed by the Board. This happens when the applicant has received his pardon from the President or when the Board's operations terminate, whichever is earlier.

(d) Upon announcement of the President's disposition of a case, the Board may publish a summary of that case after the removal of all information likely to identify the individual.

§ 101.14 Representation before the Board.

(a) Although an applicant may bring his case before the Board without a representative, each applicant is advised of his right to representation and encouraged to seek counsel experienced in military or selective service law. A representative need not be an attorney, although legal counsel is recommended to applicants. The Board staff advises applicants of those private sources which are available to provide counseling.

§ 101.15 Requests for information about the Clemency Program.

(a) Upon receipt by the Board of a request for information from an individual clearly not within the jurisdiction of the Board, the Board's staff attempts to determine his eligibility for any other part of the Presidential clemency program. If requested, the Board attorney preserves the confidentiality of the individual's location.

(b) A member of the Board's staff also informs any individual of other remedies available to him, including those from the Departments of Justice and Defense and through judicial processes.

§ 101.16 Postponement of Board consideration and of the start of alternative service.

(a) An applicant may request that the Board defer consideration of his case for a reasonable period of time. Such deferments are liberally granted provided that they do not result in an undue disruption of the Board's operations or delay the final termination of the Board's operations.

(b) An applicant who has been granted executive clemency conditioned upon a period of alternative service may ask for the postponement of the beginning of his period of alternative service for a reasonable period of time. The reasons for which a postponement may be granted include personal hardship and conflicting obligations. The Board makes every effort, consistent with its own authority and that of the Selective Service System to accommodate postponement requests.

2. Part 102 is added to read as follows:

PART 102—SUBSTANTIVE STANDARDS

Sec.

AUTHORITY: Executive Order 11803, 39 FR 33297, as amended.

§ 102.1 Purpose and scope.

This section contains the standards which the Board employs in deciding whether or not to recommend that the President grant executive clemency, whether or not clemency should be conditioned upon satisfactory completion of a period of alternative service, and, if so, what the length of this alternative service is.

§ 102.2 Board recommendations.

In each case the Board decides first whether or not it will recommend to the President that the applicant be granted executive clemency. In reaching this decision, the Board considers the aggravating circumstances in § 102.3 and the mitigating circumstances in § 102.4.

§ 102.3 Aggravating circumstances.

(a) Presence of any of the aggravating circumstances listed below may either disqualify an individual for executive clemency or cause the Board to recommend to the President a period of alternative service exceeding the applicant's "baseline period of alternative service," as determined under § 102.5.

(b) Aggravating circumstances of which the Board takes notice are:

(1) Other adult criminal convictions;

(2) False statement by applicant to the Presidential Clemency Board;

(3) Use of force by applicant collaterally to AWOL, desertion, or missing movement or civilian draft evasion offense;

(4) Desertion during combat;

(5) Evidence that applicant committed offense for obviously manipulative and selfish reasons;

(6) Prior refusal to fulfill court ordered alternative service;
(7) Violation of probation or parole;
(8) Multiple AWOL/UA offenses; and
(9) AWOL/UA of extended length.

(c) Whenever an additional aggravating circumstance not listed is considered by the Board in the discussion of a particular case, and is material to the disposition of that case, the Board postpones final decision of the case and immediately informs the applicant and his representative of their opportunity to submit evidence material to the additional circumstance.

§ 102.4 Mitigating circumstances.

(a) Presence of any of the mitigating circumstances listed below or of any other appropriate mitigating circumstance is considered as cause for recommending that the President grant executive clemency to an applicant, and as cause for reducing the applicant's alternative service below the baseline period, as determined under § 102.5.

(b) Mitigating circumstances of which the Board takes notice are:

(1) Lack of sufficient education or ability to understand obligations or remedies available under the law;
(2) Personal and family problems either at the time of offense or if applicant were to perform alternative service;
(3) Mental or physical condition;
(4) Employment and other activities of service to the public;
(5) Service-connected disability, wounds in combat or decorations for valor in combat;
(6) Period of creditable military service;
(7) Tours of service in the war zone;
(8) Substantial evidence of personal or procedural unfairness;
(9) Denial of conscientious objector status, of other claim for Selective Service exemption or deferment, or of a claim for hardship discharge, compassionate reassignment, emergency leave, or other remedy available under military law, on procedural, technical, or improper grounds, or on grounds which have subsequently been held unlawful by the judiciary;
(10) Evidence that an applicant acted for conscientious, not manipulative or selfish reasons;
(11) Voluntary submission to authorities by applicant;
(12) Behavior which reflects mental stress caused by combat;
(13) Volunteering for combat, or extension of service while in combat;
(14) Above average military conduct and proficiency; and
(15) Personal decorations for valor.

(c) An applicant may bring to the Board's attention any other factor which he believes should be considered.

§ 102.5 Calculation of length of alternative service.

(a) Having reached a decision to recommend that the President grant executive clemency to a particular applicant, the Board will then decide whether or not clemency should be conditioned upon a specified period of alternative service and, if so, what length that period should be:

(1) The starting point for calculation of length of alternative service will be 24 months.

(2) The starting point will be reduced by three times the amount of prison time served.

(3) The starting point will be further reduced by the amount of prior alternative service performed, provided that the prescribed period of alternative service has been satisfactorily completed or is being satisfactorily performed.

(4) The starting point will be further reduced by the amount of time served on probation or parole, provided that the prescribed period has been satisfactorily completed or is being satisfactorily performed.

(5) Subject to paragraphs (b) and (c) of this section, the baseline period of alternative service will be the remainder of these four subtractions or final sentence to imprisonment, whichever is less.

(b) In no case will the baseline period of alternative service be less than three (3) months.

(c) For applicants who have received an Undesirable Discharge from a military service, the baseline period of alternative service shall be three (3) months.

(d) The Board may consider mitigating circumstances as cause for recommending clemency upon satisfactory completion of a period of alternative service that is less than an applicant's baseline period of alternative service, or for recommending an immediate pardon.

(e) In cases in which aggravating circumstances are present and are not, in the Board's judgment, balanced by mitigating circumstances, the Board may consider such aggravating circumstances as cause for recommending clemency upon satisfactory completion of a period of alternative service exceeding, by three (3), six (6), or nine (9) additional months, the applicant's baseline period of alternative service. In extraordinary cases, as an alternative to denying clemency, the Board may increase the baseline period to a maximum of not more than 24 months.

PART 201—[REVOKED]

3. Part 201 is revoked.

PART 202—[REVOKED]

4. Part 202 is revoked.

[FR Doc.75-7464 Filed 3-20-75;8:45 am]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

ACTION

Section 213.3359 is amended to show that one position of Special Assistant to the Deputy Director is excepted under Schedule C.

Effective on March 21, 1975, § 213.3359 (s) is added as set out below.

§ 213.3359 ACTION.

* * * * *

(s) One Special Assistant to the Deputy Director.

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954–1958, Comp. p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7437 Filed 3-20-75;8:45 am]

PART 213—EXCEPTED SERVICE

Department of Commerce

Section 213.3314 is amended to show that one position of Confidential Assistant to the Assistant Secretary for Economic Development is excepted under Schedule C. This Section is further amended to show that one position of Confidential Secretary to the Assistant Secretary for Economic Development is reestablished under Schedule C.

Effective on March 21, 1975, §§ 213.3314 (q) (1) is amended and (q) (12) is added as set out below.

§ 213.3314 Department of Commerce.

* * * * *

(q) *Office of the Assistant Secretary for Economic Development.* (1) Confidential Secretary to the Assistant Secretary.

* * * * *

(12) One Confidential Assistant to the Assistant Secretary.

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954–58, Comp. p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc.75-7438 Filed 3-20-75;8:45 am]

PART 213—EXCEPTED SERVICE

Department of the Treasury

Section 213.3305 is amended to show that one position of Staff Assistant to the National Director, U.S. Savings Bonds Division, is excepted under Schedule C.

Effective on March 21, 1975, § 213.3305 (a) (7) is added as set out below.

§ 213.3305 Department of the Treasury.

(a) *Office of the Secretary.* * * *

(7) One Staff Assistant to the National Director, U.S. Savings Bonds Division.

* * * * *

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954–58, Comp. p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] JAMES C. SPRY,
Executive Assistant to the Commissioner.

[FR Doc.75-7439 Filed 3-20-75;8:45 am]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

SPLENETIC FEVER IN CATTLE; SCABIES IN CATTLE AND SHEEP

Deletion of Vatside and Field Tests as Requirements for Specific Approval of Proprietary Dips

Statement of considerations. The provisions in 9 CFR Parts 72, 73 and 74 allow certain cattle and sheep to be moved interstate after dipping in certain permitted proprietary brands of pesticides when such pesticides have been specifically approved by the Veterinary Services unit of the Department. Heretofore, as a condition for such approval, Veterinary Services required that a vatside or field test be available as a means of determining the strength of the dip. It has been found that such tests are of limited use and that they are not fully reliable in some cases. Therefore, such vatside or field tests are deleted as requirements for specific approval of such proprietary dips by Veterinary Services. A dip will be granted specific approval if it is registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.) and if it meets requirements for efficacy and stability and effectiveness under field conditions.

Accordingly, Part 72, Part 73, and Part 74, Title 9, Code of Federal Regulations are amended in the following respects:

PART 72—TEXAS (SPLENETIC) FEVER IN CATTLE

In § 72.13, in footnote 2 in the second sentence the phrase "and vatside tests," is deleted; paragraph (b)(1) and the second sentence in paragraph (c) are amended to read:

§ 72.13 Permitted dips and procedures.

* * * * *

(b) * * *

(1) Approved proprietary brands of an arsenical solution used at a concentration of twenty-two hundredths of 1 percent of arsenous oxide in solution.[2]

* * * * *

(c) * * * Before a dip will be specifically approved as a permitted dip for the eradication of ticks, the Veterinary Services will require that the product be registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.); that its efficacy and stability have been demonstrated; that trials have been conducted to determine that its concentration can be maintained and that under actual field conditions the dipping of cattle in a bath of definite strength will effectually eradicate ticks without injury to the animals dipped.

* * * * * *

PART 73—SCABIES IN CATTLE

In § 73.10, in paragraph (c) the second sentence is amended to read:

§ 73.10 Permitted dips; substances allowed.

* * * * *

(c) * * * Before a dip will be specifically approved as a permitted dip for the eradication of scabies in cattle, the Veterinary Services will require that the product be registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.); that is efficacy and stability have been demonstrated; that trials have been conducted to determine that its concentration can be maintained and that under actual field conditions the dipping of cattle in a bath of definite strength will effectually eradicate scabies infection without injury to the animals dipped.

PART 74—SCABIES IN SHEEP

In § 74.24, in paragraph (c) the second sentence is amended to read:

§ 74.24 Permitted dips; substances allowed.

* * * * *

(c) * * * Before a dip will be specifically approved as a permitted dip for the eradication of scabies in sheep, the Veterinary Services will require that the product be registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. 135 et seq.); that its efficacy, and stability have been demonstrated; that trials have been conducted to determine that its concentration can be maintained and that under actual field conditions the dipping of sheep in a bath of definite strength will effectually eradicate scabies infection without injury to the animals dipped.

(Secs. 4 and 5, 23 Stat. 32, as amended; sec. 2, 32 Stat. 792, as amended; sec. 3, 33 Stat. 1265, as amended; (21 U.S.C. 111, 120, 125); 37 FR 28464, 28477; 38 FR 19141.)

Effective date. The foregoing amendments shall become effective March 21, 1975.

The amendments in effect relieve restrictions presently imposed but no longer deemed useful to prevent the spread of Texas (splenetic) fever, cattle scabies, and sheep scabies, and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedures provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendments are impracticable and unnecessary, and good cause is found for making them effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 17th day of March 1975.

PIERRE A. CHALOUX,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.75-7403 Filed 3-20-75;8:45 am]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

Area Quarantined

This amendment quarantines an additional portion of Suffolk County in New York because of the existence of exotic Newcastle disease. Therefore, the restrictions pertaining to the interstate movement of poultry, mynah and psittacine birds, and birds of all other species under any form of confinement, and their carcasses and parts thereof, and certain other articles, from quarantined areas, as contained in 9 CFR Part 82, as amended, will apply to the quarantined area.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respect:

In § 82.3, paragraph (a)(1) relating to the State of New York is amended to read:

§ 82.3 Areas quarantined.

(a) * * *

(1) *New York.* (i) The premises of Robert Novak d/b/a Novak Tropical Aviary, located at 1472 Sunrise Highway, Bay Shore, Long Island, in Suffolk County.

(ii) The premises of Robert and Cathleen Novak, located at 118 South Bay Avenue, City of Brightwaters in Suffolk County.

* * * * *

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; secs. 1–4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111–113, 115, 117, 120, 123–126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

Effective date. The foregoing amendment shall become effective on March 18, 1975.

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 18th day of March 1975.

PIERRE A. CHALOUX,
Acting Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc.75-7458 Filed 3-20-75;8:45 am]

Title 13—Business Credit and Assistance

CHAPTER III—ECONOMIC DEVELOPMENT ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 301—ESTABLISHMENT AND ORGANIZATION

Disclosure of Information to the Public

Part 301 of Chapter III of Title 13 of the Code of Federal Regulations is hereby amended by revising Subpart D.

The purpose of these amendments is to conform with criteria set forth in section 552, title 5 United States Code, as amended by Pub. L. 93-502. Among other things these regulations delineate the procedures to be followed by members of the public in requesting documents under the Freedom of Information Act, and by EDA in searching for and providing requested documents, and the maintenance and dissemination of a current index of public information.

In that a delay in implementing these regulations would be contrary to the public interest, the relevant provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation and delay in effective date are inapplicable.

1. Part 301, Subpart D, consisting of § 301.50 through § 301.60 is hereby revised in its entirety to read as follows:

§ 301.50 Disclosure of information to the public.

This subpart describes the arrangements whereby the materials specified in 5 U.S.C. 552(a)(2) and repeated below, § 301.52(a), are made available for public inspection and copying, and the procedures and other conditions whereby identifiable records requested by persons may be made available to them under 5 U.S.C. 552(a)(3).

§ 301.51 Publication in the Federal Register.

Materials required to be published in the FEDERAL REGISTER under 5 U.S.C. 552(a)(1) and repeated below, § 301.53, shall be published in the FEDERAL REGISTER and shall, to the extent practicable and to further assist the public, be made available for inspection and copying at the facility identified in § 301.52(c).

§ 301.52 Availability of materials for inspection and copying.

(a) In accordance with 5 U.S.C. 552(a)(2) and other provisions of law, EDA shall maintain a reference facility for the public inspection and copying of:

(1) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases.

(2) Those statements of policy and interpretations which have been adopted by EDA and are not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(4) A current index, EDA Directive Systems Index, providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required to be made available by § 552(a)(2). Section 552(a)(2) also requires indexes to be published at least quarterly unless an agency claims an exemption in the FEDERAL REGISTER. EDA is exempted from the requirements to maintain a quarterly index on the grounds that quarterly publication would be unnecessary and impracticable because of infrequent changes in the index.

(5) Additional materials as the Assistant Secretary of Commerce for Economic Development in his discretion considers desirable and practicable to make available for the convenience of the public.

(b) In order to prevent unwarranted invasion of personal privacy, EDA may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction, and shall, in each such case, explain in writing the justification for the deletion.

(c) The above materials may be inspected in the Office of Public Affairs, EDA, Room 7019, U.S. Department of Commerce Building, 14th Street between Constitution and E Streets, NW., Washington, D.C. 20230. In addition, for the convenience of the public, most of these materials may also be inspected at each of the EDA Regional Offices listed in § 301.31. The Office of Public Affairs, Washington, D.C., and the respective EDA Regional Offices are open to the public Monday through Friday of each week, except on official holidays, between the hours of 9 a.m. and 4:30 p.m. There are no fees or formal requirements for such inspections. Copies of these materials may be obtained at these facilities at cost (see fee schedule, § 301.56 of this subpart). In addition, copies of various EDA materials regularly available for sale by EDA may be purchased from the Office of Public Affairs, and EDA Regional Offices.

(d) Correspondence concerning materials available in the facility should be sent to the Office of Public Affairs at the above address.

§ 301.53 Federal Register public information.

In accordance with 5 U.S.C. 552(a)(1), the EDA public information facility described in § 301.52(c) also maintains a reference facility for the public inspection and copying of the following public information published in the FEDERAL REGISTER.

(a) Descriptions of EDA central and field organizations and the established places at which, the employees from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions.

(b) Statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available.

(c) Rules of procedures, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports or examinations.

(d) Substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency.

(e) Each amendment, revision, or repeal of the foregoing.

§ 301.54 Requests for records.

(a) A person who wishes to inspect a record which is not customarily available to the public as part of the regular informational activities of EDA shall, as described in Section 301.53, submit a request in writing, giving a reasonable description of the record, to the Office of Public Affairs, EDA, Room 7019, U.S. Department of Commerce, 14th and Constitution, NW., Washington, D.C., 20230. A request may also be submitted to an EDA Regional Office listed in sec. 301.31 if the project or activity relating to the request is within the jurisdiction of that Regional Office. All other requests shall be submitted to the Office of Public Affairs in Washington, D.C.

(b) Employees at the above offices shall assist the public to a reasonable extent in framing requests. The responsibility, however, rests with the requester to describe each record sought in sufficient detail so that it can be located by personnel familiar with the filing of agency records. When more than one record is requested, requests shall clearly itemize each record requested so that it may be identified and its availability separately determined.

(c) Requests shall indicate the approximate costs requesters are willing to pay for the search and duplication of requested records.

(d) To further assist expeditious handling of requests, requesters should clearly and prominently mark their requests to distinguish their communications from other EDA mail. Accordingly, it is suggested that the underlined words "FOIA Request" be placed at the top of requests and on the outside of envelopes.

(e) Requests for agency records not customarily made available to the public received by an EDA Regional Office, and not relating to a project or activity within the jurisdiction of the Regional Office shall promptly be referred to the Office of Public Affairs, Washington, D.C.

(f) Requests are considered received by EDA when they arrive at EDA's Office of Public Affairs, Washington, D.C. (see above address), or the Regional Office having jurisdiction of the project or activity about which the inquiry is being made. Requests filed with Regional Offices not having jurisdiction of the project or activity, shall not be deemed as having been filed until such request is received at EDA's Office of Public Affairs, Washington, D.C. The receiving office shall date stamp the time of receipt of a request and shall enter its receipt in a public log. The following information shall be entered in the log: the date and time received; the nature of the records requested; the action taken on the request; the date of the determination letter sent under § 301.55; the name and title of the person making the determination; the date(s) records

are furnished; the number of staff hours and grade levels of EDA employees who assisted in responding to the request; and the fee requested and received.

§ 301.55 Determinations of availability of records.

(a) When a request for information is received, the Office of Public Affairs or appropriate Regional Office (hereafter both offices are referred to as appropriate office) initially determines:

(1) Whether the requested record can be identified based on the information in the request. If the record cannot be identified, the appropriate office shall write the requester, within the time period specified in subsection (b) (1) infra, specifying why it is not identifiable and what additional clarification is needed to assist EDA in its identification. Upon the failure to identify the requested record, the processing of the request for the record in question shall be deemed to be denied. If the request is reviewed with additional information the time period specified in subsection (b) (1) shall start anew.

(2) Whether the record, if identifiable, is still in existence or has been destroyed as provided by law, or is not in the possession of EDA. If the record no longer exists, the requester shall be notified, and provided an explanation regarding why the record no longer exists. If the record is not in EDA's possession and its existence is not otherwise reasonably ascertainable, the requester shall be notified. If the requested record is in another organization of the Department of Commerce, or is the primary concern of another executive department or agency, the request for the record shall be promptly referred to the other organization or agency for further action under its rules. The deadline for processing requests in subsection (b) (1) does not start to run if the request is referred to another organization. The requester, however, shall be notified by the appropriate office that his request has been referred to another organization or otherwise cannot be filled within the period specified in subsection (b) (1).

(b) If the requested record is identifiable and is in EDA's possession, the record shall be reviewed by one or more EDA officials to initially determine its availability. In making this review, the following procedures shall be followed by EDA:

(1) The official shall determine within 10 working days after receipt (as defined in § 301.54(f) of this subpart) of a request, whether to comply with the request, and by the end of these 10 days notification shall be dispatched to the requester of the determination. This deadline may be extended as provided in § 301.59.

(2) The record shall be made available unless it meets the criteria contained in the following exemptions in accordance with 5 U.S.C. 552(b) (1-9);

(i) (A) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(ii) Related solely to the internal personnel rules and practices of an agency;

(iii) Specifically exempt from disclosure by statute;

(iv) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(v) Inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(vi) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(vii) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(viii) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(ix) Geological and geophysical information and data, including maps, concerning wells.

(3) If it is determined, after consultation with EDA's Office of the Chief Counsel, that, as provided by law, the record or a portion of a record is not to be made available tothe requester, the notification shall be made by the Director, Office of Public Affairs, and be in writing and inform the requester of:

(i) The specific reasons for the denial including the statutory authority for the claimed exemption;

(ii) The names and titles or positions of each person responsible for the denial; and

(iii) The right of the requester to appeal the determination as provided in § 301.58 and the address to which an appeal is to be sent.

(4) When a requested record or a portion of a record is not made available to the requester, the official shall review the entire record to determine whether there are reasonably segregable portions of the record for which statutory exemptions from release do not apply. These portions of the record shall be made available to the requester after deleting portions for which a statutory exemption is claimed.

(5) If the record is to be made available, and there are no further fees, it shall be promptly furnished to the requesting person through the appropriate office specified in § 301.57. If there are fees to be recovered from the requester under § 301.56, the appropriate office shall determine the amount and notify the requester that when fees are paid, the record shall promptly be made available in the appropriate office or a copy mailed by it to the requester.

§ 301.56 Fees.

A uniform schedule of fees for the U.S. Department of Commerce has been promulgated to recover the direct costs of search and duplication of records in responding to freedom of information requests. This fee schedule and procedures for collecting fees are published in the U.S. Department of Commerce regulations (15 CFR 4.9), and apply to all requests for EDA records.

§ 301.57 Arrangement for public inspection and copying of agency records subject to disclosure.

(a) Upon receipt of the records search fee, and any fees for additional services requested, the record which has been determined to be available shall, unless the requester indicates otherwise, be transferred to EDA's Office of Public Affairs, or the appropriate Regional Office, where it will be held for inspection by the requester for 5 working days. The address, and hours of operation of this office are stated in § 301.42(c) of this subpart and in § 301.31. If a requester does not want to inspect a record by personal visit to an appropriate office, he may request that a copy be mailed to him upon payment of the copying and postage fees referred to in § 301.56 of this subpart.

(b) During this inspection of the record at the appropriate office, the requester may copy by hand the record, and, subject to the payment of copying fees referred to in § 301.56 of this subpart, may obtain a xeroxed or similar copy thereof, and certification of a machine-copied record.

(c) No changes or alteration of any type may be added or deleted. Papers bound or otherwise assembled in a record file may not be disassembled during inspection. Staff of the appropriate office shall provide assistance if disassembly of a record is necessary for copying purposes, and are authorized to supervise public inspection as necessary to protect EDA records.

(d) No person may, without permission, remove records made available to him for inspection or copying under this subpart from the office where it is made available.

§ 301.58 Appeals for decisions of nonavailability.

(a) A person whose request to inspect a record has been denied under § 301.55 (b) (3) may appeal the initial denial.

(b) Appeals must be made within 30 days of either the requester's receipt of the initial denial, or, in cases of partial denials, his receipt of the records made available under the initial determination. Appeals must be in writing. In submitting an appeal, the requester shall include written arguments he believes will support his appeal that the requested record

should be made available. No personal appearance, oral argument, or hearing are permitted. Appeals shall be sent to EDA's Office of Public Affairs, and the envelope shall be prominently marked with the underlined words "FOIA Appeal". Appeals are considered received by EDA when they arrive at the Office of Public Affairs, EDA, Room 7019, U.S. Department of Commerce, 14th Street between Constitution and E Streets, NW., Washington, D.C. 20230.

(c) The Assistant Secretary of Commerce for Economic Development shall make the decision whether to make available records initially denied and requested in an appeal. This decision shall be based on the original request, the denial, and any written argument submitted by the requester.

(d) The Assistant Secretary shall make a determination regarding an appeal within 20 working days after receipt of an appeal, and by the end of these 20 days dispatch notification to the requester of his determination. This deadline may be extended as provided in § 301.59. If the decision is wholly or partially in favor of the requester, the requested record to such extent shall be promptly made available for inspection or copying as described in § 301.56 and § 301.57, and the requester shall be so informed. If the denial of the request for records is in whole or part upheld, notification to the requester shall be in writing, and inform the requester of:

(1) the specific reasons for the decision;

(2) the names and titles or positions of each person responsible for the denial or an appeal; and

(3) the right to obtain judicial review of the determination under 5 U.S.C. 552(a)(4)(B).

(e) A decision regarding an appeal under this paragraph shall constitute the final decision and action by EDA concerning the availability of a requested record, except as may be required by court proceedings under 5 U.S.C. 552(a)(4)(B).

(f) Appeals resulting in final decisions shall be indexed and kept available for public reference in the Office of Public Affairs.

§ 301.59 Extensions of time for processing requests.

(a) The time limits for processing initial requests and appeals in §§ 301.55(b)(1) and 301.58(d) may be extended up to an additional 10 working days by written notice from the Office of Public Affairs to the requester. This notice shall state the reasons for the extension and the date a determination is expected to be dispatched.

(b) An extension of time for processing a request may occur if reasonably necessary for the proper processing of the request, and one of the following conditions is met:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation with another agency having a substantial interest in the determination of the request or among two or more components of the agency having subject-matter interest therein.

(c) Because of EDA's regional organization, and the involvement of Regional Offices as well as the Washington, D.C., office in program decisions and file maintenance, it is anticipated that EDA shall in most cases extend the period for processing requests based on (1) The need to collect records from field facilities, and (2) the need to consult with components of the agency.

(d) Extension of time may occur at both the initial and appeal stages or several times in either stage, however, the total period of extensions for a request may not exceed 10 working days.

§ 301.60 Record of application.

The Assistant Secretary shall maintain as a permanent part of the records of EDA a list of applications approved for financial assistance. This list is available for public inspection during regular business hours of the Department of Commerce. The following information shall be posted in the list as soon as an application is approved:

(a) The name of the applicant, and, in the case of corporate applications, the names of the officers and directors thereof;

(b) The amount and duration of the loan and grant for which application is made;

(c) The purpose for which the proceeds of the loan or grant are to be used; and

(d) A general description of the security offered in the case of a loan.

AUTHORITY: Sec. 701, Pub. L. 89-136 (August 26, 1965); (42 U.S.C. 3211); 79 Stat. 570 and Department of Commerce Organization Order 10-4, April 1, 1970 (35 FR 5970)

Effective date. This amendment becomes effective on February 19, 1975.

Dated: March 17, 1975.

WILMER D. MIZELL,
Assistant Secretary for Economic Development.

[FR Doc.75-7457 Filed 3-20-75;8:45 am]

Title 14—Aeronautics and Space

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Docket No. 75-CE-6-AD; Amdt. 39-2132]

PART 39—AIRWORTHINESS DIRECTIVES

Cessna Models 177, 177RG, and F177RG Airplanes

There have been incidents of separation of air filter foam rubber seals that were bonded to the filter by double-backed contact adhesive tape on Cessna Model 177RG airplanes. These seals or pieces thereof, when separated, may block the induction air or affect fuel metering. The manufacturer has issued Service Letter No. SE 75-3, dated January 24, 1975, requesting replacement of these seals on the affected air filters with new seals bonded with a more-effective contact adhesive.

Since the condition described herein is likely to exist or develop in other airplanes of the same type design, an Airworthiness Directive (AD) is being issued, applicable to those Cessna Model 177, 177RG and F177RG airplanes which are known to have or may have air filters with the inadequately bonded seals installed, making compliance with the Service Letter mandatory.

Since a situation exists which requires expeditious adoption of this amendment, notice and public procedure hereon are impracticable and good cause exists for making the amendment effective in less than thirty (30) days.

In consideration of the foregoing and pursuant to the authority delegated to me by the Administrator 14 CFR 11.89 (31 FR 13697), § 39.13 of Part 39 of the Federal Aviation Regulations is amended by adding the following new AD.

CESSNA. Applies to Models 177, 177RG and F177RG airplanes.

Compliance: Required as indicated, unless already accomplished.

To preclude separation of the foam rubber air filter seal, within 25 hours' time in service, after the effective date of this AD, accomplish the following:

A) On Models 177 (Serial Numbers 1770-2040 through 17702220); 177RG (Serial Numbers 177RG0433 through 177RG0625); and Model F177RG (Serial Numbers F177RG0093 through F177RG0122) airplanes, remove the air filter seal attached with double-backed adhesive tape and replace with a new P11-0766 air filter seal using EC1300LP adhesive in accordance with Cessna Service Letter SE 75-3, dated January 24, 1975, or later revision.

B) On Models 177 (Serial Numbers 601 and 17700001 through 17702039); 177RG (Serial Numbers R177RG0001 through 177RG-0442); and F177RG (Serial Numbers F177-RG0001 through F177RG0092) airplanes, visually inspect the air filter for the date of manufacture and on those air filters manufactured between November 1, 1973, and November 1, 1974, replace the air filter seal in accordance with Paragraph A above.

C) Any alternate method of compliance with this AD must be approved by the Chief, Engineering and Manufacturing Branch, FAA, Central Region.

This amendment becomes effective March 26, 1975.

(Secs. 313(a), 601 and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 and 1423), and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655 (c)))

Issued in Kansas City, Missouri, on March 12, 1975.

GEORGE R. LACAILLE,
Acting Director, Central Region.

[FR Doc.75-7352 Filed 3-20-75;8:45 am]

[Docket No. 75-GL-5; Amdt. 39-2135]

PART 39—AIRWORTHINESS DIRECTIVES

Grumman American Model AA-1, AA-1A, AA-1B, AA-5 and AA-5B Aircraft

Pursuant to the authority delegated to me by the Administrator (31 FR 13697 and 14 CFR 11.89) § 39.13 of the Federal Aviation Regulations, an Airworthiness Directive was adopted on March 5, 1975, and made effective immediately to all known United States operators of Grumman American Model AA-1, AA-1A, AA-1B, AA-5 and AA-5B aircraft certified in all categories delivered prior to February 18, 1975. The directive requires inspection of the rudder control bars located inside the forward portion of the fuselage for missing welds.

Since it was found that immediate corrective action was required, notice and public procedure thereon was impracticable and contrary to the public interest and good cause existed for making the Airworthiness Directive effective immediately as to all known United States operators of Grumman American Model AA-1, AA-1A, AA-1B, AA-5 and AA-5B aircraft delivered prior to February 18, 1975 and certified in all categories. Notification was provided to the operators by individual air mail letters dated March 6, 1975. These conditions still exist and the Airworthiness Directive is hereby published in the FEDERAL REGISTER as an amendment to § 39.13 of Part 39 of the Federal Aviation Regulations to make it effective as to all persons.

Pursuant to the authority of the Federal Aviation Act of 1958 delegated to me by the Administrator, the following Airworthiness Directive is issued applicable to operators of Grumman American AA-1, AA-1A, AA-1B, AA-5 and AA-5B airplanes delivered prior to February 18, 1975 and certified in all categories. The directive requires an inspection prior to further flight, unless already accomplished, and is effective immediately upon receipt of the airmail letter because there may be missing welds in the rudder control bar assemblies P/N 601031-501 located inside the forward portion of the fuselage.

Before further flight, unless already accomplished, inspect Grumman American Model AA-1, AA-1A, AA-1B, AA-5 and AA-5B airplanes certified in all categories for missing welds in the rudder control bar assemblies P/N 601031-501.

1. Inspect the rudder pedal posts and rudder cable attaching arm inserted through the rudder torque tube bar for missing welds. At each intersection, there should be a minimum of two (2) 90 degree circumferential welds located both top and bottom (fore and aft) at the intersection of each tube.

2. If inspection reveals that there are no missing welds, no further action is required and the aircraft may be approved for return to service.

3. If inspection reveals missing welds, replace rudder control bar assembly P/N 601031-501 with a new part of the same part number.

4. If parts are unavailable, repair may be accomplished by contacting the local FAA Maintenance Inspector concerning a repair procedure which must be approved by the Chief, Engineering and Manufacturing Branch, Great Lakes Region.

5. A special flight permit per FAR 21.197 may be issued after accomplishment of Paragraph 1 to allow repairs in accordance with this Airworthiness Directive.

This amendment is effective upon publication in the FEDERAL REGISTER and was effective prior to further flight for all recipients of the air mail letters dated March 6, 1975 which contained this amendment.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, and 1423) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c))).

Issued in Des Plaines, Illinois, on March 14, 1975.

JOHN M. CYROCKI,
Director, Great Lakes Region.

[FR Doc.75-7355 Filed 3-20-75;8:45 am]

[Docket No. 75-GL-6; Amdt. 39-2136]

PART 39—AIRWORTHINESS DIRECTIVES

Hartzell Propellers

There have been reports of blade separations which were experienced with certain Compact Hartzell HC-C2Y Series Propellers. These failures are attributed to fatigue cracks which originated in the blade shank retention area. Since this condition may exist or develop in other blades of the same design, an Airworthiness Directive is being issued to require inspection, and repair or replacement of the propeller blades.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical and good cause exists for making this amendment effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13697 and 14 CFR 11.89) § 39.13 of Part 39 of the Federal Aviation Regulations is amended by adding the following new airworthiness directive:

HARTZELL PROPELLERS. Applies to all Hartzell ( )( )7666A-( ) type blades with serial numbers below C38994 used on, but not limited to, the Model HC-C2YK-1( )( ), HC-C2YK-2( )( ), and HC-C2YK-4( )( ) propellers. Those blades only used with Hartzell HC-C2YK-2(-G)( ) dampered type propellers (hub model designation with "-G" suffix letter) are excluded. These propellers are installed on, but not limited to, Pitts S-2A, Piper PA-28-180 (STC SA2213WE), Piper PA-28R-200, Piper PA-34-200, and Mooney M20( ) series aircraft models.

Compliance required as indicated, unless already accomplished. To detect cracks or indentations and prevent possible blade shank failures, accomplish the following:

(a) Within the next 100 hours' time in service after the effective date of this Airworthiness Directive, inspect and repair or replace propeller blades in accordance with Paragraphs (b) and (c), and reinspect every 1,000 hours from the last inspection.

(b) Remove propeller from the aircraft and remove blades from the hub. Inspect the blade shanks (retention area) for cracks, indentations and wear in accordance with (Required Overhaul Procedures) Paragraphs B (1) and (2) of Hartzell Bulletin No. 97A dated March 1, 1973; or later Federal Aviation Administration approved revisions; or an equivalent procedure approved by the Chief, Engineering and Manufacturing Branch, Great Lakes Region.

(c) Repair or replace blades in accordance with (Required Overhaul Procedures) Paragraphs B(2) thru B(10) of Hartzell Bulletin No. 97A dated March 1, 1973, and (Required Action) Paragraphs 2 and 3 of Hartzell Bulletin No. 108 dated January 27, 1975; or later Federal Aviation Administration approved revisions; or an equivalent procedure approved by the Chief, Engineering and Manufacturing Branch, Great Lakes Region.

(d) Upon request of the operator, a Federal Aviation Administration Maintenance Inspector, subject to prior approval of the Chief, Engineering and Manufacturing Branch, Federal Aviation Administration, Great Lakes Region, may adjust the repetitive inspection intervals specified in Paragraph (a), if the request contains substantiating data to justify the adjustment for that operator.

(Hartzell Overhaul Manuals 113(B) and 117(D), or later Federal Aviation Administration approved revisions, also pertain to this subject.)

This amendment becomes effective March 27, 1975.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 and 1423) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c))).

Issued in Des Plaines, Illinois, on March 14, 1975.

JOHN M. CYROCKI,
Director,
Great Lakes Region.

[FR Doc.75-7354 Filed 3-20-75;8:45 am]

(Airworthiness Docket No. 75-WE-4-AD; Amdt. 39-2133)

PART 39—AIRWORTHINESS DIRECTIVES

Lockheed L-1011-385-1 Series Airplanes

Through laboratory testing, several possible single failures in the Trim Augmentation Computer, Lockheed P/N 672 443-(105, -107 or -109) have been identified which can cause the loss of the MACH FEEL, MACH TRIM, and PITCH TRIM systems with incorrect annunciation. The indications of one of the possible single failures are two "MACH FEEL" fail annunciations, two "MACH TRIM" fail annunciations, and one "PITCH TRIM" fail annunciation together with a caution and warning light. The remaining "PITCH TRIM" channel is failed but is not annunciated. By cycling channel selection switches for "MACH TRIM" and "MACH FEEL", it may be possible to clear the "FAIL" light in one channel of each system. This could result in an apparent single channel operative condition for "PITCH TRIM", "MACH TRIM" and "MACH FEEL" when, in fact, both channels of each system are inoperative or not operating properly.

Since this condition is likely to exist or develop in other airplanes of the same type design, an airworthiness directive (AD) is being issued to require:

(a) Compliance with Lockheed Service Bulletin 093-22-069, dated November 26, 1974, or later FAA-approved revisions;

(b) Incorporation of revised Airplane Flight Manual Limitations; and

(c) Installation of a placard in full view of the flight crew. The placard prohibits use of the autopilot below 100 feet

above ground level if either "PITCH TRIM" system fails during descent to 100 feet above the ground level.

The AD exempts the Lockheed Company from the placard requirement, if the airplane being operated without the placard is equipped with a Trim Augmentation Computer, modified as required in the body of the AD, and a sign-off on the aircraft release form indicates compliance with this provision of the AD.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13697) § 39.13 of Part 39 of the Federal Aviation Regulations is amended by adding the following new airworthiness directive:

LOCKHEED. Applies to L-1011-385-1 series airplanes certificated in all categories.

Compliance required as indicated.

To prevent the possibility of an out-of-trim Autopilot upon manual disconnect from occurring at close proximity to the ground, and to prevent operation at speeds at which the airplane may not meet stability requirements with inoperative MACH TRIM and MACH FEEL systems, and to advise the flight crew of possible incorrect failure annunciations, accomplish the following:

(a) Within 100 hours time in service after the effective date of this AD, unless already accomplished,

(1) Install the following placard in full view of the flight crew, "DUAL PITCH TRIM REQ'D TO 100 FT. FOR A/P USE BELOW 100 FT."

(2) Revise L-1011-385-1, FAA Approved Airplane Flight Manual (AFM) Limitations sections as follows: LR 25925 by incorporating pages 1-6 and 1-7 dated March 6, 1975, or later FAA-approved revisions; and LR 25225 by incorporating pages 1-6.2 and 1-6.3 dated March 6, 1975, or later FAA-approved revisions. Also revise appropriate operations manuals to incorporate the TRIM/FEEL system failure limitations included in the above AFM pages.

(b) An operator may remove the placards and discontinue the instructions imposed by this AD on his fleet of airplanes after the following actions have been accomplished.

(1) All Trim-Augmentation Computers, Lockheed P/N 672 443-(105, -107 or -109) in service and in spares inventory are modified per Lockheed Service Bulletin 093-22-069, dated November 26, 1974, or later FAA-approved revisions; and

(2) A system of parts pooling is established to insure that only spares, modified as defined in (b)(1), above, are installed.

(c) The Lockheed Company may operate and deliver an airplane to an operator without the placard required by this AD after the individual operator provides written notification to the Lockheed Company that his fleet no longer requires the placard as provided in (b), above.

(d) All Trim Augmentation Computers, Lockheed P/N 672 443-(105, -107, or -109), must be modified in accordance with Lockheed Service Bulletin 093-22-069, dated November 26, 1974, or later FAA-approved revisions, by December 1, 1976.

(e) Equivalent procedures and modifications may be approved by the Chief, Aircraft Engineering Division, FAA Western Region.

(f) An airplane may be flown to a base for the performance of the work required by this AD, per FAR's 21.197 and 21.199.

(g) For those airplanes not provided for in paragraph (c), above, the Lockheed Company may operate these airplanes without the placard required by this AD if the following actions are accomplished: (1) A Lockheed P/N 672 443-113 Trim Augmentation Computer or later FAA-approved version is installed; and (2) a sign-off indicating compliance with paragraph (g) of the AD is made on the aircraft release form prior to each flight.

This amendment becomes effective March 27, 1975.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, and 1423) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Los Angeles, California, on March 12, 1975.

LARRY L. HINK,
Deputy Director,
FAA Western Region.

[FR Doc.75-7353 Filed 3-20-75;8:45 am]

[Docket No. 75-NE-8; Amdt. 39-2137]

PART 39—AIRWORTHINESS DIRECTIVES

Pratt & Whitney Aircraft Model JT9D Engines

Amendment 39-2109 (40 FR 8544), AD 75-05-16, requires a repetitive measurement of the No. 3 breather tube temperature on Pratt & Whitney Aircraft JT9D-3A, -7, -7H, -7A, -7AH, -7F, and -20 turbofan engines.

After issuing Amendment 39-2109, additional data pertaining to the compliance schedule were made available to the agency. Accordingly, the Airworthiness Directive is being revised as indicated below.

1. Engines which have not had certain types of major maintenance do not require the initial breather tube temperature check at 300 hours. Therefore, the inspection requirement for these engines has been deleted.

2. Certain major engine sections can be removed or replaced without affecting the No. 3 compartment. Therefore, the requirement for a temperature check when these components are removed or replaced has been deleted.

3. Due to design differences in the JT9D-20 breather, a new temperature probe was required for this engine model. The new probe may not be available in sufficient time to comply with the AD. Therefore, an additional paragraph is being added permitting an operator to request approval for an adjustment in the initial compliance time.

Since this amendment relieves a restriction and imposes no additional burden on any person, notice and public procedure hereon are unnecessary ad the amendment may be made effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13697) § 39.13 of Part 39 of the Federal Aviation Regulation, Amendment 39-2109 (40 FR 8544), AD 75-05-16 is amended as follows:

PRATT & WHITNEY AIRCRAFT. Applies to all Pratt & Whitney Models JT9D-3A, -7, -7H, -7A, -7AH, -7F, and -20 turbofan engines.

To prevent possible engine fires due to excessive No. 3 bearing compartment labyrinth seal clearances, measure the No. 3 compartment breather air temperature in accordance with Pratt & Whitney Bulletin No. 4391, dated February 19, 1975, or later FAA approved revision, whenever any of the following major engine sections are removed or replaced:

a. Intermediate case.

b. Rear compressor rotor and stator assembly.

c. Rear compressor drive turbine rotor assembly due to:

(1) Turbine blade root fracture.

(2) Multiple turbine blade airfoil fracture.

(3) Failure that causes release of any other rotating part.

d. Front compressor drive turbine rotor assembly due to loss of complete blade.

e. Turbine exhaust case due to loose or missing tailcone.

f. Diffusor case.

Engines which have had any of the major engine sections described in (a) through (f) removed or replaced prior to the effective date of this AD, must be inspected within the next 300 hours time in service after the effective date of this AD, unless already accomplished.

If the measured breather air temperature is above the limit defined by Pratt & Whitney Curve Number 4391, dated February 14, 1975, remove the engine from service prior to further flight.

Upon request of the operator, an FAA maintenance inspector, subject to prior approval of the Chief, Engineering and Manufacturing Branch, FAA, New England Region, may adjust the initial inspection compliance time specified in this AD.

This amendment becomes effective March 24, 1975.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to Pratt & Whitney Aircraft, Division of United Aircraft Corporation, 400 Main Street, East Hartford, Connecticut 06108. These documents may also be examined at Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, and at FAA headquarters, 800 Independence Avenue SW., Washington, D.C. A historical file on this AD which includes the incorporated material in full is maintained by the FAA at its headquarters in Washington, D.C., and at New England Region.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, and 1423) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c))).

Issued in Burlington, Massachusetts, on March 14, 1975.

The incorporation by reference provisions in this document was approved by

the Director of the Federal Register on June 19, 1967.

QUENTIN S. TAYLOR,
Director, New England Region.

[FR Doc.75-7357 Filed 3-20-75;8:45 am]

[Airspace Docket No. 75-SO-25]

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

Alteration of Transition Area

The purpose of this amendment to Part 71 of the Federal Aviation Regulations is to alter the Dublin, Ga., transition area.

The Dublin transition area is described in § 71.181 (40 FR 441). In the description, an extension is predicated on Dublin VORTAC 069° radial. Effective June 19, 1975, the Dublin VORTAC will be relocated and the final approach radial of the instrument approach procedure will be changed to Dublin VORTAC 272°. It is necessary to amend the description to reflect this change. Since this amendment is minor in nature, notice and public procedure hereon are unnecessary.

In consideration of the foregoing, Part 71 of the Federal Aviation Regulations is amended, effective 0901 G.m.t., June 19, 1975, as hereinafter set forth.

In § 71.181 (40 FR 441), the Dublin, Ga., transition area is amended as follows:

"* * * 069° radial, extending from the 6-mile radius area to 1.5 miles east of the VORTAC * * *" is deleted and "* * * 272° radial, extending from the 6-mile radius area to the VORTAC * * *" is substituted therefor.

(Sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c))

Issued in East Point, Ga., on March 13, 1975.

PHILLIP M. SWATEK,
Director, Southern Region.

[FR Doc.75-7356 Filed 3-20-75;8:45 am]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket No. C-2616]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Albert's Furniture Co., Inc., et al.

Subpart—Advertising falsely or misleadingly: § 13.73 *Formal regulatory and statutory requirements;* 13.73-92 Truth in Lending Act; § 13.155 *Prices;* 13.155-95 Terms and conditions; 13.155-95(a) Truth in Lending Act. Subpart—Failing to maintain records: § 13.1051 *Failing to maintain records;* 13.1051-30 Formal regulatory and/or statutory requirements. Subpart—Misrepresenting oneself and goods—Prices: § 13.1823 *Terms and conditions;* 13.1823-20 Truth in Lending Act. Subpart—Neglecting, unfairly or deceptively, to make material disclosure: § 13.1852 *Formal regulatory and statutory requirements;* 13.1852-75 Truth in Lending Act; § 13.1905 *Terms and conditions;* 13.1905-60 Truth in Lending Act.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 82 Stat. 146, 147; 15 U.S.C. 45, 1601-1605) [Cease and desist order, Albert's Furniture Company, Inc., et al., Miami, Opa Locka and Ft. Lauderdale, Fla., Docket C-2616, Dec. 17, 1974.]

In the Matter of Albert's Furniture Company, Inc., a corporation, Albert's 27th Avenue Corporation, a corporation, Albert's Wilton Manor Corporation, a corporation, and Samuel Albert and Carl Nierenburg, individually and as officers of said corporations.

Consent order requiring three Florida furniture dealers, among other things to cease violating the Truth in Lending Act by failing to disclose to consumers, in connection with the extension of consumer credit, such information as required by Regulation Z of the said Act and failing to maintain records.

The Decision and Order, including further order requiring report of compliance therewith, is as follows: [1]

It is ordered, That respondents Albert's Furniture Company, Inc., a corporation, Albert's 27th Avenue Corporation, a corporation, and Albert's Wilton Manor Corporation, a corporation, their successors and assigns, and their officers, and Samuel Albert and Carl Nierenburg, individually and as officers of the corporations, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with any extension of consumer credit or advertisement to aid, promote or assist directly or indirectly any extension of consumer credit, as "consumer credit" and "advertisement" are defined in Regulation Z (12 CFR 226) of the Truth in Lending Act (Pub. L. 90-321 (15 U.S.C. 1601 et seq.)), do forthwith cease and desist from:

1. Failing to provide any customer, prior to consummation of the credit transaction, with a copy which the customer may retain, of all disclosures enumerated in § 226.8 of Regulation Z, in the form and manner prescribed therein, as required by § 226.8(a) of Regulation Z.

2. Failing to disclose the "annual percentage rate" accurately to the nearest quarter of one percent, in accordance with § 226.5 of Regulation Z, as required by § 226.8(b) (2) of Regulation Z.

3. Failing to disclose the number, amount and due dates or period of payments scheduled to repay the indebtedness, as required by § 226.8(b) (3) of Regulation Z.

4. Failing to disclose the sum of the payments scheduled to repay the indebtedness, and to describe that sum as the "total of payments," as required by § 226.8(b) (3) of Regulation Z.

5. Failing to disclose the amount, or method of computing the amount of any default, delinquency or similar charges, payable in the event of late payments, as required by § 226.8(b) (4) of Regulation Z.

6. Failing to disclose in conjunction with the description or identification of the type of security interest held, retained or required, that future indebtedness is secured by the property in which the security interest is retained, as required by § 226.8(b) (5) of Regulation Z.

7. Failing to identify the method of computing the unearned portion of the finance charge in the event of prepayment of the obligation, as required by § 226.8(b) (7) of Regulation Z.

8. Failing to disclose the price at which respondents offer, in the regular course of business, to sell for cash the property or services which are the subject of the credit sale and to describe that price as the "cash price," as required by § 226.8 (c) (1) of Regulation Z.

9. Failing to disclose the downpayment in money made in connection with a credit sale and to describe that downpayment as the "cash downpayment," as required by § 226.8(c) (2) of Regulation Z.

10. Failing to disclose the downpayment in property made in connection with a credit sale and to describe that downpayment as the "trade-in," as required by § 226.8(c) (2) of Regulation Z.

11. Failing to disclose the sum of the cash downpayment and the trade-in and to describe that sum as the "total downpayment," as required by § 226.8(c) (2) of Regulation Z.

12. Failing to disclose the difference of the cash price and the total downpayment and to describe that difference as the "unpaid balance of the cash price," as required by § 226.8(c) (3) of Regulation Z.

13. Failing to disclose the amount of credit extended and to describe that amount as the "amount financed," as required by § 226.8(c) (7) of Regulation Z.

14. Failing to disclose the "finance charge" in accordance with Section 226.4 of Regulation Z, as required by § 226.8 (c) (8) (i) of Regulation Z.

15. Failing to disclose the sum of the cash price, all other charges which are included in the amount financed but which are not part of the finance charge, and the finance charge, and to describe that sum as the "deferred payment price," as required by § 226.8(c) (8) (ii) of Regulation Z.

16. Failing to maintain evidence of compliance with Regulation Z for two years after the date of each disclosure, as required by § 226.6(i) of Regulation Z.

17. Failing in any consumer credit transaction or advertising to make all disclosures determined in accordance with §§ 226.4 and 226.5 of Regulation Z at the time and in the manner, form and amount required by §§ 226.6, 226.7, 226.8, and 226.10 of Regulation Z.

It is further ordered, That respondents deliver a copy of this order to all present

[1] Copies of the Complaint, Decision and Order, filed with the original document.

and future personnel of respondents engaged in the consummation of any extension of consumer credit or in any aspect of preparation, creation or placing of advertising, and that respondents secure a signed statement acknowledging receipt of said order from each such person.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That the individual respondents named herein promptly notify the Commission of the discontinuance of their present business or employment and of their affiliation with a new business or employment. Such notice shall include respondents' current business address and a statement as to the nature of the business or employment in which they are engaged as well as a description of their duties and responsibilities.

It is further ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

The Decision and Order was issued by the Commission, December 17, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7430 Filed 3-20-75;8:45 am]

[Docket No. 8851-o]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Crown Central Petroleum Corp.

Subpart—Advertising falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.20 *Comparative data or merits;* § 13.170 *Qualities or properties of product or service;* 13.170-16 Cleansing, purifying; § 13.205 *Scientific or other relevant facts;* § 13.265 *Tests and investigations;* § 13.280 *Unique nature or advantages.* Subpart—Misrepresenting oneself and goods—Goods: § 13.1710 *Qualities or properties;* § 13.-1730 *Results;* § 13.1740 *Scientific or other relevant facts;* § 13.1762 *Tests, purported.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Cease and desist order, Crown Central Petroleum Corporation, Baltimore, Md., Docket 8851-o, Nov. 26, 1974.]

In the Matter of Crown Central Petroleum Corporation, a corporation.

Consent order requiring a Baltimore, Md., seller and distributor of gasoline and other petroleum products, among other things to cease misrepresenting that its gasoline additive will produce pollution-free exhaust.

The Final Order, including further order requiring report of compliance therewith, is as follows: [1]

This matter is before the Commission pursuant to cross appeals of respondent and complaint counsel after the filing of an Initial Decision finding respondent in violation of section 5 of the Federal Trade Commission Act. The Commission has received written briefs from the parties, heard oral arguments on the appeals and considered the record developed during the adjudicative proceedings before the Administrative Law Judge. For the reasons set forth in the opinion [2] accompanying this order, we have determined that complaint counsel's appeal should be granted in part and respondent's appeal granted in part, and that, except to the extent it is inconsistent with the Commission's opinion, the Initial Decision [3] of the Administrative Law Judge should be, and it hereby is, adopted along with the opinion accompanying this order as the final findings of fact and conclusions of law of the Commission in this matter. We have also determined, for the reasons stated in the opinion accompanying this order that the order of the Administrative Law Judge should be modified and the provisions set forth herein adopted as the final order of the Commission in this case. Accordingly;

It is ordered, That the following cease-and-desist order shall be and it hereby is entered:

It is ordered, That respondent Crown Central Petroleum Corporation, a corporation, its successors and assigns, and its officers, representatives, agents, and employees, directly or through any corporate or other device in connection with the advertising, offering for sale, sale or distribution of Crown gasolines, or the additive CA-101, or any other product in commerce as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing directly or by implication that any such product:

(a) Will produce or result in motor vehicle exhaust which is pollution free or generally pollution free; or

(b) Will eliminate or reduce air pollution caused by motor vehicles; or

(c) Will eliminate or reduce emissions from all or any number or group of motor vehicles in which it is used;

or that:

(d) Any gasoline or gasoline additive product has any other quality, performance ability or other characteristic; or

(e) Tests, demonstrations, research or experiments have been conducted which prove or substantiate any of said representations;

Unless and only to the extent that each and every such representation is true and has been fully and completely substantiated by competent scientific tests. The results of said tests, the original data collected in the course thereof and a detailed description of how said tests were performed shall be kept available in written form for at least three years following the final use of the representation.

2. Representing directly or by implication that any such product has any effectiveness in reducing air pollution or any air pollutant or air pollutants without at the same time, in the same advertisement or other form of communication, conspicuously disclosing that not all of the harmful pollutants in automotive exhaust are affected by said product.

3. Representing directly or by implication that any product will reduce any emissions of pollutants from automobile exhaust by any percentage or numerical quantity unless in connection therewith there is a clear, accurate and conspicuous disclosure of the type of vehicle which can expect to achieve reductions of such magnitude and the approximate percentage of such vehicles in the general car population.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondent shall, within sixty (60) days after service of the order upon it, file with the Commission a written report, signed by the respondent, setting forth in detail the manner and form of its compliance with the order to cease and desist.

Commissioners Hanford and Nye did not participate since oral argument was heard prior to their assumption of Office.

The Final Order was issued by the Commission, Nov. 26, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7428 Filed 3-20-75;8:45 am]

[Docket No. C-2606]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

General Foods Corp.

Subpart—Advertising falsely or misleadingly: § 13.10 *Advertising falsely or misleadingly;* § 13.45 *Content;* § 13.170 *Qualities or properties of product or service;* 13.170-53 Medicinal, etc.—Animal; 13.170-64 Nutritive; § 13.205 *Scientific or other relevant facts.* Subpart—Corrective actions and/or requirements: § 13.533 *Corrective actions and/or requirements;* 13.533-45 Maintain records; 13.533-45(a) Advertising substantiation.

Subpart—Misrepresenting oneself and goods—Goods: § 13.1605 *Content;* § 13.-1710 *Qualities or properties;* § 13.1740

[1] Copies of the Complaint, Opinion, Appendices, Initial Decision and Final Order filed with the original document.

[2] Filed with original document.

[3] Filed with original document.

Scientific or other relevant facts. Subpart—Offering unfair, improper and deceptive inducements to purchase or deal: § 13.2063 *Scientific or other relevant facts.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Cease and desist order, General Foods Corporation, White Plains, N.Y., Docket C-2606, Dec. 3, 1974.]

In the Matter of General Foods Corporation, a corporation.

Consent order requiring a White Plains, N.Y., distributor of "Gainesburgers" dog food, among other things to cease misrepresenting the nutrient content of its product; misrepresenting the nutritional need of pets; misrepresenting the nutritional value of any of the ingredients contained in its product; and failing to maintain accurate records which support any advertising claims made by respondent.

The Decision and Order, including further order requiring report of compliance therewith, is as follows.[1]

It is ordered, That respondent General Foods Corporation, a corporation, its successors and assigns, and its agents, officers, representatives and employees, directly or through any corporate or other devices, in connection with the advertising, offering for sale, sale or distribution of any pet food, forthwith cease and desist from:

1. Disseminating or causing the dissemination of any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which contains the following:

a. Any representation, directly or indirectly, orally, visually, or by any other means, that "Gaines.burgers" contain any nutrient ingredient unless that ingredient is present in a nutritionally significant amount, *provided, however,* that "Gainesburgers" may be described as flavored with a certain ingredient or tasting of a certain ingredient without that ingredient being present in a nutritionally significant amount.

b. Any representation, directly or indirectly, orally, visually, or by any other means, that pets have a need for a nutrient which they do not in fact need.

c. Any statement or representation, direct or indirect, as to the nutritional value of any pet food or any nutrient ingredient in any pet food unless at the time of such representation respondent has a reasonable basis for such statement or representation, which shall consist of competent scientific, veterinary medical, or other similar objective material.

2. Failing to maintain and produce accurate records which may be inspected by Commission staff members upon reasonable notice:

a. Which consist of documentation in support of any claim included in advertising or sales promotional material disseminated by respondent, insofar as the text of such claim is prepared, or is authorized and approved by any person who is an officer or employee of respondent, or of any division or subdivision of respondent, or by any advertising agency engaged for such purpose by respondent or by any such division or subsidiary, which claim concerns the nutritional characteristics of any General Foods pet food; and

b. Which provided the basis upon which respondent relied as of the time the claim was made; and

c. Which shall be maintained by respondent for a period of three years from the date such advertising or sales promotional material was last disseminated by respondent or any division or subsidiary of respondent.

The provisions of paragraph 2 shall be in effect for a period of ten (10) years from the date this order becomes final.

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That respondent shall, within sixty (60) days after the service of the order upon them, file with the Commission a report in detail of the manner and form of its compliance with the order to cease and desist.

The decision and order was issued by the Commission December 3, 1974.

CHARLES A. TOBIN,
Secretary.

[FR Doc.75-7429 Filed 3-20-75;8:45 am]

[1] Copies of the Complaint, Decision and Order, filed with the original document.

Title 19—Customs Duties

CHAPTER I—UNITED STATES CUSTOMS SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 75-66]

PART 153—ANTIDUMPING

Potassium Chloride From West Germany

On January 17, 1975, there was published in the FEDERAL REGISTER (40 FR 3017) a "Notice of Tentative Determination to Revoke Dumping Finding" with respect to potassium chloride, otherwise known as muriate of potash, from West Germany. A finding of dumping applicable to this merchandise was published as T.D. 69-264, in the FEDERAL REGISTER of December 19, 1969 (34 FR 19905).

The above-mentioned notice set forth the reasons for the proposed revocation, and interested parties were offered an opportunity to make written submissions or request the opportunity to present oral views in connection therewith.

No requests to present oral views having been received and all written views being in accord with the tentative determination, I hereby determine that, for the reasons stated in the "Notice of Tentative Determination to Revoke Dumping Finding," potassium chloride, otherwise known as muriate of potash, from West Germany is no longer being, nor is it likely to be, sold in the United States at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160 et seq.), and I hereby revoke the finding of dumping published as T.D. 69-264, supra.

§ 153.43 [Amended]

Accordingly, § 153.43 of the Customs Regulations (19 CFR 153.43) is hereby amended by deleting, from the column headed "Merchandise," the words "Potassium chloride, otherwise known as muriate of potash," from the column headed "Country," the words "West Germany," and from the column headed "T.D.," reference to T.D. 69-264.

This determination is published pursuant to § 153.41(d), Customs Regulations (19 CFR 153.41(d)).

(Secs. 201, 407, 42 Stat. 11, as amended, 18; (19 U.S.C. 160, 173))

[SEAL] DAVID R. MACDONALD,
Assistant Secretary of the Treasury.

MARCH 18, 1975.

[FR Doc.75-7493 Filed 3-20-75;8:45 am]

Title 27—Alcohol, Tobacco Products and Firearms

CHAPTER I—BUREAU OF ALCOHOL, TOBACCO AND FIREARMS, DEPARTMENT OF THE TREASURY

[Notice 274; Reference: T.D. ATF-14]

PART 6—INDUCEMENTS FURNISHED TO RETAILERS

Inside Signs Furnished to Retailers of Wine by Industry Members; Correction

In FR Doc. 75-5917 appearing on page 10456 for Thursday, March 6, 1975, reference to "27 CFR 6.23a" in the "Summary of Notice" and "Summary of Comments" should read "27 CFR 6.23b".

REX D. DAVIS,
Director, Bureau of Alcohol, Tobacco and Firearms.

MARCH 13, 1975.

[FR Doc.75-7436 Filed 3-20-75;8:45 am]

Title 32—National Defense

CHAPTER VI—DEPARTMENT OF THE NAVY

SUBCHAPTER A—UNITED STATES NAVY REGULATIONS AND OFFICIAL RECORDS

PART 701—AVAILABILITY OF DEPARTMENT OF THE NAVY

Records and Publication of Department of the Navy Documents Affecting the Public

Subparts A through D of this revision are based on the provisions of Secretary of the Navy Instruction 5720.42B, February 13, 1975, which implements, within the Department of the Navy, the provisions of Department of Defense Directive 5400.7, February 14, 1975 (32 CFR Part

286) pertaining to action on requests for release of departmental records under the Freedom of Information Act (5 U.S.C. 552, as amended by Pub. L. 93-502). The latter directive was published on February 26, 1975 (40 FR 8190) with an invitation for public comment. It is contemplated that the provisions of this Part 701 will be reconciled with the requirements of the aforementioned Department of Defense Directive when the latter requirements are finalized in the manner indicated at 40 FR 8191. Department of the Navy regulations implementing the further provisions of the Freedom of Information Act and related administrative requirements will be published when issued, as additional subparts of this Part 701.

32 CFR Part 701 is revised to read as follows:

Subpart A—Requests for Records

Subpart B—Guidelines on Matters Which Are Exempt From Public Disclosure

Subpart C—Addresses for Requests for Department of the Navy Records and Locations at Which Department of the Navy Records Are Available for Public Inspection

Subpart D—Schedules of Fees

Subpart E—[Reserved]

AUTHORITY: 5 U.S.C. 552, as amended by Pub. L. 93-502, 32 CFR Part 286 (40 FR 8190).

Subpart A—Requests for Records

§ 701.1 Purpose.

Subparts A through D of this Part 701 implement the Freedom of Information Act (5 U.S.C. 552) and DoD Directive 5400.7 of February 14, 1975 (32 CFR Part 286; 40 FR 8190), by delineating responsibilities and prescribing policies, procedures, conditions, and criteria applicable to responding to requests of members of the public for copies of Department of the Navy Records, and is published for the guidance of the public.

§ 701.3 Scope and effect.

(a) *Applicability.* Subparts A through D of this Part 701 shall govern responses by Department of the Navy officials and military and civilian personnel to written requests from members of the public for permission to examine, or to be provided with copies of Department of the Navy records. Informal requests, requests of members of the public for information other than records, and inquiries not clearly contemplating the furnishing of records, are not subject to the technical requirements of this subpart, but shall be answered promptly in accordance with other established procedures and practices. See § 701.6. Additionally, the following categories of requests for information or records are specifically excluded from the scope of this instruction:

(1) Requests from the Congress or Members of Congress, which are governed by Secretary of the Navy Instruction 5730.12, and by § 1-1006.1 of the Armed Services Procurement Regulation (32 CFR 1.1006-1);

(2) Requests from Department of the Navy military or civilian personnel (active, reserve, former, or retired) for information contained in their personnel or medical records, or for copies of documents contained therein, which, unless specifically stating that they are submitted pursuant to this instruction or the Freedom of Information Act, will be presumed to have been submitted pursuant to other regulations or procedures specifically designed to ensure the protection of the privacy of the individuals concerned.

(3) Requests from the General Accounting Office for records in connection with audits, which are governed by Secretary of the Navy Instruction 5741.2D;

(4) Court orders or subpoenas demanding production of records, discovery, or testimony of witnesses, which are governed by the Manual of the Judge Advocate General (JAGINST 5800.7A), chapter XIII (32 CFR Part 720) or

(5) Requests from other Federal agencies, or Federal Government employees whose official duties require or entitle them to have the particular information or records.

(b) *Publication and Public Availability of Special Classes of Records.* The requirements in 5 U.S.C. 552 that certain classes of Department of the Navy regulatory, rule-making, and organizational records be published in the FEDERAL REGISTER for the guidance of the public, and requirements that records having precedential effect concerning the public be currently indexed and held available for public inspection and copying, are implemented in subpart E.

(c) *Public Affairs Regulations.* This instruction is intended to complement, and not restrict, the conduct of Department of the Navy public affairs, media relations, community relations, or internal relations functions and practices authorized in Secretary of the Navy Instruction 5720.44, Department of the Navy Public Affairs Regulations. Should the latter instruction conflict in any respect with any provisions of this Part 701, however, the provisions of this part shall be controlling.

(d) *U.S. Navy Regulations.* For the purposes of article 1116.3, U.S. Navy Regulations, 1973, [32 CFR 700.1116(c)] the release of a record to a member of the public upon a request granted in accordance with §§ 701.8 or 9 shall be deemed to have been done in the discharge of official duties. For the purposes of article 1116.4 [§ 700.1116(d)], the release of a record designated as "For Official Use Only" to a member of the public upon a request granted in accordance with §§ 701.8 or 9, shall not be deemed to have been a release to the "general public."

(e) *Other Directives.* Other directives which, to the extent that they do not conflict with this subpart, serve to supplement it with respect to particular categories of information or records, include:

(1) Bureau of Naval Personnel Instruction 1070.12A and Marine Corps Manual, paragraph 1070 (also, for Headquarters, Marine Corps, HQO P5000.3A, chapter 30)—release of information from the personnel records of members and former members of the Navy and Marine Corps.

(2) Federal Personnel Manual, chapters 293, 294, 335, 339 and 713—release of information from active and inactive civilian personnel records.

(3) Manual of the Medical Department, U.S. Navy, NAVMED P-117, chapter 23, section III—release of information from active and inactive medical records.

(4) Armed Services Procurement Regulation (32 CFR 1.329) and Navy Procurement Directives (32 CFR Part 737)—release of procurement records and information.

§ 701.4 "Record(s)" defined.

(a) As used in subparts A through D, the term "record(s)" is intended to include any books, papers, maps, photographs, or other documentary materials, regardless of physical form or characteristics, made or received by any agency of the United States Government in pursuance of Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data contained therein. "Records" are not limited to permanent or historical documents but include contemporary documents as well.

(b) "Record(s)" described in § 701.4 (a) (1) which are stored in computers are not excluded from the provisions of this subpart. See § 701.5 (b) (2).

(c) However, the term "record(s)" does not include objects or articles such as structures, furniture, paintings, sculpture, three-dimensional models, vehicles, equipment, etc., whatever their historical value or value as "evidence." Formulae, designs, drawings, research data, computer programs, technical data packages, etc., are not considered "records" within the Congressional intent of 5 U.S.C. 552, even though maintained in documentation form. Because of development costs, utilization, or value, these

items are considered property, not preserved for informational value nor as evidence of agency functions, but as exploitable resources to be utilized in the best interest of all the public. Requests for copies of such material shall be evaluated in accordance with policies expressly directed to the appropriate dissemination or use of such property. Requests to inspect such material to determine its content for informational purposes shall normally be granted, however, unless inspection is inconsistent with the obligation to protect the property value of the materal, as, for example, may be true for certain formulae.

§ 701.5 General provisions.

(a) *Policy.* In accordance with the spirit and intent of 5 U.S.C. 552 and 32 CFR Part 286, the Department of the Navy will make available to the public the maximum information concerning its operations, activities, and administration. Subject to the conditions in subparts A through D concerning exemptions and the requesters, compliance with prescribed minimum requirements, records requested by the public will be made available promptly, fully, and willingly, as a matter of right.

(b) *Requests for Records.* Upon receipt of written or oral requests to naval activities, all reasonable efforts should be made to advise members of the public on the correct means for securing permission to examine desired records at appropriate times at locations where they are held, or for obtaining copies of such records. Subject to the requesters' compliance with the minimum requirements prescribed in § 701.6(a), the following provisions shall apply, at all activities and all echelons of command, to written requests for examination or copies of records under the cognizance of the Department of the Navy:

(1) *Time limits.* Except in the limited instances where brief time extensions are authorized under § 701.8(b)(2), an official having responsibility for making the initial determination to grant or deny a request for examination or a copy of a record shall transmit that determination in writing to the requester within 10 working days after it is received by that official in form satisfying the minimum requirements. The record shall be made available for examination at the activity, or a copy will be furnished, as applicable, upon or promptly after a determination that it may be released in whole or part. Within the framework of this subpart, and utilizing their existing resources, naval activities are expected to develop internal procedures for ensuring the expeditious handling of requests, the prompt retrieval and review of the requested records, and the timely transmittal of determinations. Where a request is denied, in whole or part, an appeal is to be anticipated, and every effort will be made to facilitate the determination of the appeal within the applicable time limit.

(2) *Identification of records.* Subject to the provisions of subparts A through D, requests shall be honored for records which are "reasonably described." See § 701.6(a)(2). It is expected that naval activities will use their superior knowledge of the contents of their files and expend reasonable efforts to assist the public in identifying the records which contain the particular information which is sought. However, a record must exist at the time of the request, and it is not required that a record be "created" or compiled for the purpose of furnishing information not already provided in existing records. A record that is maintained by computer is normally deemed to exist for this purpose only if retrievable in approximately the form desired without substantial reprogramming.

(3) *Fees.* The fees associated with searching for and duplicating records requested under this subpart shall be determined in accordance with § 701.40. Such fees normally must be paid (or waived) in advance of rendering such search or duplication services, and, normally, the time limit for transmitting a determination on a request will not begin to run until the fee is paid or the requester's entitlement to a waiver is established. An exception exists where the requester promises in writing at the time of the request to pay, upon receipt of a bill therefor, all fees incurred in complying with the request (or pay such fees up to a specified limit) and represents that he will be able to make such payment; provided that, at the time of the request, the requester is not known to be in default of payment of fees incurred in connection with a previous request for records under this subpart. Fees shall be charged only for direct costs of searches and duplication and shall not include indirect costs or costs attributable to reviewing records. See § 701.6.

(4) *Records containing exempt matters.*

(i) *Determinations.* A requested record will be deemed "releasable" and shall be released to the public unless it is affirmatively determined both that the record contains matters which are exempt from disclosure under § 701.5(b)(4)(ii) and that a significant and legitimate governmental purpose will be served by withholding it. The determination of whether a significant and legitimate governmental purpose is served by withholding information is within the sole discretion of the Department of the Navy. If exempt matters in a record are "reasonably segregable" from nonexempt portions, the nonexempt portions shall be made available. See § 701.22. In no event shall a determination that a requested record is exempt, that a significant and legitimate governmental purpose would be served by withhholding it, or that it has not been requested in accordance with prescribed procedures be influenced by the possibility that its release might suggest administrative error or inefficiency, or might embarrass the Department of the Navy or its military or civilian officials in the performance of their duties.

(ii) *Exemptions.* Even though it might otherwise appear that a significant and legitimate governmental purpose would be served by withholding it, no matter shall be withheld from disclosure to the public unless it is included within one of the exemptions listed in 5 U.S.C. 552(b). These exemptions, which are amplified in subpart B, are limited to:

(A) Matters that are specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive order. (5 U.S.C. 552(b)(1))

(B) Matters that are related solely to the internal personnel rules and practices of an agency. (5 U.S.C. 552(b)(2))

(C) Matters that are specifically exempted from disclosure by statute. (5 U.S.C. 552(b)(3))

(D) Trade secrets and commercial or financial information obtained from a person and privileged or confidential. (5 U.S.C. 552(b)(4))

(E) Inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. (5 U.S.C. 552(b)(5))

(F) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (5 U.S.C. 552(b)(6))

(G) Investigatory records compiled for law enforcement purposes but only to the extent that the production of such records would:

(*1*) interfere with enforcement proceedings;

(2) deprive a person of a right to a fair trial or an impartial adjudication;

(*3*) constitute an unwarranted invasion of personal privacy;

(*4*) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source;

(*5*) disclose investigative techniques and procedures, or

(*6*) endanger the life or physical safety of law enforcement personnel. (5 U.S.C. 552(b)(7))

(H) Matters contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions. (5 U.S.C. 552(b)(8)) or

(I) Geological and geophysical information and data, including maps, concerning wells. (5 U.S.C. 552(b)(9))

(c) *Identification and Marking "For Official Use Only" (FOUO).* (1) Unless properly classified under Chief of Naval Operations Instruction 5510.1E, Department of the Navy Information Security Program Regulation, a record may be designated as being "For Official Use Only" (FOUO) if at the time of its origination it is considered to contain matters which are included within the exemptions listed in § 701.5(b)(4)(ii) and which must be protected from release to

the general public and indiscriminate handling because of significant and legitimate governmental reasons. No other records shall be so designated or marked. The procedures for marking, handling, and safeguarding of "For Official Use Only" materials are set forth in Secretary of the Navy Instruction 5570.2B.

(2) The presence or absence of a "For Official Use Only" marking on a record shall not relieve an official acting on a request for the record from his responsibility for reviewing it and making an independent determination on its releasability in accordance with § 701.5(b)(4)(ii). Such a marking on a record shall not be cited or referred to as a reason for denying a request for its release. The presence of such marking should be regarded as a signal for alerting the reviewing official to the possibility that the record may contain nonreleasable matters.

§ 701.6 Form and addresses for requests for records.

(a) *Minimum Requirements.* To qualify as a request within the technical requirements of this subpart, a request for copies of, or for permission to examine, Department of the Navy records must, at the minimum,

(1) Be in writing and indicate expressly, or by clear implication, that it is a request under the Freedom of Information Act or this regulation;

(2) Contain a reasonable description of the particular records requested—i.e., a sufficiently accurate and specific description to enable naval personnel to locate and identify the particular records desired with a reasonable amount of effort; and

(3) Contain a check or money order for the anticipated search and duplication fees determined in accordance with § 701.40 (at least a substantially adequate approximation of the actual fees); or a clear statement that the requester will be willing and able to pay all fees or to pay such fees, up to a specified limit; or satisfactory evidence establishing that the requester is entitled to waiver of such fees in accordance with § 701.40.

(b) *Recommended Additional Contents.* Though not deemed to be essential requisites for a request under this subpart, it is recommended that the following additional matters be included, as applicable, in a request for records:

(1) A notation on the outside of the envelope that it is a request under the Freedom of Information Act;

(2) If the request does not specifically identify the desired records, an explanation of the purposes for which they are desired might assist naval personnel in identifying the relevant records.

(c) *Addressing Requests.* Section 701.31 is a list of commonly requested types of records and the addresses of the naval activities from which such records normally can be obtained. A request for a record held by a Department of the Navy activity normally will not be deemed to have been received for purposes of the time limits specified in § 701.8(b) until it is received by the appropriate activity listed in § 701.31. Misdirected requests will be handled in accordance with § 701.7(c)(3).

(d) *Treatment of Requests Not Meeting Minimum Requirements.* (1) Requests which do not qualify for treatment within the technical requirements of this subpart because they do not conform to the minimum requirements specified in § 701.6(a) should nevertheless be answered promptly (within ten working days after receipt, if possible) in writing, in a manner calculated to assist the requesters in obtaining the desired records in accordance with the provisions of subparts A through D. For example, if such a request fails to contain a reasonable description of a desired record, the requester should be offered appropriate assistance in framing a new request in a way which might facilitate identification of the record. If a request fails to contain payment or a promise of payment of anticipated fees, information should be furnished upon which the requester may reasonably estimate the probable range of the fees which may be involved. Telephone contacts will frequently be useful for supplementing the required written communications.

(2) In a case where a request fails to qualify for treatment within the technical requirements of this subpart because of omission to include payment or a promise of payment of the applicable fees, but it is ascertained that the requested record is conveniently available and is releasable in its entirety, the official responsible for responding to the request may, if he determines that it will be in the best interests of the activity to do so, provide a copy of such record in advance of payment or promise of payment of the applicable fees. The application of this provision shall be within the sole and exclusive discretion of the responsible official of the activity concerned and shall not be construed as creating an exception to, or grounds for waiver of, the minimum requirements specified in § 701.6(a).

§ 701.7 Responsibility and authority for determinations.

(a) *Release Authorities.* Subject to § 701.7(c)(2), commanding officers and heads of all Navy and Marine Corps activities (departmental and field) are authorized to furnish copies of records in their custody, or to make such records available for examination, upon proper request. Coordination with the official having cognizance of the subject matter of the requested record, or with the originator of the record, is advised where there is a question as to its releasability.

(b) *Denial Authorities.* The following officials (and their principal assistants authorized to act "by direction") are authorized to deny (as well as grant) requests for documents or records, when the information sought relates to matters within their respective areas of responsibility:

(1) For the Navy Department, the Civilian Executive Assistants, the Chief of Naval Operations, the Commandant of the Marine Corps, the Chief of Naval Material, the Chief of Naval Personnel, the Chief, Bureau of Medicine and Surgery, and the heads of Navy Department offices and boards. The Judge Advocate General and his Deputy, and the General Counsel and his Deputies are excluded from this grant of authorization, but the Assistant Judge Advocates General and the Assistants to the General Counsel, and the Director, Contract Appeals Division, Office of the General Counsel, are so authorized.

(2) For shore activities, commanders of naval systems commands; commandants of naval districts; the Commanders of the Naval Intelligence Command, Naval Security Group, Naval Telecommunications Command, and Naval Weather Service; the Auditor General of the Navy; the Naval Inspector General; the Chief of Naval Education and Training; the Chief of Naval Reserve; and the Oceanographer of the Navy.

(3) For the Operating Forces, fleet commanders in chief, and the Commander, Military Sealift Command.

(4) Commanders of major Navy and Marine Corps activities designated by the Chief of Naval Operations or the Commandant of the Marine Corps.

(c) *Responsibility for Acting on Requests.*

(1) *General rule.* Subject to § 701.7(c)(2), when any Department of the Navy activity receives a request for a copy of, or permission to examine, a record in its custody, that activity is responsible for acting on the request in the time and manner prescribed in this subpart. § 701.31 is a list of commonly requested types of records and the addresses of the activities which normally have custody of the records of each type. A request for a record will not be deemed to have been received for the purposes of the time limit specified in § 701.8(b) until it is received either by the appropriate official indicated in § 701.31 or [except in cases involving the records specified in § 701.7(c)(2)] by any other Department of the Navy official which has the record in its custody.

(2) *Exceptions.* The following exceptions exist with regard to the general rule in § 701.7(c)(1) that any naval activity receiving a request for a record in its custody is responsible for acting on the request.

(i) *Classified records.* If records requested from the appropriate naval activity indicated in § 701.31 include classified records, and if the head of that activity is not the original classifier or does not have classification jurisdiction over the subject matter in accordance with Chief of Naval Operations Instruction 5510.1E, he shall promptly readdress and forward the request to the official originating the classification, if a denial authority under § 701.7(b), or else to a denial authority having cognizance of the classified matters in the record, for review and determination as to the classified records, and the requester shall be so notified. If the naval activity which

received the request is the proper addressee as indicated in § 701.31, the time limit specified in § 701.8(b) commences when the request is received by that activity. If the naval activity which initially receives the request is not the proper addressee as indicated in § 701.31, the request will be treated as a misdirected request in accordance with § 701.7(c)(3), and the time limit will commence when the request is received by the original classifier or the denial authority having cognizance of the classified records.

(ii) *NIS reports.* A request for a Naval Investigative Service report shall promptly be readdressed and forwarded directly to the Director, Naval Investigative Service, for review and determination, and the requester shall be so notified. Direct liaison is encouraged. The time limit specified in § 701.8(b) will commence when the request is received by the Director, Naval Investigative Service.

(iii) *Technical documents controlled by distribution statements.* A request for a technical document to which "Distribution Statement B" is affixed shall promptly be readdressed and forwarded directly to the "controlling DoD office" in accordance with Chief of Naval Material Instruction 5200.29, for review and determination, and the requester shall be so notified. Direct liaison is encouraged. The time limit specified in § 701.8 (b) will commence when the request is received by the controlling office.

(iv) *Records originated by other agencies.* A request for a record originated by an agency outside the Department of the Navy [except a technical document within the purview of Chief of Naval Material Instruction 5200.29; see § 701.7(c)(2)(iii)] shall promptly be readdressed and forwarded to such agency, and the requester shall be so notified. Guidance, when necessary, may be obtained from the Chief of Naval Operations (OP–09B16) or the Commandant of the Marine Corps (Code PA), as appropriate. Direct liaison is authorized.

(3) *Misdirected requests.* A request for a copy of, or permission to examine, a Department of the Navy record received by an activity which is not the appropriate naval activity indicated in § 701.31 and does not have the record in its custody, shall promptly be readdressed and forwarded directly to the appropriate naval activity. The requester shall be notified of the readdressal. Direct liaison between the original recipient and the correct addressee is encouraged for ensuring the expeditious handling of the request.

§ 701.8 Procedures for processing requests.

(a) *Administrative Controls.* Upon receipt of a written request for examination or copies of a record, the receipient activity will immediately ensure that action is taken to control the request and provide for its expeditious and priority handling, and for responding to the requester within the time limits specified in § 701.8(b).

(1) *Receipt controls.* At the minimum, controls shall include the date stamping of the request upon receipt, establishment of a suspense control record and follow-up procedures, and the conspicuous stamping or labelling of the request as a "FREEDOM OF INFORMATION ACT" request to flag it as requiring priority handling throughout its processing.

(2) *Forwarding controls.* When a request is forwarded to another activity for review or other action, the request, the letter of transmittal, and the envelope or cover, shall be conspicuously stamped or labelled "FREEDOM OF INFORMATION ACT" and a record shall be kept of the request and the date and the activity to which it was forwarded.

(3) *Consultation records.* A concise record shall be maintained of the dates, parties, and substance of all significant consultations with representatives of other activities or agencies, and all consultations with the requester.

(b) *Time Limits for Determinations*

(1) *Normal requirement.* Except in an unusual instance where a brief time extension is authorized under § 701.8(b)(2), it is required that the determination on each request for examination or copies of records be sent to the requester within ten working days (i.e., excluding Saturdays, Sundays, and legal public holidays) after the request is received by the activity having responsibility for acting on it. Such determination shall be transmitted in the appropriate form prescribed in §§ 701.8 (c) or (d).

(2) *Extensions of time limits.* Only those officials authorized in § 701.7(b) to deny requests for records are authorized to extend the time limits for responding to such requests. Should any other official require an extension of time in which to complete processing of a request on which he is responsible for acting, he shall request (by formal or informal communication) authorization for such extension from the appropriate denial authority designated in § 701.7(b). Such extension may be authorized only in accordance with the following conditions:

(i) An extension may be authorized only if necessitated by one or more of the following unusual circumstances provided for in 5 U.S.C. 552:

(A) The need to search for and collect records that are located in whole or part at places separate from the office processing the request;

(B) The need to search for, collect, and examine a substantial number of records in response to a request; or

(C) The need to consult with another naval activity or another agency which has a substantial subject-matter interest in the determination of the request.

(ii) Such extension may be authorized only for that additional period of time which will be reasonably necessary for the proper processing of the request, but in no event may the period of extension exceed ten working days.

(iii) If there appears to be a substantial possibility that the request might ultimately be denied, in whole or part, the Judge Advocate General (Code 14L) or the General Counsel, as appropriate [see § 701.9(c)], shall be consulted by expeditious means prior to authorizing such extension.

(3) *Method of effectuating extensions.* If properly authorized in accordance with § 701.8(b)(2), an extension shall be effectuated by sending written notification to the requester prior to the expiration of the original time limit indicated in § 701.8(b)(1), briefly stating the reasons for the extension and specifying the date on which the determination on the request is expected to be transmitted.

(c) *Action by Officials Who Are Not Denial Authorities.* Where the head of the activity responsible for acting on a request is not authorized under § 701.7b to deny requests, such official shall, within the applicable time limit, take one of the following actions:

(1) If it is determined that the requested record is releasable in its entirety and is available, and the fees for search and duplication have been paid, waived, or the unpaid balance is less than $100.00 and the requester has promised in writing to pay the balance, then a copy of such record normally will be forwarded directly to the requester (with a bill for the unpaid balance of the fee or a refund of excessive fee paid in advance, if appropriate). Otherwise, if the record is releasable in its entirely and is available, the requester shall be notified that a copy of the requested record will be forwarded upon receipt of payment of the fee.

(2) If it is determined that the requested record is releasable in its entirety but is not yet available, the requester shall be notified that the request has been approved and that the requested record will be forwarded by a specified date, subject to appropriate directions concerning the payment of fees.

(3) In a case of approval of a request for examination of records, the requester shall be notified of the time and place where the records may be examined, subject to appropriate directions concerning the payment of fees, if any, incurred for searching records.

(4) In any of the following cases, a request shall be expeditiously referred, with information and recommendations, directly to the appropriate official authorized under § 701.7(b) to deny requests:

(i) If the referring official is unable to make a determination on the releasability of a requested record within the applicable time limit because the record has not been located or obtained;

(ii) If, in the opinion of the referring official, the requested record, or any part thereof, is not releasable under § 701.5b(4);

(iii) If the requester of a releasable record claims an entitlement to a waiver of applicable fees and the referring official disagrees; or

(iv) If the record is classified and it is not within the authority of the refer-

ring official to review the basis of its classification.

(d) *Action by Denial Authorities.* With respect to a request referred to him by a subordinate official under § 701.8c(4), or any other request to which his activity appropriately may respond, an official authorized under § 701.7a(2) to deny requests shall, within the applicable time limit, take one of the following actions:

(1) Execute one of the actions specified in § 701.8c (1) through (3), or, if appropriate, direct a subordinate to do so;

(2) If the processing of a request cannot be completed within the applicable time limit, this shall be explained to the requester, with notification that he may treat this delay as an initial denial with a right to appeal to the designee of the Secretary of the Navy [Judge Advocate General or General Counsel, as indicated in § 701.9a] within 120 days, or that he may agree to await a substantive determination by a specified date. It will be made clear that any such agreement does not prejudice the right of the requester to appeal an adverse substantive determination.

(3) If the denial authority determines that the requested record contains matters which are not releasable under § 701.5b(4) and that any releasable matters which may be contained in the record are not reasonably segregable from the nonreleasable portions, he shall notify the requester of such determination, the reasons therefor, and the name and title of each person responsible for such denial. Such notification shall also include specific citation of the exemption(s) upon which the denial is based, a brief discussion of the significant and legitimate governmental purpose(s) served by invoking the exemption(s), and advisement of the requester's right to appeal to the designee of the Secretary of the Navy [Judge Advocate General or General Counsel, as indicated in § 701.9a] within 120 days. Additionally, if the denial is based in whole or part on a security classification, the notification shall include a summary of the particular provisions of paragraph 2-303 of Chief of Naval Operations Instruction 5510.1E which contain the rationale for the correct classification of the requested record, and shall, if the record is more than ten years old, advise the requester of his optional right under that directive to seek declassification review by the Department of the Navy Classification Review Committee as an alternative to the statutory appeal to the Secretary's designee.

(4) If he determines that the requested record contains releasable portions that are reasonably segregable from nonreleasable portions, he shall—

(i) With respect to the releasable portions of the record, take the action indicated in §§ 701.8c (1), (2), or (3); and

(ii) With respect to the portions which are not releasable, take the action indicated in § 701.8d(3).

(5) If a requested record is releasable, in whole or part, and the requester relies upon a claimed entitlement to a waiver of applicable fees, a denial authority shall, if he determines that the requester's entitlement to such waiver is not established, notify the requester of such determination, the reasons therefor, the name and title of each person responsible for the determination, and the right of the requester to appeal that determination to the designee of the Secretary of the Navy [Judge Advocate General or General Counsel, as indicated in § 701.9a] within 120 days.

(e) *Consultation Encouraged.* Consultation with other officers and activities having a substantial interest in, or useful advice concerning, the determination of requests under the purview of this subpart is encouraged wherever practicable, and, in some instances, is required.

(1) Consultation is required with other activities or agencies having substantial interest in the subject matter of requested records which may be exempt under § 701.5b(4) (ii).

(2) Consultation with the Office of the Judge Advocate General, the Office of the General Counsel, or their field representatives, is encouraged concerning the interpretation and application of the technical provisions of subparts A through D or where a denial of a request is expected to be appealed or judicially challenged.

(3) Consultation with a public affairs officer or the Office of Information is encouraged where the subject matter of a request is considered newsworthy, where a request is received from a news media representative, or where a denial of a request is expected to be publicly challenged.

(f) *Forwarding of Case Files.* A copy of the file, containing all pertinent correspondence (and the requested record, if practicable, or else representative samples of the material contained therein) shall be immediately forwarded directly to the Chief of Naval Operations (OP-09B16) or the Commandant of the Marine Corps (Code PA), as appropriate, in every case where a request within the purview of this subpart is denied, in whole or part, either because it contains nonreleasable matters or because a request for waiver of fees was not granted. These officials shall maintain copies of all initial denials in a form suitable for rapid retrieval, periodic statistical compilation, and management evaluation.

§ 701.9 Appeals from denials of requests for records.

(a) *Addressees for Appeals.* Appeals to the Secretary of the Navy under the provisions of 5 U.S.C. 552 and this subpart are to be addressed—

(1) To:

The Judge Advocate General (Code 14L)
Department of the Navy
Washington, D.C. 20370

if concerning records which pertain to any matters not excepted in § 701.9(2)(c)(i);

(2) Or to:

The General Counsel
Department of the Navy
Washington, D.C. 20360,

if concerning records which pertain to the matter specified in § 701.9(c)(2)(ii).

(b) *Time and Form for Filing Appeals.* To be effective for purposes of the provisions of 5 U.S.C. 552 and this subpart, an appeal from an initial denial, in whole or in part, of a request for records, or a refusal to waive fees, must be in writing and be received by the appropriate official specified in § 701.9(a) not more than 120 days following the date of transmittal of the notification of the initial denial. Additionally, such appeal must clearly state that it is an appeal from a denial of a request made under the "Freedom of Information Act" or this subpart, and must either fully describe the circumstances of the request and initial denial or have attached a copy of the letter denying the request.

(c) *Responsibility and Authority*

(1) *Delegation of authority.* The Judge Advocate General and the General Counsel are authorized to determine appeals made to the Secretary of the Navy on denials of requests for copies of such Department of the Navy records, or portions thereof, or refusals to waive fees, as pertain to the matters which are within their respective areas of cognizance for legal services. This shall include the authority to release or withhold records, or portions thereof, waive fees, and to perform such other acts as may be required of the Secretary of the Navy in connection with the appeals made under 5 U.S.C. 552.

(2) *Respective areas of cognizance.* As delineated in Secretary of the Navy Instructions 5430.25c and 5430.27, the respective areas of cognizance of the Judge Advocate General and the General Counsel for providing legal services for the Department of the Navy are:

(i) *Judge Advocate General.* All matters except the business and commercial law matters assigned to the cognizance of the General Counsel, which are specified in the following:

(ii) *General Counsel.* The business and commercial law aspects of matters relating to (A) the acquisition, custody, management, transportation, taxation, and disposition of real and personal property, and the procurement of services, including the fiscal, budgetary, and accounting aspects thereof; excepting, however, tort claims and admiralty claims arising independently of contract, and matters relating to the naval petroleum reserves; (B) operations of the Military Sealift Command, excepting tort and admiralty claims arising independently of contract; (C) the Office of the Comptroller of the Navy; (D) procurement matters in the field of patents, inventions, trademarks, copyrights, royalty payments, and similar matters, including those in the Armed Services Procurement Regulations and the Navy Procurement Directives and deviations therefrom; and (E) industrial security and claims and litigation concerning the foregoing.

(d) *Procedures for Processing Appeals*

(1) *Administrative controls.* The principles in § 701.8(a) are also applicable, where appropriate, to the handling and processing of appeals.

(2) *Time limits for determining appeals*

(i) *Normal requirement.* Except in an instance where a brief time extension is authorized under the § 701.9(d)(2)(ii); it is required that the final determination on an appeal to the Secretary of the Navy under 5 U.S.C. 552 and this subpart be sent to the appellant within 20 working days after the appeal is received in the Office of the Judge Advocate General or the Office of the General Counsel, as prescribed in § 701.9(a).

(ii) *Extensions of time limits.* If necessitated by one or more of the reasons specified in § 701.8(b)(2)(i), the Judge Advocate General or the General Counsel, as appropriate, is authorized to extend the time limit for that additional period of time which will be reasonably necessary for the proper processing of the appeal. Provided, that such period of extension, when added to any period of extension used in the initial processing of the request, may not exceed a total of ten working days. Such extension shall be effectuated in the manner prescribed in § 701.8(b)(3).

(3) *Action upon receipt.* Upon receipt of an appeal, the Judge Advocate General or the General Counsel shall inform the Chief of Naval Operations (OP-09B16) or the Commandant of the Marine Corps (Code PA), as appropriate, who shall expeditiously forward the case file with such comments and recommendations as he or other interested officials may deem appropriate. Immediate coordination shall be established with the Director of Naval Intelligence (OP-009D) in an appeal involving a classified record. All naval activities are enjoined to provide rapid and responsible assistance, as required, for facilitating correct and timely determinations of appeals. Direct liaison with appropriate officials within the Department of the Navy and other interested Federal agencies is authorized at the discretion of the determining official, and he shall be responsible for coordinating with appropriate officials of the Departments of Defense and Justice in such manner as may be prescribed by directives of the Secretary of Defense. The Secretary of the Navy or the appropriate Civilian Executive Assistants shall be consulted and kept advised of cases having unusual implications, and the Chief of Information shall be consulted and kept advised on cases described in § 701.8(e)(3).

(4) *Notification of final determination.* Upon resolving the issues involved, the determining official shall give the appellant an appropriate written notification of the final determination made on the appeal. If such determination has the effect of granting a request, in whole or part, the determining official shall cause the requester's right to seek judicial reportions thereof, to be made promptly available. If the final determination has the effect of denying a request, in whole or part, the notification shall contain the names and titles of each person responsible for such denial, an advisement of the requester's right to seek judicial review, and the following additional matters, as applicable:

(i) An explanation of the exemption(s) under § 701.5(b)(4)(ii) upon which the determination is based and the significant and legitimate governmental purpose served by withholding the requested record;

(ii) If the determination is based, in whole or part, upon a security classification—

(A) A statement that, based on such declassification review as could reasonably be accomplished within the time limit for responding to the appeal, it is determined that the record meets specified criteria and rationale of Chief of Naval Operations Instruction 5510.1E; and

(B) An advisement of the requester's optional right to seek declassification of the record by the Department of the Navy Classification Review Committee, with a further right to appeal to the Interdepartmental Classification Review Committee established pursuant to Executive Order 11652, 8 March 1972, in lieu of immediate judicial review;

(iii) Such other matters as may be prescribed by directives of the Secretary of Defense.

§ 701.13 Effective date.

Although subparts A through D are effective on February 13, 1975, compliance with the requirements and procedures provided in §§ 701.5b (1) through (3) and §§ 701.6 through 9 shall be required only with respect to requests and appeals received on and after February 19, 1975. However, the spirit of those provisions should be followed, where practicable, with respect to pending requests and appeals received prior to that date.

Subpart B—Guidelines on Matters Which Are Exempt From Public Disclosure

§ 701.21 General rule.

Matters contained in records may be withheld from public disclosure if they come within one or more of the specific exemptions listed in § 701.5(b)(4)(ii). However, even exempt matters in a record are releasable and should be made available to a member of the public, unless, in the judgment of the officer or official responsible for making the determination—

(a) Release of the matters would be inconsistent with a statutory requirement or Chief of Naval Operations Instruction 5510.1E; or

(b) Some other significant and legitimate governmental purpose will be served by invoking the exemption(s) and withholding the matters.

§ 701.22 "Reasonably segregable" matters.

If a requested record contains both releasable and nonreleasable matters, the releasable portions should be made available if they are reasonably segregable from the nonreleasable matters in the record. Releasable matters are "reasonably segregable" if they would provide the requester with meaningful and undistorted information after the nonreleasable matters are excised and it can reasonably be assumed that a skillful and knowledgeable person could not reconstruct the nonreleasable matters. Reasonable segregation may be based on a system of designating nonreleasable portions at the time the record is originated, although the continuing validity of the original determination must be reevaluated in response to a request for the record. The paragraph designations of classified information under Chief of Naval Operations Instruction 5510.1E is an example of such a system for segregating releasable and nonreleasable matters.

§ 701.23 Judicial Review.

In determining whether a record is exempt from disclosure under §§ 701.5(b)(4)(ii) and 701.24, it should be kept in mind that, in the event of judicial review of a denial of a request for a record, a court is empowered to examine the record in its entirety in private to determine whether it is, in fact, exempt.

§ 701.24 Specific exemptions.

The following types of matters may be withheld from public disclosure unless otherwise prescribed by law:

(a) *"Exemption 1" Matters.* Those properly and currently classified in the interest of national defense or foreign policy, as specifically authorized under the criteria established by Executive order and implementing regulations, such as Chief of Naval Operations Instruction 5510.1E. If a requested record is classified in accordance with that directive the record must be reviewed for the basis of the security classification. The following general rules are applicable:

(1) The request must be referred, with information and recommendations, to an official who is authorized under § 701.7(b) to deny requests and who has cognizance of the classified matters in the record, if the basis of the classification is:

(i) An approved security classification guide promulgated in accordance with Chief of Naval Operations Instruction 5510.1E;

(ii) A source document originated by another naval activity or government agency;

(iii) An original classification determination for which there is written justification for classification, and the justification remains valid; or

(iv) Not readily identifiable, but classification is believed to be warranted on the basis of classification criteria contained in Chief of Naval Operations Instruction 5510.1E.

(2) If the original classifier of a record within his classification jurisdiction receives a request for the record and, upon review, can see no basis for continued classification, the record should be declassified and reviewed to determine whether any other exemptions listed in § 701.5(b)(4)(ii) are applicable and, if so, whether a significant and legitimate governmental purpose would be served by withholding it.

(b) *"Exemption 2" Matters.* Those containing rules, regulations, orders,

manuals, directives, and instructions relating to the internal personnel rules or to the internal practices of the Departments of Defense or the Navy, if their release to the public would substantially hinder the effective performance of a significant function of the Departments of Defense or the Navy.

(1) Operating rules, guidelines and manuals for investigators, inspectors, auditors, or examiners, and certain schedules or methods of operation which would reveal:

(i) Negotiating and bargaining techniques.

(ii) Bargaining limitations and positions.

(iii) Inspection schedules and methods.

(iv) Audit schedules and methods.

(2) Personnel and other administrative matters such as examination questions and answers used in training courses or in the determination of the qualifications of candidates for employment, entrance to duty, advancement, or promotion.

(c) *"Exemption 3" Matters.* Those containing information which statutes authorize or require be withheld from the public. Such authorization or requirement may be found in the terms of the statute itself or in Executive orders or regulations authorized by, or in implementation of, a statute.

Examples include:

(1) 18 U.S.C. 1905—trade, technical, and financial information provided in confidence by businesses.

(2) Pub. L. 86-36 (50 U.S.C. 402 note)—National Security Agency information.

(3) 35 U.S.C. 181-188—records containing information relating to inventions which are the subject of patent applications on which Patent Secrecy Orders have been issued.

(4) 5 U.S.C. 552a (Pub. L. 93-579)—Privacy Act of 1974, effective 27 September 1975.

(5) 42 U.S.C. 2162—"Restricted Data"

(6) 18 U.S.C. 798—Communications information.

(7) 50 U.S.C. 402 (d) (3) and (g)—Intelligence sources and methods.

(d) *"Exemption 4" Matters.* Those containing trade secrets of commercial or financial information which a component receives with the understanding that it will be retained on a privileged or confidential basis in accordance with the customary handling of such records, particularly when release would adversely affect the competitive position of the source of the information. Such records include those which contain:

(1) Commercial and financial information received in confidence in connection with loans, bids, contracts, or proposals, as well as other information received in confidence or privileged, such as trade secrets, inventions and discoveries, or other proprietary data.

(2) Statistical data and commercial or financial information concerning contract performance, income, profits, losses, and expenditures, if offered and received in confidence from a contractor or potential contractor.

(3) Personal statements given in the course of inspections, investigations, or audits, where such statements are received in confidence from the individual and retained in confidence because they cover trade secrets or commercial or financial information normally considered confidential or privileged, or because they are essential to an effective inspection, investigation, or audit.

(e) *"Exempton 5" Matters.* Except as provided in subsections (2) through (5) below, internal communications within and among Federal agencies and components.

(1) Examples include:

(i) Staff papers containing staff advice, opinions, or suggestions.

(ii) Information received or generated by a component preliminary to a decision or action, including draft versions of documents, where premature disclosure would interfere with the authorized purpose for which the records were created.

(iii) Advice, suggestions, or reports prepared on behalf of the Department of Defense by boards, committees, councils, groups, panels, conferences, commissions, task forces, or other similar groups that are formed by a component to obtain advice and recommendations, or by individual consultants.

(iv) Those portions of component evaluations of contractors and their products which contain recommendations or advice by Government employees about the contractor or product.

(v) Advance information on such matters as proposed plans to procure, lease, or otherwise acquire and dispose of materials, real estate, facilities, or functions when such information would provide undue or unfair competitive advantage to private personal interests.

(vi) Records which are exchanged among agency personnel or within and among components or agencies preparing for anticipated legal proceedings before any Federal, State, or military court, or before any regulatory body.

(vii) Reports of inspections, audits, investigations, or surveys which pertain to safety, security, or the internal management, administration, or operation of the Departments of Defense or the Navy or their components.

(2) If any such intra-agency or inter-agency record, or reasonably segregable portion of such record, would routinely be made available through the discovery process (i.e., the legal process by which litigants obtain information from each other that is relevant to the issues in a trial or hearing) in the course of litigation with the agency, then such record, or reasonably segregable portions of it, should be deemed releasable. If, however, the information would only be made available through the discovery process by special order of the court based on the particular needs of a litigant balanced against the interests of the agency in maintaining its confidentiality, then the record may be considered to be nonreleasable.

(3) Purely factual material in such an inter-agency or intra-agency record is routinely made available through discovery and (if reasonably segregable and containing no other exempt matters rendering it nonreleasable) should therefore be released.

(4) A direction or order from a superior to a subordinate, though contained in internal communication, is generally releasable if it constitutes policy guidance or a decision, as distinguished from a discussion of preliminary matters that would compromise the decision-making process.

(5) An internal communication concerning an event or decision which has subsequently been made a matter of public record should normally be considered to be releasable unless it is determined that, because of special circumstances, release would prejudice the current decision-making process.

(f) *"Exemption 6" Matters.* Information in personnel and medical files, as well as information in similar files that, if disclosed to a member of the public, would result in a clearly unwarranted invasion of personal privacy.

(1) Examples of files similar to personnel and medical files include:

(i) Those compiled to evaluate or adjudicate the suitability of candidates for civilian employment and the eligibility of individuals, civilian, military or industrial, for security clearances.

(ii) Files containing reports, records, and other material pertaining to personnel matters in which administrative action, including disciplinary action, may be taken.

(2) In determining whether the release of information would result in a "clearly unwarranted invasion of personal privacy," consideration should be given to the stated or assumed purpose of the request. When determining whether a release is "clearly unwarranted," the public interest in satisfying this purpose must be balanced against the sensitivity of the privacy interest being threatened.

(3) When the only basis for withholding information is protection of the personal privacy of an individual who is the subject of the record, information should not be withheld from him or from his designated legal representative. A clearly unwarranted invasion of the privacy of others discussed in that record may, however, constitute a basis for deleting reasonably segregable portions of the record even when providing it to the subject of the record. With regard to the release of a medical record to a patient who may be adversely affected by knowledge of its contents, the principles of good medical practice should be followed.

(4) On and after 27 September 1975, an individual's personnel, medical, or similar files may be withheld from him or from his designated legal representative only in accordance with regulations implementing the Privacy Act of 1974 (5 U.S.C. 552a).

(g) *"Exemption 7" Matters.* Law enforcement records

(1) Those compiled for the purpose of enforcing civil, criminal, or military law, including the implementation of Execu-

tive orders, or regulations validly adopted pursuant to law, but only to the extent that their release would:

(i) interfere with enforcement proceedings;

(ii) deprive a person of a right to a fair trial or an impartial adjudication;

(iii) constitute an unwarranted invasion of personal privacy;

(iv) disclose the identity of a confidential source;

(v) disclose confidential information furnished only from confidential source obtained by a criminal law enforcement authority in a criminal investigation or by an agency conducting a lawful national security intelligence investigation;

(vi) disclose investigative techniques and procedures not already in the public domain and requiring protection from public disclosure to insure their effectiveness; or

(vii) endanger the life or physical safety of law enforcement personnel.

(2) Examples include:

(i) Statements of witnesses and other material based on the information developed during the course of the investigation and all materials prepared in connection with related Government litigation or adjudicative proceedings.

(ii) The identity of firms or individuals suspended from contracting with the Department of Defense or being investigated for alleged irregularities when no indictment has been obtained nor any civil action filed against them by the United States.

(iii) Information obtained in confidence in the course of:

(A) A criminal investigation by a criminal law enforcement agency or office within a component; or

(B) A lawful national security intelligence investigation conducted by an authorized agency or office for the purpose of obtaining affirmative or counter intelligence information, or background investigation information needed to determine suitability for employment or eligibility for access to classified information.

(3) The right of individual litigants to investigative records currently available by law is not diminished.

(4) On and after September 27, 1975, when the subject of an investigative record is the requester of the record, it may be withheld only in accordance with regulations implementing the Privacy Act of 1974 (5 U.S.C. 552a).

(h) *"Exemption 8" Matters.* Those contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of any agency responsible for the regulations or supervision of financial institutions.

(i) *"Exemption 9" Matters.* Those containing geological and geophysical information and data (including maps) concerning wells.

Subpart C—Addressees for Requests for Department of the Navy Records and Locations at Which Department of the Navy Records Are Available for Public Inspection

§ 701.31 Addressees for requests for Department of the Navy records.

Members of the public should address requests to the commanding officer or head of the activity where the record is located. When the official having custody of the record is not known, the request should be addressed to the originating official, or the official having primary responsibility for the subject matter involved. The cognizant official to whom requests for the most commonly requested types of records should be addressed are as indicated below.

Type of Record	*Addressee*
Civilian Personnel Records (or requests for information involving the personnel records of civilians). When requests involves civilians:	
Presently employed by the Department of the Navy, or separated from Federal employment less than 30 days.	The head of the activity where the person is employed, marked for the attention of the civilian personnel officer.
Formerly employed by the Department of the Navy, or separated from Federal employment for more than 30 days.	Manager, National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.
Chaplain Corps and religious affairs matters	Chief of Chaplains, Navy Department, Washington, D.C. 20370.
Contractual or procurement type records and related matters:	
Navy procurement directives, and armed services procurement regulation (ASPR); and related indexes.	Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
All others	Contracting officer, or head of the procurement (purchasing) activity, when known. When one of these is not known, submit the request to the Chief of Naval Material (MAT 05), Washington, D.C. 20360; except if a Marine Corps matter, submit to the Deputy Chief for Installation and Logistics, U.S. Marine Corps, Washington, D.C. 20380.

Type of Record	*Addressee*
Court-Martial Records:	
Involving bad-conduct discharge. For request involving records of trial by general court-martial, and by special court-martial involving an officer accused or involving a sentence which, as approved by the general court-martial convening authority, extends to a bad conduct discharge.	Judge Advocate General, Navy Department, Washington, D.C. 20370.
Not involving a bad-conduct discharge. For requests involving records of trial of other special and summary court-martial other than those described above (after final actions and a retention period at a shore activity for 2 years and at a fleet activity for 3 months).	Manager, National Personnel Records Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
Inspector General inspection, investigation, and related survey matters:	
Records prepared by the Naval Inspector General	Naval Inspector General, Navy Department, Washington, D.C. 20370.
Records prepared by inspector general of other Navy commanders.	The commander for whom the inspector general records were prepared.
Instructions (unclassified) of general applicability issued under the Department of the Navy's directives issuance system; and quarterly subject index thereof (NAVPUB-NOTE 5215).	Director, Navy Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19111.
Internal audit matters	The Auditor General of the Navy, Navy Department, Washington, D.C. 20350.
Legal matter records (other than those relating to court-martial records covered above):	
General counsel legal matters. Requests relating to (1) the acquisition, custody, management, transportation, taxation, and disposition of real and personal property, and the procurement of services, including the fiscal, budgetary, and accounting aspects thereof, excepting, however, tort claims and admiralty claims arising independently of contract, and matters relating to the naval petroleum reserves; (2) operations of the Military Sealift Command, excepting tort and admiralty claims arising independently of contract; (3) the Office of the Comptroller of the Navy; (4) procurement matters in the field of patents, inventions, trademarks, copyrights, royalty payments, and similar matters, including those in the armed services procurement regulation and Navy procurement directives and deviations therefrom, and (5) industrial security and claims and litigation concerning the foregoing.	The head of the activity which the request concerns, marked for the attention of the Office of Counsel, otherwise to: General Counsel, Navy Department, Washington, D.C. 20360.
Judge Advocate General legal matters. Requests for records involving all legal matters other than the above general counsel matters.	Judge Advocate General, Navy Department, Washington, D.C. 20370.
Manpower management, civilian, matters. When the request relates to:	
Local activity matters	The head of the activity which the request concerns, marked for the attention of the civilian personnel officer.
General matters relating to Marine Corps, only, manpower management.	Commandant of the Marine Corps (Code M), Washington, D.C. 20380.
All others, including any relating to overall Department of the Navy manpower management matters.	Director of Civilian Manpower Management, Navy Department, Washington, D.C. 20390.
Marine Corps records. When other specific addressee is not known, and when request is for Marine Corps directives, publications, and manuals of general Marine Corps applicability.	Commandant of the Marine Corps, Navy Department, Washington, D.C. 20380.
Medical records. When requests involve the medical records of military personnel, dependents of military personnel, and other civilians:	
For Navy and Marine Corps officer and enlisted personnel and their dependents (other than those covered below).	The medical treatment activity where the record is maintained, if known. (This generally is the activity where the patient is being treated, or recently was treated, since records are forwarded to the receiving activity when a patient is transferred.)
For former Navy and Marine Corps personnel separated prior to 1913 and their dependents.	Chief, Navy and Old Army Branch, Military Archives Division, National Archives and Records Service, GSA, Washington, D.C. 20408.

Type of Record	*Addressee*
Officer personnel who have been separated from the service (discharged, retired, or deceased) for more than 4 months, reservists not on active duty, and nonparticipating reservists.	Manager, National Personnel Records Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
Enlisted personnel on extended active duty who have been separated (discharged, retired, or deceased) for less than 4 months, and temporary disability retired enlisted personnel.	Commandant of the Marine Corps (Code M), Navy Department, Washington, D.C. 20380.
Enlisted personnel who have been separated (discharged, retired, or deceased) for more than 4 months, transferred to the fleet reserve, and inactive enlisted reservists not affiliated with a reserve unit.	Manager, National Personnel Records Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
For Marine Corps officer and enlisted personnel separated prior to 1895.	Chief, Navy and Old Army Branch, Military Archives Division, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.
Military Specifications, Standards, and Handbooks, and Department of Defense Index of Specifications and Standards (DOD-ISS):	
Specifications, standards, and handbooks	Director, Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19111.
DOD Index	Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
Naval Investigative Service Reports and Related Matters. (This covers any request for information from reports prepared by the Naval Investigative Service, even though copies may be held by other activities. Requests addressed elsewhere will be promptly forwarded to this proper address.)	Director, Naval Investigative Service, 2461 Eisenhower Avenue, Alexandria, VA 22331.
Non-current Department of the Navy Records (preserved as permanent documentation, particularly when records predate 1946).	Archivist of the United States, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.
For former Navy and Marine Corps personnel (other than those separated prior to 1913 and covered above) and their dependents.	Manager, National Personnel Records Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
For Civilian employees	The medical activity or facility where the person is being treated or was recently treated and where the record is maintained, if known. If this is not known and the record has been retired (generally, if it is 2 years or more since date of last treatment), address request to the Manager, National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.
When the location of the record is not known	Chief, Bureau of Medicine and Surgery (Code 334), Navy Department, Washington, D.C. 20372.
Military personnel records, general:	
Concerning Navy personnel matters	Chief of Naval Personnel, Navy Department, Washington, D.C. 20370.
Concerning Marine Corps personnel	Commandant of the Marine Corps (Code M), Navy Department, Washington, D.C. 20380.
Military personnel records, individual: (Requests should be addressed according to the status of the individual to whom the request relates, as indicated below.)	
For Navy (USN and USNR) officer personnel:	
Active duty officers, inactive officers, and temporary disability retired officers.	Chief of Naval Personnel (Pers 37), Bureau of Naval Personnel, Washington, D.C. 20370.

Type of Record	*Addressee*
Officers who have been separated from the service (discharged, retired, or deceased) for less than 1 year.	Chief of Naval Personnel (Pers 37), Bureau of Naval Personnel, Washington, D.C. 20370.
Officers who have been separated from the service (discharged, retired, or deceased) for more than 1 year, and inactive reservists.	Manager, National Personnel Record Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
Officers separated prior to 1902	Chief, Navy and Old Army Branch, Military Archives Division, National Archives and Records Service, GSA, Washington, D.C. 20408.
Enlisted personnel on active duty, participating inactive duty, and temporary disability retired.	Chief of Naval Personnel (Pers 38), Bureau of Naval Personnel, Washington, D.C. 20370.
Enlisted personnel (active, inactive, and temporary disability retired) who have separated (discharged, retired, or deceased) for less than 4 months.	Chief of Naval Personnel (Pers 38), Bureau of Naval Personnel, Washington, D.C. 20370.
Nonparticipating inactive enlisted personnel who have more than 18 months of their military obligation to serve.	Chief of Naval Personnel (Pers 38), Bureau of Naval Personnel, Washington, D.C. 20370.
Nonparticipating inactive enlisted personnel, when request involves the current enlistment.	Commanding Officer, Naval Reserve Manpower Center, Bainbridge, MD 21605.
Enlisted personnel transferred to the fleet reserve, nonparticipating inactive personnel who have less than 18 months of their military obligation to serve, and enlisted personnel who have been separated (discharged, retired, or deceased) for more than 4 months.	Manager, National Personnel Records Center (Military Personnel Records), 9700 Page Boulevard, St. Louis, MO 63132.
Enlisted personnel separated (discharged, retired, or deceased) prior to 1885.	Chief, Navy and Old Army Branch, Military Archives Division, National Archives and Records Service, GSA, Washington, D.C. 20408.
For Marine Corps officer and enlisted personnel:	
Officer personnel (USMC and USMCR) on extended duty who have been separated (discharged, retired, or deceased) for less than 4 months, and temporary disability retired officers.	Commandant of the Marine Corps (Code M), Washington, D.C. 20380.
Public Affairs and News Media Matters:	
Local interest, only, matters	The head of the local activity concerned, marked for the attention of the public information officer.
Marine Corps, only, matters	Commandant of the Marine Corps (PA), Washington, D.C. 20380.
All others	Chief of Information, Navy Department, Washington, D.C. 20350.
Publication and indexes (when specific addressee is not known).	Director, Naval Publications and Printing Service Office, Naval District Washington, Washington Navy Yard, Building 157, 2d Floor, Washington, D.C. 20374.
Research and Development Records (See also Technical Reports):	
When the custodian of the record is known	The head of the activity having custody of the record.
Basic research records, when other definite address is not known.	Chief of Naval Research, Navy Department, 800 N Quincy St., Arlington, VA 22217.
Other records, when definite address is not known	Director of Navy Laboratories, Navy Department, Washington, D.C. 20390.
Supply Catalogs:	
Navy and Federal supply catalogs, master cross reference indexes, and related cataloging publications, (except as noted immediately below).	Federal Clearinghouse, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 20402.
Cataloging handbooks (such as H2-1, and -2, H3, et cetera) and Federal manuals for supply cataloging (such as M1-1, -2, and -3, et cetera).	Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.
Technical reports (when definite Department of the Navy addressee is not known), and indexes of technical reports available.	Defense Documentation Center, Cameron Station, Alexandria, VA 22314.
Technical, engineering, and supply type documents and data. (Includes records relating to equipments, components, systems, drawings, etcetera, except see above for addressees for military specifications, standards, and catalogs.) For those concerning:	

Type of Record	*Addressee*
Aeronautical materials	Commander, Naval Air Systems Command, Department of the Navy, Washington, D.C. 20361.
Electronic materials	Commander, Naval Electronic Systems Command, Department of the Navy, Washington, D.C. 20360.
Facilities (design, construction, and maintenance; utilities; housing; real estate matters; etcetera).	Commander, Naval Facilities Engineering Command, Department of the Navy, Washington, D.C. 22332.
Ships and ordnance materials	Commander, Naval Air Systems Command, Department of the Navy, Washington, D.C. 20360.
Supply matters:	
Navy	Commander, Naval Supply Systems Command, Department of the Navy, Washington, D.C. 20376.
Marine Corps	Commandant of the Marine Corps (Code L), Washington, D.C. 20380.
Other requests. When not otherwise provided for in this enclosure, and for general information regarding the location of, or proper addressee for, Department of the Navy records.	Chief of Naval Operations (Op-09B16), Navy Department, Washington, D.C. 20350.

§ 701.32 Locations at which Department of the Navy records are available for public inspection.

Name of Facility and Location	*Type of Material*
In the Department (seat of government):	
Navy Department Library: Second floor of Building 220, at the Washington Navy Yard, U.S. Naval Station, 9th and M Streets SE., Washington, D.C. 20374. The facility is open from 0800 to 1630 (8 a.m. to 4:30 p.m.), Mondays through Fridays, except holidays.	An index system by subject matter to materials held. For example: (1) Department of the Navy directives issuance system consolidated subject index of unclassified instructions (an index of administrative unclassified instructions issued by Washington headquarters organizations and distributed to addressees outside the originating office); and the Marine Corps directives system quarterly checklist of directives distributed outside Headquarters, Marine Corps. These indexes assist in identifying instructions issued on any desired subject. (2) An index to the armed services procurement regulation and to Navy procurement directives. (3) Any other indexes prepared pursuant to this instruction and a master list of available indexes.
Law Library of the Office of the Judge Advocate General: Room 2527 of the Navy Arlington Annex (Federal Office Building, No. 2), Southgate Road and Columbia Pike, Arlington, VA 20370.	Published and unpublished decisions of Boards of Review and Military Courts of Review created under the Uniform Code of Military Justice. (Published decisions are available also at naval bases, as indicated below.)
Technical Library of the Navy Publications and Printing Service Office: Second floor of Building 157, Washington Navy Yard, U.S. Naval Station, 9th and M Streets, Washington, D.C. 20374.	Certain technical manuals, and indexes thereto, as made available under clearance procedures prescribed by sponsoring naval systems commands or as specified in contract documents.
Headquarters, Marine Corps: Room 1135 of the Navy Arlington Annex (Federal Office Building No. 2), Southgate Road and Columbia Pike, Arlington, VA 20380.	Marine Corps indexes, directives (orders and bulletins), and publications of general Marine Corps applicability.

Type of Record	*Addressee*
In the field (shore activities)	To the extent the material described above is received by Navy and Marine Corps field activities ashore, for the regular conduct of their business, it will be made available locally to members of the public, for inspection and copying, under procedures prescribed by this instruction, during regular working hours.
All Navy and Marine Corps shore activities: (Consult the area telephone directory for address of local Navy and Marine Corps activities.)	Current files of Department of the Navy directives of general applicability, and related indexes; also, directives of less than general applicability pertinent to their operations, and related indexes.
Navy publications and printing service offices (NPPSO): Located in Building 157-1 at the Washington Navy Yard, U.S. Naval Station, Washington, D.C. 20374; and in building 4, section D, at the Fourth Naval District, 700 Robbins Avenue, Philadelphia, PA 19111.	Technical manuals and data at field activities will be available as indicated in procurement documents. In some instances they will be made available under clearance procedures prescribed by the sponsoring naval systems command.
Naval bases and Marine Corps bases: (Consult the area telephone directory under U.S. Government for location of any nearby base.)	Published decisions of the Boards of Review and Military Courts of Review created under the Uniform Code of Military Justice can be found in "Courts-Martial Reports" maintained by these bases.

Subpart D—Schedules of Fees

§ 701.40 Uniform search and duplication fees for Department of Defense components.

(a) *Duplication.*

(1) *Publications, Forms and Reports.* Shelf stock of printed or microfiche medium (requestors may be furnished more than one copy of a publication or form if it does not deplete stock levels below projected planned usage).

Minimum fee, per request	$2.00
plus	
Forms, per copy	.05
Publications, per printed page	.01
Microfiche, per fiche	.06
Reports, per printed page	.05

(Examples: Cost of 20 forms $3; cost of a printed publication with 100 pages, $3; cost of a microfiche publication consisting of 10 fiche, $2.60.)

(2) *Office copy reproduction (when shelf stock is not available).*

Minimum charge up to six reproduced pages	2.00
Minimum charge, first fiche	5.00
Each additional page	.05
Each additional fiche	.10

(3) *Other Issuances*

Minimum charge up to six pages	2.00
Each additional page	.05

(b) *Search.*

Clerical search, per hour	6.50
Minimum charge	3.50
Professional search (includes computer programmer time), per hour	13.00
Minimum charge	10.00

Computer service charges will be based on actual computer configuration used and be based on direct costs only of the central processing unit plus input/output devices plus memory capacity.

(c) *Exceptions.*

(1) In general, charges may be waived when:

(a) the recipient of the benefits is engaged in a nonprofit activity designed for public safety, health or welfare;

(b) payment of the full costs or fee by a state, local government or nonprofit group would not be in the interest of the program;

(c) the incremental cost of collecting the fees would be an unduly large part of the receipts from the activity.

(2) A refusal to waive charges by the official responsible for the initial decision on the request for the record may be appealed to the head of the DoD Component or his designee for purposes of final approval.

(d) *Collections.* (1) Normally, collection of charges and fees will be made in advance of rendering the service. In some instances, it may be more practical to collect charges and fees at the time of conveying the service or property to the recipient, but only in those instances where the request specifically states that whatever cost involved will be acceptable or acceptable up to a specified limit that covers anticipated costs. Absent such an agreement to pay required anticipated costs, the time for responding to a request begins to run upon receipt of payment.

(2) Collection of scheduled fees and charges will normally be deposited to Miscellaneous Receipts of the Treasury.

(3) Search fees are assessable even when no records responsive to the request, or no records not exempt from disclosure are found, provided the requestor is advised of the requirement at the time the estimated charges are presented to the requestor for approval.

Dated: March 17, 1975.

WILLIAM O. MILLER,
Rear Admiral, JAGC, U.S. Navy,
Deputy Judge Advocate General.

[FR Doc.75-7363 Filed 3-20-75;8:45 am]

Title 36—Parks, Forests and Public Property

CHAPTER I—NATIONAL PARK SERVICE, DEPARTMENT OF THE INTERIOR

PART 7—SPECIAL REGULATIONS, AREAS OF THE NATIONAL PARK SERVICE

Cape Cod National Seashore, Massachusetts; Oversand Vehicle Regulations

A proposal was published at page 33375 of the FEDERAL REGISTER of September 17, 1974, to amend § 7.67 of Title 36 of the Code of Federal Regulations. Interested persons were given 30 days within which to submit written comments, suggestions, or objections in regard to the proposed amendments, and no comments, suggestions, or objections were received.

The amendments are adopted as published on September 17, 1974, with the exception of changes in language added for clarification.

The purposes of this amendment are to modify oversand vehicle registration and permit procedures, to identify the criteria that will be considered by the Superintendent prior to the issuance of permits for oversand travel and to designate routes and areas outside of established public roadways and parking areas open to oversand vehicles in accordance with criteria contained in sections 3 and 4 of Executive Order 11644 (37 FR 2877) and § 4.19(b) of this chapter as amended in the FEDERAL REGISTER on April 1, 1974 (39 FR 11883).

This revision shall take effect on April 21, 1975. (5 U.S.C. 553; 16 U.S.C. 3).

Section 7.67 is amended by revising paragraphs (a), (c)(1) and (f) to read as follows:

§ 7.67 Cape Cod National Seashore.

(a) The operation of motor vehicles in the park area other than authorized emergency vehicles is prohibited outside of established public roads and parking areas except on beaches and oversand routes designated by the Superintendent by the posting of appropriate signs and identified on maps available at the office of the Superintendent. These beaches and routes will be designated after consideration of the criteria contained in sections 3 and 4 of E.O. 11644, (37 FR 2877) and § 4.19 (b) of this chapter.

* * * * *

(c) *Private oversand vehicle operation.*

(1) Operation of privately owned passenger vehicles not-for-hire, (including the various forms of vehicles used for the travel oversand, such as but not limited to "beach buggies") on beaches or on designated oversand routes in the park area without a permit from the Superintendent is prohibited. Before a permit

will be issued, each vehicle will be inspected to assure that it contains the following equipment which must be carried in the vehicle at all times while on the beaches or on the designated oversand routes:

(i) Shovel;
(ii) Jack;
(iii) Tow rope or chain;
(iv) Board or similar support;
(v) Low pressure tire gauge.

A permit will not be issued unless it is determined that the nature and extent of use is consistent with the criteria contained in sections 3 and 4 of E.O. 11644 (37 FR 2877) including such factors as other visitor uses, safety, wildlife management, noise, erosion, geography, weather, vegetation, resource protection and other management considerations. Prior to the issuance of such permits operators must show compliance with Federal and State regulations applicable to licensing, registering, inspecting, and insuring of such vehicles. Such permits shall be affixed to the vehicles as instructed at the time of issuance.

* * * * *

(f) Shellfishing. Shellfishing, by permit from the appropriate town, is permitted in accordance with applicable Federal, State, and local laws.

LAWRENCE C. HADLEY,
Superintendent,
Cape Cod National Seashore.

[FR Doc.75-7425 Filed 3-20-75;8:45 am]

CHAPTER II—FOREST SERVICE, DEPARTMENT OF AGRICULTURE

PART 200—ORGANIZATIONS, FUNCTIONS, AND PROCEDURES

Availability of Records to the Public

Procedures for obtaining Forest Service records under the Freedom of Information Act are hereby amended in accordance with the Department's regulations issued pursuant to the Act, 7 CFR Part 1, Subpart A (40 FR 7341). The Department's regulations, as implemented by the regulations in this part, govern the availability of records of the Forest Service to the public.

Advance notice of rulemaking is not required for this amendment by 5 U.S.C. 553, since it deals with agency organization and procedures.

In consideration of the above, Subpart B of Part 200, Title 36 of the Code of Federal Regulations is amended as follows:

1. Section 200.5 is revised to read as follows:

§ 200.5 Information available.

In accordance with 7 CFR 1.2, the Forest Service shall make available for public inspection and copying all published or unpublished directives, forms, records, and final opinions, including concurring or dissenting opinions and orders made in the adjudication of cases.

2. Section 200.6 is deleted and a new § 200.6 is added to read as follows:

§ 200.6 Indexes.

Publication of the indexes described in § 200.4 is deemed both unnecessary and impractical because of the large volume of material involved. However, copies of the indexes are available for public review in the Forest Service headquarters office in Washington, D.C., and at field offices listed under § 200.2(d). The Forest Service will provide copies of any index upon request at a cost not to exceed the direct cost of duplication.

3. Section 200.7 is revised to read as follows:

§ 200.7 Offices where information is available.

Information which is to be made available for public inspection and copying by provisions of 5 U.S.C. 552(a)(2) (7 CFR 1.2) may be obtained at the Office of the Chief, or the office of any Regional Forester, Research Station Director, Area Director, Forest Supervisor, or District Ranger. The addresses of such offices are set forth in §§ 200.1 and 200.2. Forest Service personnel at these offices will also assist members of the public seeking any other Forest Service records. All information on all activities may not be available at a given office. When the information desired is not available at a given location, the office where the request is received will assist the applicant by directing him to another office where the information may be obtained. Except for such information as is generally available to the public, requests should be in writing and submitted in accordance with 7 CFR 1.3 and §§ 200.10 and 200.11 of this Part.

* * * * *

4. Section 200.10 is redesignated as § 200.11 and a new § 200.10 is added to read as follows:

§ 200.10 Request for records.

The Regional Forester, Research Station Director, and Area Director at the field locations and addresses listed in § 200.2(d) and the Deputy Chief for the program area involved, located in Washington, D.C., are authorized to receive requests for records submitted in accordance with 7 CFR 1.3(a), and to make determinations regarding whether to grant or deny requests for records exempt from mandatory disclosure under the provisions of 5 U.S.C. 552(b). All these officials are authorized to (1) extend the ten-day administrative deadline for reply pursuant to 7 CFR 1.8, (2) make discretionary releases pursuant to 7 CFR 1.11(b) of records exempt from mandatory disclosure, and (3) make determinations regarding the charging of fees.

5. The redesignated § 200.11 is revised to read as follows:

§ 200.11 Appeals.

(a) Appeals from denials of requests submitted under § 200.10 shall be submitted in accordance with 7 CFR 1.3(c) to the Chief, Forest Service, Department of Agriculture, 12th Street and Independence Avenue, SW., Washington, D.C. 20250.

(b) The Chief shall determine whether to grant or deny the appeal. He shall also make all necessary determinations relating to an extension of the twenty-day administrative deadline for reply pursuant to 7 CFR 1.8, discretionary release pursuant to 7 CFR 1.11(b) of records exempt from mandatory disclosure under 5 U.S.C. 552(b), and the charging of appropriate fees.

Effective Date: This amendment takes effect March 21, 1975.

(5 U.S.C. 552).

ROBERT W. LONG,
Assistant Secretary.

MARCH 18, 1975.

[FR Doc.75-7461 Filed 3-20-75;8:45 am]

Title 41—Public Contracts and Property Management

CHAPTER 114—DEPARTMENT OF THE INTERIOR

PART 114-3—ANNUAL REAL PROPERTY INVENTORIES

Pursuant to the authority of the Secretary of the Interior contained in 5 U.S.C. 301, and Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c), Subpart 114-3.2 to Chapter 114, Title 41 of the Code of Federal Regulations, is amended as set forth below.

Since these amendments relate to matters of internal policy only, it is determined that the proposed rule making procedure is unnecessary and these amendments shall become effective on April 21, 1975.

Dated: March 17, 1975.

RICHARD R. HITE,
Deputy Assistant Secretary of the Interior.

1. In § 114-3.204(b) (1) and (2) are revised to read as follows:

§ 114-3.204 Reports to be submitted.

* * * * *

(b) * * *

(1) For purposes of this inventory, the reporting entity is an "installation".

(i) Except as provided in § 114-3.204 (b) (1) (ii), below, Bureaus and Offices are authorized to determine what constitutes an "installation" for reporting purposes. However, to increase the usefulness of the real property inventory report, Bureaus and Offices are urged to:

(A) Report separately those units physically separate from each other, particularly if in different counties, or if such units have been separately authorized, individually mentioned in budget justifications, serve a different local population center, etc.

(B) Coordinate this report with the accounting system and all other complementary reporting requirements, such as budget justification and preparation, quarters' surveys and reports, land utilization and status reports, etc. The more realistically "installation" is fitted in

with the bureau's other needs for information, the more readily all such data can be cross-checked, and one submission serves several reporting requirements.

(ii) Separate reports on GSA Form 1166 shall be submitted for Job Corps Conservation Centers. A separate summary report on GSA Form 1209 is not required, but Conservation Centers should be included in the summary Form 1209 for the Bureau.

(2) Bureaus and Offices shall assign an agency control number (Block 2) to each installation. This number shall identify both this Department and the Bureau, e.g., I–BIA–118, or I–EBM–224.

* * * * *

2. Section 114–3.205 is revised to read as follows:

§ 114–3.205 Optional reporting method.

Any Bureau or Office desiring to submit its real property inventory in the form of a machine listing supported by punch cards shall notify the Director of Management Services so that appropriate arrangements can be made with the central office of the General Services Administration.

3. Section 114–3.206 is revised to read:

§ 114–3.206 Preparation and due dates.

The annual inventory report on GSA Forms 1166 and 1209 shall be prepared as of June 30 of each year and transmitted to reach the Director of Management Services by not later than August 21, in the number of copies indicated below.

GSA Form 1166. An original and one copy. A complete file of all current individual installation reports shall be maintained by the bureau headquarters office.

GSA Form 1209. An original and two copies, and one copy to be retained by the bureau headquarters office.

Consolidated GSA Form 1166. An original only is required for retention and use by the Director of Management Services.

[FR Doc. 75–7393 Filed 3–20–75;8:45 am]

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 57—GRANTS FOR CONSTRUCTION OF HEALTH RESEARCH FACILITIES (INCLUDING MENTAL RETARDATION RESEARCH FACILITIES), TEACHING FACILITIES, STUDENT LOANS, EDUCATIONAL IMPROVEMENT AND SCHOLARSHIPS

Nursing Special Project Grants

In the FEDERAL REGISTER of July 31, 1974 (39 FR 27690), the Assistant Secretary for Health, with the approval of the Acting Secretary of Health, Education, and Welfare, proposed to amend Part 57 by adding a new Subpart T to implement section 805(a) of the Public Health Service Act. That section authorizes the Secretary to award grants to public or other non-profit schools of nursing, agencies, organizations and institutions to assist in meeting the costs of special projects, as set forth in the authorizing legislation.

Interested persons were afforded the opportunity to participate in the rulemaking through submission of comments on or before August 30, 1974. Following is a summary of the comments received and the response to such comments:

(1) One comment suggested that § 57.1905 of the proposed regulations, "Evaluation and grant award", be revised to include as one factor to be considered by the Secretary any particular local need to which a proposed project is addressed. The regulations have been revised accordingly.

(2) One comment suggested that § 57.1903 of the proposed regulations, "Eligibility", be revised to allow individuals or groups of individuals to be eligible for nursing special project grants. Eligibility for such grants is statutorily limited however to public or non-profit private schools of nursing, agencies, organizations, or institutions and the suggested revision therefore has not been made.

(3) One comment concerned the need for adequate reviews by § 314(a) and 314(b) agencies to assure that proposed nursing special projects are integrated into and address the needs identified by various health planning agencies. Section 57.1905(a) of the proposed regulation has been revised to state that the Secretary will consider, in determining whether to make a grant award under this subpart, for projects related to health services or comprehensive health planning programs, comments of the appropriate State and/or areawide health planning agencies.

In addition to the changes described above, there are several minor self-explanatory changes in the regulation as proposed, which are merely editorial and technical in nature.

Accordingly, a new subpart T is added to 42 CFR Part 57 and is adopted as set out below.

Effective date: These regulations are effective April 21, 1975.

Dated: February 18, 1975.

THEODORE COOPER,
Acting Assistant Secretary for Health.

Approved: March 17, 1975.

CASPAR W. WEINBERGER,
Secretary

Subpart T—Nursing Special Project Grants

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216). Sec. 805(a), 85 Stat. 469 (42 U.S.C. 296d).

Subpart T—Nursing Special Project Grants

§ 57.1901 Applicability.

The regulations of this subpart are applicable to the award of grants to public and other nonprofit private schools of nursing, agencies, organizations, and institutions under section 805(a) of the Public Health Service Act (42 U.S.C. 296d) to assist in meeting the cost of nursing special projects.

§ 57.1902 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

(c) "Council" means the National Advisory Council on Nurse Training (established by section 841(a) of the Act).

(d) "Budget period" means the interval of time into which the project period is divided for budgetary purposes as specified in the grant award document.

(e) "Project period" means the total time for which support for a project has been approved, as specified in the grant award document.

(f) "State," except as otherwise provided herein, means a State, Puerto Rico, the District of Columbia, the Canal Zone, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

(g) "School of nursing" means a collegiate, associate degree or diploma school of nursing, as such are defined in section 843 of the Act.

(h) "Nonprofit" means as applied to any school, agency, organization or institution one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inure or may lawfully inure to the benefit of any private shareholder or individual.

(i) "Section 314(a) State health planning agency" means the agency of a State which administers or supervises the administration of a State's health planning functions under a State plan approved under section 314(a) of the Act.

(j) "Section 314(b) areawide health planning agency" means a public or nonprofit private agency or organization which has developed a comprehensive regional, metropolitan, or other local area plan or plans referred to in section 314(b) of the Act.

§ 57.1903 Eligibility.

To be eligible for a grant under this subpart the applicant shall:

(a) Be a public or other nonprofit private school of nursing, agency, organization or institution; and

(b) Be located in a State.

§ 57.1904 Application.

(a) Each eligible applicant desiring a nursing special project grant shall submit an application in such form and manner and at such time as the Secretary may prescribe.[1] The application shall contain a full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart, a budget and justification of the amount of grant funds requested, and such other pertinent information as the Secretary may require.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the regulations of this subpart and the terms and conditions of any award.

§ 57.1905 Evaluation and grant award.

(a) Within the limits of funds available for such purpose, the Secretary, after consultation with the Council, may award grants to those applicants whose projects will in his judgment best promote the purposes of section 805(a) of the Act, taking into consideration among other pertinent factors:

(1) The potential effectiveness of the proposed project in carrying out such purposes;

(2) The national or special local need which the particular project proposes to serve;

(3) The comments made by the appropriate section 314(a) State health planning agency and/or the section 314(b) areawide health planning agency with respect to projects related to health services or comprehensive health planning programs. The Secretary will request comments from such agencies with respect to such projects and will provide a 60 day period for submission of such comments;

(4) The administrative and managerial capability, and competence of the applicant to carry out the project successfully; and

(5) The soundness of the plan for assuring effective utilization of grant funds and the potential of the project to continue on a self sustaining basis.

(b) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (1) on the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage of all or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limit of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which such funds will be available for obligation by the grantee.

(d) Neither the approval of any project nor the award of any grant shall commit or obligate the United States in any way to make any additional, supplemental, continuation or other award with respect to any approved project or portion thereof. For continuation support grantees must make separate application at such times and in such form as the Secretary may prescribe.

§ 57.1906 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved project.

§ 57.1907 Expenditure of grant funds.

(a) Any funds granted pursuant to this subpart shall be expended solely for carrying out the approved project in accordance with section 805(a) of the Act, regulations of this subpart, the terms and conditions of the award and cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Any unobligated grant funds remaining in the grant account at the close of a budget period may be carried forward and be available for obligation during a subsequent budget period of the project period. The amount of a subsequent award will take into consideration the amount remaining in the grant account. At the end of the last budget period of the project period any unobligated grant funds remaining in the grant account must be refunded to the Federal Government.

§ 57.1908 Nondiscrimination.

(a) Attention is called to the requirements of section 845 of the Act and 45 CFR Part 83 which together provide that the Secretary may not make a grant, loan guarantee, or interest subsidy payment under Title VIII of the Act to, or for the benefit of, any entity unless he receives satisfactory assurance that the entity will not discriminate on the basis of sex in the admission of individuals to its training programs.

(b) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) which provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(c) Attention is called to the requirements of Title IX of the Education Amendments of 1972 and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(d) Grant funds used for remodeling, alterations, or repairs shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (Sept. 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 57.1909 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for costs meeting the requirements of this subpart: *Provided however,* That when the amount awarded for indirect cost was based on a fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant shall be accounted for as follows:

(1) *State and local governments.* Where the grantee is a State or local government as those terms are defined in 45 CFR 74.3, royalties shall be accounted for as provided in 45 CFR 74.44.

(2) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, royalties shall be accounted for as follows:

(A) Patent royalties, whether received during or after the grant period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health, Education, and Welfare, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(B) Copyright royalties, whether received during or after the grant period,

[1] Applications and instructions may be obtained from the Regional Health Administrator of the Regional Office of the Department of Health, Education, and Welfare for the region in which the applicant is located.

shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials, and any royalties in excess of the costs of publishing or producing the materials shall be distributed in accordance with Chapter 1-420, Department of Health, Education, and Welfare Grants Administration Manual.[2]

(c) *Grant closeout.* (1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of- (i) any amount not accounted for pursuant to paragraphs (a) and (b) of this section; to Subparts F, M, and O of 45 CFR Part to subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assigns by setoff or other action as provided by law.

§ 57.1910 Publications and copyrights.

(a) *State and local governments.* Where the grantee is a State or local government, as those terms are defined in 45 CFR 74.3 the Department of Health, Education, and Welfare copyright requirement set forth in 45 CFR 74.140 shall apply with respect to any book or other copyrightable materials developed or resulting from a project supported by a grant under this subpart.

(b) *Grantees other than State and local governments.* Where the grantee is not a State or local government, as so defined, except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this subpart, subject to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate and dispose of such materials, and to authorize others to do so.

§ 57.1911 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to all other grantee organizations under this subpart:

Subpart:
- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-Related Income.
- K Grant Payment Requirements.
- L Budget Revision Procedures.
- M Grant Closeout, Suspension, and Termination.
- O Property.
- Q Cost Principles.

§ 57.1912 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved activity, the interest of the public health or the conservation of grant funds.

[FR Doc.75-7398 Filed 3-20-75;8:45 am]

Title 45—Public Welfare

CHAPTER VI—NATIONAL SCIENCE FOUNDATION

PART 612—AVAILABILITY OF RECORDS AND INFORMATION

NSF Regulation Pursuant to the Freedom of Information Act

The following regulations provide that requests for certain categories of records other than publications will be made available pursuant to appropriate requests within ten working days after receipt, unless conditions for an extension are present, and that determinations on appeals will be rendered by the Deputy Director within twenty days of receipt. The regulations also provide that NSF policy documents and staff instructions may be inspected and copied at the NSF Library and that publications may be obtained from specified sources. Fees for providing copies are set forth.

These regulations were published in proposed form in 40 FR 3313 on January 21, 1975. Although NSF invited the public to make comment, it received none. Part 612 is published herein in final form and without change in the substance thereof, although the location of certain provisions has been rearranged and clarifying language has been inserted.

Accordingly, Part 612 of Title 45 of the Code of Federal Regulations is hereby promulgated as set forth below, effective February 19, 1975.

Dated: March 14, 1975.

H. GUYFORD STEVER,
Director.

AUTHORITY: The provisions of this Part 612 are issued under 5 U.S.C. 552, as amended by Pub. L. 93-502.

§ 612.1 Scope.

This part establishes procedures for the National Science Foundation (NSF) to implement the provisions of the Administrative Procedure Act (5 U.S.C. 552(a)) relating to the availability to the public of records of NSF.

§ 612.2 Information policy.

(a) It is the policy of NSF to make the fullest possible disclosure of information to any person who requests information, without unnecessary expense or delay. The Deputy Director, NSF, may, in particular instances except where prohibited by law, order disclosure in the public interest of records exempt from mandatory disclosure under § 612.9 of this regulation.

(b) A collection of NSF policy documents, staff instructions, and of agency opinions and orders in the adjudication of cases, with respective indices, shall be physically located in the National Science Foundation library at 1800 G Street, NW., Washington, D.C. where they will be available for inspection by the public during regular working hours on Monday through Friday. Copies of such documents shall be furnished in accordance with these regulations.

(c) The Assistant Director for Administrative Operations (AD/AO) shall be responsible for maintaining, publishing, distributing and making available for inspection and copying the current indexes and supplements thereto which are required by 5 U.S.C. 552(a)(2). Such indexes shall promptly be published, quarterly or more frequently, unless the ADAO determines by order published in the FEDERAL REGISTER that the publication would be unnecessary. The fee for furnishing copies of indexes and supplements shall not exceed the direct cost of duplication.

§ 612.3 Procedures applicable to the public—requests and appeals.

(a) *Publications excluded.* For the purpose of public requests for records the term "record" does not include publications which are available to the public in the FEDERAL REGISTER, or by sale or free distribution. Such publications may be obtained from the Government Printing Office, the National Technical Information Service, the NSF Distribution Section or NSF grantees or contractors. Requests for such publications will be referred to or the requester informed of the appropriate source. The booklet, Publications of the National Science Foundation, which is available without charge from the Central Processing Section, National Science Foundation, Washington, D.C. 20550, identifies Annual Reports, Descriptive Brochures, Program Announcements, Science Resources Studies, Special Studies, and Periodicals descriptive of Foundation activities, policies, and procedures, sets forth the cost of each, and tells how copies may be obtained.

(b) *Form of request.* A request need not be in any particular format, but it

[2] The Department of Health, Education, and Welfare Grants Administration Manual is available for public inspection and copying at the Department and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

(1) must be in writing, (2) must be clearly identified both on the envelope and in the letter as a Freedom of Information Act or FOIA request, (3) must describe the records sought with sufficient specificity to permit identification, and (4) must state that the requester promptly will pay the fees chargeable under this regulation, Provided however, That when the requester places an inadequate limit on the amount he will pay or the requester has failed to make payment for previous requests, the notice of determination whether or not to comply with the request will be furnished within ten days as provided in § 612.7 of this regulation but no copies will be furnished until appropriate payment is received.

(c) *Place of request.* Any request for a record under FOIA shall be addressed to the National Science Foundation, Public Information Office, 1800 G Street, NW., Washington, D.C. 20550. A request which meets the requirements of subsection (a) above and is properly addressed shall be deemed received on the date of arrival in the NSF mailroom. Since NSF liaison offices located outside of Washington, D.C. maintain no permanent records, any request received by such offices will be returned to the requester with instructions for submission as provided herein.

(d) *Time for appeal.* A person whose request has been denied or partially denied may initiate an appeal by filing a request for review within ten days of the receipt of the denial, Saturdays, Sundays, legal public holidays, and the date of receipt excluded.

(e) *Form of appeal.* The appeal shall include a copy of the written request and the denial together with any written argument the requester wishes to submit, and shall be signed by the requester.

(f) *To whom appeal is made.* An appeal shall be addressed to the Deputy Director, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550.

(g) *Decisions on appeal.* Decisions on appeal shall be made by the Deputy Director in writing within 20 days (excepting the date of receipt, Saturdays, Sundays, and legal public holidays) from receipt of the appeal. If the decision is in favor of the requester it shall order the record made available promptly to the requester. If adverse to the requester in whole or in part it shall briefly state the reasons and notify the requester that he may seek judicial review of the decision pursuant to paragraph (4) of section 552(a), Title 5, United States Code. Before final denial the Deputy Director, acting through the Office of General Counsel, shall consult the Department of Justice concerning the proposed denial.

§ 612.4 Copies of records.

If it is determined that a requested record may be disclosed, copies will be furnished the requester as promptly as possible provided payment of fees has been arranged for pursuant to § 612.6(a) of this regulation. Copying service shall be limited to not more than two copies of any page, except that additional copies may be made where administrative considerations permit. Records shall not be released for copying by non-NSF personnel.

§ 612.5 Creation of records.

A record will not be created by compiling selected items from other documents at the request of a member of the public nor will a record be created by analysis, computation or other processing specifically for the requesting party. If such analysis or computation is available in the form of a record, copies shall be made available as provided in this regulation.

§ 612.6 Fees.

(a) *General.* User fees shall be charged according to the schedule contained in paragraph (b) of this section for services rendered in responding to requests for NSF records under this regulation. Copies shall be furnished without charge or at a reduced charge where it is determined that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Fees shall be charged only where they amount to more than $3.00 in the aggregate for a request or series of related requests. Ordinarily, fees shall not be charged if the records requested are not found, or if all of the records located are withheld as exempt.

(b) *Services charged for, and amounts charged.* For the services listed below expended in locating or making available records or copies thereof, the following charges will be assessed:

(1) Copies. For photocopies of documents $0.10 per copy of each page. Where records are not susceptible to photocopying, e.g., punchcards, magnetic tapes, or oversize materials, the amount charged will be actual cost as determined on a case-by-case basis.

(2) Clerical searches. For each one quarter hour spent by clerical personnel after the first quarter hour, in searching for producing a requested record, $1.25.

(3) Certification or authentication of true copies—each: $3.00.

(4) Nonroutine, nonclerical searches. Where a search cannot be performed by clerical personnel, for example, where the task of determining which records fall within a request and collecting them requires the time of professional or managerial personnel, and where the amount of time that must be expended in the search and collection of the requested records by such higher level personnel is substantial, charges for the search may be made at a rate in excess of the clerical rate, namely for each one quarter hour spent in excess of the first quarter hour by such higher level personnel in searching for a requested record, $3.75.

(5) Examination and related tasks in screening records. No charge shall be made for the time spent in resolving legal or policy issues affecting access to records of known contents. In addition, no charge shall ordinarily be made for the time involved in examining records in connection with determining whether they are exempt from mandatory disclosure and should be withheld as a matter of sound policy. However, where a broad request requires NSF personnel to devote a substantial amount of time to examining records for the purpose of screening out certain records or portions thereof in accordance with determinations that material of such a nature is exempt and should be withheld as a matter of sound policy, a fee may be assessed for the time consumed in such examination. Where such examination can be performed by clerical personnel, time will be charged for at the rate of $1.25 per quarter hour, and where higher level personnel are required, time will be charged for at the rate of $3.75 per quarter hour.

(6) Computerized Records. Fees for services in processing requests maintained in whole or in part in computerized form shall be in accordance with this section so far as practicable. Services of personnel in the nature of a search shall be charged for at rates prescribed in paragraph (c)(4) of this section unless the level of personnel involved permits rates in accordance with paragraph (c)(2) of this section. A charge shall be made for the direct cost of the computer time involved, based upon the prevailing level of costs to governmental organizations and upon the particular types of computer and associated equipments and the amounts of time on such equipments that are utilized. A charge shall also be made for the direct costs of special supplies or materials used to contain, present, or make available the output of the computers. Nothing in this paragraph shall be construed to entitle any person as of right, to any special processing of computerized records such as a reordered listing of or special summaries of file contents.

(c) *Notice of anticipated fees in excess of $25.* Where it is anticipated that the fees chargeable under this section will amount to more than $25, and the requester has not indicated in advance his willingness to pay fees as high as are anticipated, the requester shall be notified of the amount of the anticipated charges. In appropriate cases, an advance deposit may be required. The notice or request for an advance deposit shall extend an offer to the requester to confer with knowledgeable NSF personnel in an attempt to reformulate the request in a manner which will reduce the fees and meet the needs of the requester.

(d) *Form of payment.* Payment should be made by check or money order payable to the National Science Foundation.

§ 612.7 Agency actions on receipt of a properly presented request for record.

(a) *Monitoring of requests.* The NSF Public Information Office (PIO) will serve as central office for internal administration of these regulations. PIO will control incoming requests, assign them to appropriate action offices, monitor compliance, consult with action offices on disclosure, approve unavoidable

extensions, dispatch denial letters, and maintain administrative records.

(b) *Action offices.* Upon assignment of a particular request, the head of the action office shall be responsible to obtain the requested record so that appropriate agency action can be completed within 10 days (excepting the date of receipt, Saturdays, Sundays, and legal public holidays). In a situation where the record may exist only in a retired file which has been placed in storage, the head of the action office shall immediately notify the requester by letter that the record has been ordered from storage and that the time limit for acting on the request is extended by the length of time required to obtain the record, setting forth the date on which a determination is expected to be dispatched. If the request seeks a voluminous amount of separate and distinct records requiring an unusual length of time for search, collection, and appropriate examination, and determination on the request cannot be made within 10 working days after agency receipt, the office head shall within such ten-day period furnish to the requester written notice extending the period for not more than ten working days. This notice shall set forth the reasons for such extension and the date on which a determination is expected to be dispatched. If the record has not been obtained and examined and notice of the determination whether to comply with the request has not been given by the last day of the period as extended, the requester shall be notified on that last day that the request is denied because the record has not yet been found and examined. Such denial shall state that NSF will reconsider the denial as soon as the search and examination is complete, which should be within a specifically stated number of days, but that the requester may, if he wishes, file an administrative appeal as provided in § 612.3 of this regulation. This same procedure for extending the period shall be followed if the nature of the record requires consultation with another agency having a substantial interest in the determination of the request or requires consultation among two or more components of NSF having substantial subject-matter interest therein.

(c) *Denial of request.* No written request for record shall be denied except by the Director of the Office of Government and Public Programs. Notice of the denial of a request shall briefly set forth the reasons therefor which shall be based solely upon one or more of the exemptions specified in § 612.9 of this regulation. Each notice of denial also shall set forth the names and title or positions of each person responsible for the denial and shall inform the requester of the right to appeal as provided in § 612.3 of this regulation.

(d) *Oral requests.* Nothing in these regulations shall be deemed to preclude NSF from honoring oral requests for information where feasible, but if the requester is dissatisfied with the disposition of such a request, he shall be asked to put the request in writing.

§ 612.8 Records available.

The following categories of records shall, unless exempted under the provisions of § 612.9, be made available in addition to the policy documents and final opinions and orders in adjudicated cases specified in 5 U.S.C. 552(a) (1) and (2).

(a) *Correspondence.* Correspondence between NSF or any official of NSF and individuals or organizations outside the Federal Government relating to or resulting from the conduct of the official business of the agency.

(b) *Records pertaining to grants and fellowships.* (1) Portions of funded grant applications and other supporting documents submitted by applicants which are not exempt from disclosure under this regulation; (2) Grant award documents; and (3) Portions of funded fellowship applications and other supporting documents submitted by applicants, the disclosure of which would not constitute a clearly unwarranted invasion of personal privacy.

(c) *Contracts.* (1) Contract instruments, (2) Portions of offers reflecting final prices submitted in negotiated procurements.

(d) *Reports on grantee or contractor performance.* Final reports of audits, surveys, reviews, or evaluations by, for, or on behalf of NSF or performance by any grantee or contractor under any NSF financed or supported program or activity, which reports have been transmitted to the grantee or contractor.

(e) *Reports and other items prepared by grantees and contractors.* The final report of a grantee or contractor of the performance under any grant or contract. To the extent that NSF has taken delivery of other items produced in connection with grants and contracts, such as films, computer software, other copyrightable materials and reports of inventions, such materials will be made available except that considerations relating to obtaining copyright and patent protection may require delay in disclosure for such period as necessary to accomplish such protection. Release of records which are copyrightable or which disclose patentable inventions shall not confer upon the requester any license or other interest in the subject matter or the expression thereof.

§ 612.9 Records not available.

(a) *Exemptions.* The following types of records are not normally available for inspection and copying:

(1) Records specifically authorized and in fact properly classified pursuant to Executive Order to be kept secret in the interest of national defense or foreign policy.

(2) Records related solely to the internal personnel rules and practices of NSF. This exemption does not apply to rules relating to the work hours, leave, and working conditions of NSF personnel, or similar matters, to the extent that they can be disclosed without harm to the functions to which they pertain. Examples of exempt records of the type specified in the first sentence of this paragraph include, but are not limited to:

(i) Operating rules, guidelines, manuals on internal procedure, schedules and methods utilized by NSF auditors and examiners;

(ii) Negotiating positions and limitations involved in a negotiation prior to the execution of a contract or the completion of the action to which the negotiating positions or limitations were applicable except as they may be exempt pursuant to other provisions of this section.

(iii) Personnel policies, procedures and instructions, internal staffing plans, requirements, authorizations, controls, and supporting data relating to position management and manpower utilization and information involved in the determination of the qualifications of candidates for employment or advancement.

(3) Records specifically exempted from disclosure by statute such as 18 U.S.C. 1905 which prohibits disclosure of information which concerns or relates to the trade secrets, processes, operations, style of work, or apparatus or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation or association.

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential. Matter subject to this exemption is that which is customarily held in confidence by the originator without regard to whether or not the originator is, or is not employed by, a nonprofit organization. It includes, but is not limited to:

(i) Information received in confidence, such as grant applications, fellowship applications and research proposals prior to award;

(ii) Statistical data or information if received in confidence from a contractor or potential contractor concerning contract performance, income, profits, losses, and expenditures.

(5) Inter-agency or intra-agency memoranda or letters which would not be available by law to a private party in litigation with NSF. To the extent not so available by law, examples include, but are not limited to:

(i) Reports, memoranda, correspondence, workpapers, minutes of meetings (other than those governed by the Federal Advisory Committee Act), and staff papers prepared for use within NSF or within the Executive Branch of the Government by personnel and consultants of NSF, or any Government agency.

(ii) Advance information on proposed NSF plans to procure, lease, or otherwise acquire, or dispose of materials, real estate, facilities, services or functions, when such information would provide undue or unfair competitive advantage to any person;

(iii) Records prepared for use in proceedings before any Federal or State court or administrative body;

(iv) Evaluations of and comments on specific grant applications, research proposals, or potential contractors, whether made by NSF personnel or by

external reviewers acting either individually or in committees;

(v) Preliminary, draft unapproved recommendations, evaluations, and opinions, such as evaluations of invention disclosures, of research projects, and of incomplete studies conducted or supported by NSF;

(vi) Proposed budget requests and supporting projections used or arising in the preparation and/or execution of a budget; proposed annual and multi-year policy, priorities, program and financial plans and supporting papers.

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Information in such files which is not otherwise exempt from disclosure pursuant to other provisions of this section will be released to the subject or to his designated legal representative, and it may be disclosed to others with his written consent. Examples of personnel files exempt from disclosure include, but are not limited to, file containing reports, records and other materials pertaining to individual cases in which disciplinary or other administrative action has been or may be taken. Similar files include reports and evaluations which reflect upon the qualifications or competence of individuals. Opinions and orders resulting from those proceedings shall be disclosed without identifying details if used, cited, or relied upon as precedent.

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trail or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel.

(8) Matters contained in or related to examination, operating, or condition reports prepared by, or on behalf of, or for the use of any government agency responsible for the regulation or supervision of financial institutions.

(9) Geological and geophysical information and data (including maps) concerning wells.

(10) Records belonging to another government agency or dealing with subject matter as to which government agency, other than NSF, has exclusive or primary responsibility. Requests for such records shall be promptly forwarded to the appropriate government agency for disposition or for guidance with respect to disposition.

(b) *Deletion of exempt portion and identifying details.* Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt. Whenever any final opinion, order, or other materials required to be made available relates to a private party or parties and the release of the name or names or other identifying details will constitute a clearly unwarranted invasion of personal privacy, the record shall be published or made available with such identifying details left blank, or shall be published or made available with obviously fictitious substitutes and with a notification such as the following as a preamble:

Names of parties and certain other identifying details have been removed (and fictitious names substituted) in order to prevent a clearly unwarranted invasion of the personal privacy of the individuals involved.

§ 612.10 Records and reports on requests for information.

The Director of the Office of Government and Public Programs will be responsible for maintaining a record of denials of written requests for information. On or before March 1 of each year, OGPP shall prepare and submit it to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress a report concerning requests received during the preceding calendar year. The report shall include: (1) The number of determinations made not to comply with requests for records and the reasons for each such determination; (2) the number of appeals made, the result of such appeals, and the reason for the action upon each appeal that results in a denial of information; (3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each; (4) the results of each court order which requires the production of a record, including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken; (5) a copy of every rule made by NSF regarding this section; (6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and (7) such other information as indicates efforts to administer fully the provisions of 5 U.S.C. 502.

[FR Doc.75-7392 Filed 3-20-75;8:45 am]

Title 47—Telecommunication

CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION

[FCC 75-290]

PART 0—COMMISSION ORGANIZATION

PART 76—CABLE TELEVISION SERVICES

Organization; Cable Television

In the matter of amendment of Part 0 and Part 76, subpart A, of the Commission's rules and regulations concerning delegations of authority to the Chief, Cable Television Bureau and procedures in the cable television service relating to dismissal of requests for special relief.

1. In recent months, we have had cause to consider a deficiency in the Commission's procedures dealing with petitions for special relief filed pursuant to section 76.7. Under the present cable television rules, procedures for dismissing special relief petitions are not clearly delineated. We have concluded, therefore, that amendment to the present procedures contained in part 76, subpart A, of the Commission's rules is in order. The new rule (section 76.8), which is akin to dismissal procedures contained in § 76.20 concerning applications for certificates of compliance, will aid the Cable Television Bureau in expediting the processing of pending cases and in reducing its backlog. In addition, we are amending § 0.288(d) of the rules in order to delegate authority to the Chief, Cable Television Bureau, to dismiss special relief petitions upon the request of the petitioner, for failure of the petitioner to prosecute a petition, and for failure to respond to official Commission correspondence or request for additional information.

2. Since these amendments are either editorial or relate to Commission organization, procedures, or practice, or restate existing requirements, the prior notice and effective date provisions of section 4 of the Administrative Procedure Act, 5 U.S.C. 553, do not apply.

Authority for the rule amendments adopted herein is contained in sections 2, 3, 4(i) and (j), 5(b) and (d), 301, 303, 307, 308 and 309 of the Communications Act of 1934, as amended.

Accordingly, *It is ordered*, That effective March 25, 1975, Part 0 and Part 76 of the Commission's rules and regulations are amended as set forth below.

(Secs. 2, 3, 4, 5, 301, 303, 307, 308, 309, 48 Stat., as amended, 1064, 1065, 1066, 1068, 1081, 1082, 1083, 1084, 1085; 47 U.S.C. 152, 153, 154, 155, 301, 303, 307, 308, 309.)

Adopted: March 11, 1975.

Released: March 18, 1975.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

1. Part 0—Commission Organization Paragraph (d) of Section 0.288 is amended as follows:

§ 0.288 Delegated Authority.

* * * * *

(d) To dismiss petitions and applications, as provided in §§ 76.8, 76.20 and 78.21 of this Chapter, or those which are not timely filed under the Commission's rules, not acceptable under the Commission's rules, or clearly moot;

* * * * *

2. Part 76—Cable Television Service A new Section 76.8 is added, as follows:

§ 76.8 Dismissal of Special Relief Petitions.

(a) A petition for special relief may, upon request of the petitioner, be dismissed without prejudice as a matter of right prior to the adoption date of any final action taken by the Commission with respect to the petition. A petitioner's request for the return of a petition will be regarded as a request for dismissal.

(b) Failure to prosecute a petition, or failure to respond to official correspondence or request for additional information, will be cause for dismissal. Such dismissal will be without prejudice if it occurs prior to the adoption date of any final action taken by the Commission with respect to the petition.

[FR Doc.75-7407 Filed 3-20-75;8:45 am]

Title 49—Transportation

CHAPTER V—NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Docket No. 74-10; Notice 15]

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

Air Brake Systems

This notice amends Standard No. 121, *Air brake systems,* 49 CFR 571.121, in response to petitions for reconsideration of requirements established for trucks and buses, by revision of the retardation force requirements applicable to on/off highway vehicles until September 1, 1975, or September 1, 1976.

The National Highway Traffic Safety Administration (NHTSA) established the final form of Standard No. 121 for purposes of judicial review in November 1974 (39 FR 39380, November 21, 1974) (Notice 6). Notice 6 established interim stopping distance requirements for standard highway vehicles, and retardation force requirements for some on/off highway vehicles. Petitions for reconsideration of the decision were received from White Motor Corporation, Mack Trucks, International Harvester, PACCAR Corporation, Diamond Reo, and Breeze Corporations. General Motors effectively requested reconsideration in its response to a separate November notice (39 FR 40168, November 14, 1974) (Notice 7) by supporting reduced trailer requirements only with corresponding reduction of truck stopping distance requirements.

General Motors, in its response to Notice 7, indicated that similar 121 vehicles can register as much as a 20-percent difference in stopping distances as a result of uncontrolled variability in brake component performance. International Harvester, which until recently had supported 5-percent longer stopping distances on an interim basis, now points to certain variables, including brake linings, in requesting longer distances on a permanent basis. Diamond Reo reported the same experience in its comments to Notice 2 of Docket No. 74-10. PACCAR requested that S5.3 (stopping distance) be "temporarily repealed" and that longer stopping distances be considered for the future. The NHTSA concludes that PACCAR's request is essentially a petition for rulemaking to increase the stopping distances on a permanent basis.

These positions raise issues which can arise whenever a standard is first implemented: (1) that production variables are so great that inordinate compliance margins are required and (2) that the brake packages necessary to achieve these compliance margins are so aggressive that the handling qualities and durability of affected vehicles are significantly degraded. The NHTSA is, of course, interested in receiving on a continuing basis any new technical information (particularly test data on production vehicles) that bears on these important safety issues. Based on the information submitted to date, however, NHTSA is not prepared to grant the outstanding petitions at this time.

PACCAR also requested that the stopping distance requirements be delayed until the performance of antilock systems and certain test procedures, conditions, and the control trailer test device are specified in areas considered deficient by PACCAR. While these issues might appropriately be considered for future rulemaking, the NHTSA does not agree that change of these important elements of the standard should delay orderly implementation of the standard. Accordingly, the PACCAR request in these areas is denied.

The second area of the standard in which manufacturers seek reconsideration is limited relaxation of requirements for vehicles with front steerable drive axles (S5.3.1.2). Based on unavailability of this axle design, vehicles manufactured before September 1, 1975, with a front steerable drive axle of any size may meet retardation force requirements in place of stopping distance requirements. Because of unavailability of the lighter front driving axles for a greater period, vehicles manufactured before September 1, 1976, with a front steerable drive axle with a gross axle weight rating (GAWR) of less than 18,000 pounds may meet retardation force requirements in place of stopping distance requirements.

Diamond Reo, International Harvester, and Mack Trucks, Inc., now request that the heavier axles also be permitted relaxed requirements until September 1, 1976. White Motor Company in its response to Notice 10 of Docket No. 74-10 requested the relaxed requirements until September 1, 1977. The NHTSA indicated in Notice 6 that this axle type is available and has been offered by Oshkosh Truck Company to the other manufacturers of this vehicle class. While Diamond Reo does not indicate it considered the Oshkosh axle, the other manufacturers indicate that redesign of their limited vehicle output in this area to accept the Oshkosh axle would be unjustified because of cost. Oshkosh, on the other hand, has offered to provide, at cost, technical assistance in the installation of Oshkosh axles to non-Oshkosh pilot test vehicles, and consultation and review of test data obtained from truck-manufacturer-conducted tests.

The NHTSA concludes, based on all information available, that the axle is available at this time and that sufficient leadtime has been made available for the location and testing of an axle of this type. The manufacturers who request further delay do not claim that the installation is technologically unfeasible or otherwise impracticable. Although they cite adverse economic consequences for the limited numbers of vehicles they produce in this category, this argument does not consider the major economic consequences for the Oshkosh Company, who state that 72 percent of their vehicle production would be adversely affected by any further delay. The petitions of White, International Harvester, Diamond Reo, and Mack are accordingly denied.

Due to unavailability until September 1, 1976, front steerable non-driving axles with a GAWR in excess of 16,000 pounds are permitted the same relaxed requirements as the driving axles just discussed. White Motor Corporation, in its comments to Notice 10 of Docket No. 74-10, requested the relaxed requirements be extended to September 1, 1977, because of the long leadtime associated with manufacture of these vehicles. The NHTSA will monitor the availability of these axles to ensure their readiness for September 1, 1976, and will consider a later effective date for them if they are not available as presently schedued. At this time, however, it appears that the axles will be ready sufficiently in advance of September 1, 1976, to permit satisfaction of the full requirements on that date. Accordingly White's petition is denied.

As earlier noted, both the vehicles equipped with certain driving or non-driving front steerable axles are permitted to meet retardation force requirements in place of distance requirements for an interim period. A reduction of these retardation force requirements was the subject of a proposal in Notice 7, which was acted on for trailers in Notice 11 (40 FR 1246, January 7, 1975). It was concluded that no argument had been made for a temporary reduction of retardation forces on the front axle of heavy trucks, most of which are integral trucks which experience high levels of dynamic load shift during braking. Comments by PACCAR to Notice 6, however, emphasized that retardation force requirements at the rear axle could be reduced because the load shift off the rear axle effectively results in over-torque of that axle.

The NHTSA's intent in substituting retardation force requirements for stopping distance is to ensure the best braking that is presently available, and it appears that rear brake retardation requirements may, in some cases, inhibit the tailoring of brake systems on different vehicles to achieve this goal. The most satisfactory means to reduce rear axle requirements while maintaining front axle requirements is to eliminate requirements for the vehicle as a whole, to permit the manufacturer latitude in selecting retardation force requirements

at the rear axle. The present requirements for front axle retardation forces remain in the standard, and by this notice, the NHTSA deletes the requirement for retardation force values for the vehicle as a whole.

PACCAR requested complete withdrawal of the retardation force requirements, as well as the brake power and fade requirements as they affect all trucks. The NHTSA, of course, considers these characteristics of a brake system fundamental, and does not agree that the requirements are impracticable or should be withdrawn. PACCAR's request is therefore denied.

With regard to the vehicles that may meet retardation force requirements in place of stopping distances, International Harvester requested confirmation that S6.3.1.2 is an option that the manufacturer may choose to ignore in the loaded or unloaded condition if the vehicle in question meets the stopping distance requirements in that condition. This agency stated in the preamble to Notice 6 that "the NHTSA considers it crucial to maintain complete directional stability in a panic stop, loaded or unloaded, if the vehicle is unable to meet the stopping distance requirements in that condition." International Harvester's understanding of this language is correct.

PACCAR requested deletion of brake actuation requirements as redundant in view of stopping distance requirements. The NHTSA has considered elimination of the requirements previously, and concluded at that time that the requirement should be maintained (37 FR 3905, February 24, 1972). At this time the actuation requirements ensure fast braking on the vehicles under S5.3.1.2 which need not meet stopping distance requirements. The NHTSA will consider this PACCAR request for future rulemaking but does not act on the petition for amendment at this time.

Finally, PACCAR requested specification of antilock performance characteristics. The standard does not require antilock systems, and the NHTSA has concluded that specification for manufacturers who utilize these devices would be design restrictive, without a corresponding safety benefit. No manufacturer other than PACCAR indicates that a safety need exists to specify the cycling of antilocks, and the NHTSA is unable to determine from the PACCAR petition what evidence exists that antilock specification would improve vehicle handling. PACCAR's petition is accordingly denied.

In areas unrelated to the petitions for reconsideration, the NHTSA corrects an error in S6.1.8.1 and adds a clarifying word to S5.7.1.2, without in any way changing the requirements of those paragraphs.

In consideration of the foregoing, Standard No. 121 (49 CFR 571.121) is amended as follows:

§ 571.106–121 [Amended]

1. S5.3.1.2 is amended to read:

S5.3.1.2 When stopped in accordance with S5.3.1, with its brakes fully applied, a truck manufactured before September 1, 1976, that has a front steerable non-driving axle with a GAWR of 16,000 pounds or more, or a front steerable drive axle with a GAWR of less than 18,000 pounds, and a truck manufactured before September 1, 1975, that has a front steerable drive axle of any GAWR, need not meet the requirement that it stop in the distance specified in Table II for stops on a surface with a skid number of 75 if the brakes on its front axle conform to the retardation formula and Column 1 values of S5.4.1. These vehicles must nevertheless meet the requirements of staying within the 12-foot lane and those relating to wheel lock-up.

2. In S5.7.1.2, the word "quotient" is added following the phrase "static retardation force".

3. In the first sentence of S6.1.8.1, the word "not" is deleted.

Effective date. March 21, 1975.

Because of Standard No. 121's March 1, 1975, effective date and because this order relieves a restriction, it is found for good cause shown that an effective date sooner than 30 days from the date of publication of the order is in the public interest.

(Sec. 103, 119, 89–563, 80 Stat. 718 (15 U.S.C. 1392, 1407); delegation of authority at 49 CFR 1.51).

Issued on March 14, 1975.

JAMES B. GREGORY,
Administrator.

[FR Doc.75–7346 Filed 3–18–75;9:29 am]

Title 7—Agriculture

SUBTITLE A—OFFICE OF THE SECRETARY OF AGRICULTURE

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

Revision of Delegations of Authority to Reflect Establishment of the Office of the Sales Manager

Part 2, Subtitle A, Title 7, Code of Federal Regulations, is amended so as to reflect the establishment of an office of the Sales Manager, delegate authority to the Sales Manager to formulate policies with respect to certain export programs, and revoke the authority to formulate such policy previously delegated to and by the Assistant Secretary for International Affairs and Commodity Programs. In addition, the heading for Subpart C is amended to change "Directors" to the "Director of Agricultural Economics."

Subpart C—Delegations of Authority to the Under Secretary, Assistant Secretaries, and Director of Agricultural Economics

1. Section 2.21 is amended by revising paragraphs (d) (11), (12), (19) and (21) to read as follows:

§ 2.21 Delegations of Authority to the Assistant Secretary for International Affairs and Commodity Programs.

* * * * *

(d) *Related to foreign agriculture.* * * *

(11) Administer operations for programs under section 5(f) of the CCC Charter Act (15 U.S.C. 714c(f)) and section 4, Pub. L. 89–808 (7 U.S.C. 1707a) to finance commercial export credit sales of agricultural commodities by U.S. exporters.

(12) Administer operations for barter programs, under which agricultural commodities are exported, under sections 4 (h) and 5(f) of the CCC Charter Act (15 U.S.C. 714b(h) and 714c(f)) and section 303 of Pub. L. 480 (7 U.S.C. 1692).

* * * * *

(19) Administer operations for sales programs for export of CCC-owned agricultural commodities, except for tobacco, peanuts, tung oil, and gum naval stores.

* * * * *

(21) Administer operations for export payment programs (other than those under section 32, Pub. L. 320, 74th Congress (7 U.S.C. 612c)), and other programs as assigned to encourage or cause the export of U.S. agricultural commodities.

* * * * *

Subpart D—Delegations of Authority to Other General Officers and Agency Heads

2. A new § 2.37 is added to read as follows:

§ 2.37 Delegations of Authority to the Sales Manager.

The following delegations of authority are made by the Secertary of Agriculture to the Sales Manager:

(a) Formulate policies for programs under section 5(f) of the CCC Charter Act (15 U.S.C. 714c(f)) and section 4, Pub. L. 89–808 (7 U.S.C. 1707a) to finance commercial export credit sales of agricultural commodities by U.S. exporters.

(b) Formulate policies for barter programs, under which agricultural commodities are exported, under sections 4(h) and 5(f) of the CCC Charter Act (15 U.S.C. 714b(h) and 714c(f)) and section 303 of Pub. L. 480, 83rd Congress (7 U.S.C. 1692).

(c) Formulate policies for sales programs for export of CCC-owned agricultural commodities, except for tobacco, peanuts, tung oil, and gum naval stores.

(d) Formulate policies for export payment programs (other than those under section 32, Pub. L. 320, 74th Congress (7 U.S.C. 612c)), and other programs as assigned to encourage or cause the export of U.S. agricultural commodities.

Subpart H—Delegations of Authority by the Assistant Secretary for International Affairs and Commodity Programs

3. Section 2.68 is amended by revising paragraphs (a) (11), (12), (19), and (21) to read as follows:

* * * * *

§ 2.68 Administrator, Foreign Agricultural Service.

(a) *Delegations.* * * *

(11) Administer operations for programs under section 5(f) of the CCC Charter Act (15 U.S.C. 714c(f)) and section 4, Pub. L. 89–808 (7 U.S.C. 1707a) to

finance commercial export credit sales of agricultural commodities by U.S. exporters.

(12) Administer operations for barter programs, under which agricultural commodities are exported, under sections 4(h) and 5(f) of the CCC Charter Act (15 U.S.C. 714b(h) and 714c(f)) and section 303 of Pub. L. 480 (7 U.S.C. 1692).

* * * * *

(19) Administer operations for sales programs for export of CCC-owned agricultural commodities, except for tobacco, peanuts, tung oil, and gum naval stores.

* * * * *

(21) Administer operations for export payment programs (other than those under section 32, Pub. L. 320, 74th Congress (7 U.S.C. 612c), and other programs as assigned to encourage or cause the export of U.S. agricultural commodities.

These amendments shall become effective March 6, 1975.

Dated: March 18, 1975.

For Subparts C and D.

EARL L. BUTZ,
Secretary of Agriculture.

Dated: March 13, 1975.

For Subpart H.

CLAYTON K. YEUTTER,
Assistant Secretary for International Affairs and Commodity Programs.

[FR Doc.75-7462 Filed 3-20-75;8:45 am]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Lemon Regulation 684]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

This regulation fixes the quantity of California-Arizona lemons that may be shipped to fresh market during the weekly regulation period March 23-29, 1975. It is issued pursuant to the Agricultural Marketing Agreement Act of 1937, as amended, and Marketing Order No. 910. The quantity of lemons so fixed was arrived at after consideration of the total available supply of lemons, the quantity of lemons currently available for market, the fresh market demand for lemons, lemon prices, and the relationship of season average returns to the parity price for lemons.

§ 910.984 Lemon Regulation 684.

(a) *Findings.* (1) Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, established under the said amended marketing agreement and order, and upon other available information, it is hereby found that the limitation of handling of such lemons, as hereinafter provided, will tend to effectuate the declared policy of the act.

(2) The need for this regulation to limit the quantity of lemons that may be marketed during the ensuing week stems from the production and marketing situation confronting the lemon industry.

(i) The committee has submitted its recommendation with respect to the quantity of lemons it deems advisable to be handled during the ensuing week. Such recommendation resulted from consideration of the factors enumerated in the order. The committee further reports the demand for lemons is fairly active. Average f.o.b. price was $5.45 per carton the week ended March 15, 1975, compared to $5.04 per carton the previous week. Track and rolling supplies at 155 cars were up 25 cars from last week.

(ii) Having considered the recommendation and information submitted by the committee, and other available information, the Secretary finds that the quantity of lemons which may be handled should be fixed as hereinafter set forth.

(3) It is hereby further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rule-making procedure, and postpone the effective date of this regulation until 30 days after publication hereof in the FEDERAL REGISTER (5 U.S.C. 553) because the time intervening between the date when information upon which this regulation is based became available and the time when this regulation must become effective in order to effectuate the declared policy of the act is insufficient, and a reasonable time is permitted, under the circumstances, for preparation for such effective time; and good cause exists for making the provisions hereof effective as hereinafter set forth. The committee held an open meeting during the current week, after giving due notice thereof, to consider supply and market conditions for lemons and the need for regulation; interested persons were afforded an opportunity to submit information and views at this meeting; the recommendation and supporting information for regulation during the period specified herein were promptly submitted to the Department after such meeting was held; the provisions of this regulations, including its effective time, are identical with the aforesaid recommendation of the committee, and information concerning such provisions and effective time has been disseminated among handlers of such lemons; it is necessary, in order to effectuate the declared policy of the act, to make this regulation effective during the period herein specified; and compliance with this regulation will not require any special preparation on the part of persons subject hereto which cannot be completed on or before the effective date hereof. Such committee meeting was held on March 18, 1975.

(b) *Order.* (1) The quantity of lemons grown in California and Arizona which may be handled during the period March 23, 1975, through March 29, 1975, is hereby fixed at 255,000 cartons.

(2) As used in this section, "handled", and "carton(s)" have the same meaning as when used in the said amended marketing agreement and order.

(Secs. 1-19, 48 Stat. 31, as amended; (7 U.S.C. 601-674))

Dated: March 19, 1975.

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.75-7677 Filed 3-20-75;12:25 pm]

CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS, PURCHASES, AND OTHER OPERATIONS

[CCC Grain Price Support Regs., 1975 Crop Barley Supplement]

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

1975 Crop Barley Loan and Purchase Program

On July 17, 1974, notice of proposed rulemaking regarding loan and purchase rates for 1975 crop barley and operating provisions to carry out the 1975 crop barley loan and purchase program was published in the FEDERAL REGISTER (39 FR 26159).

Six responses were received from interested individual producers, a farm organization, and other interested parties. These responses included requests ranging from an increase in price support to the elimination of the price support program. Recommendation was also received to change the loan maturity date to the anniversary date of the loan.

After consideration of all responses, it has been determined that loan and purchase rates for 1975 crop barley on a national average will remain the same as in 1974. Support rates at the county level reflect adjustments necessary to reflect changes in rail freight rate structure and historical prices received by farmers by State and districts. Loans will no longer have identical maturity dates but will mature 12 months from the first day of the month in which the loan is made. Other operating provisions for the 1975 crop remain the same as those for the 1974 crop.

The General Regulations Governing Price Support for the 1970 and Subsequent Crops, published at 35 FR 7363 and 7781, and any amendments thereto, and the 1970 and Subsequent Crops Barley Loan and Purchase Program Regulations, published at 35 FR 11166 and 11902, and any amendments to such regulations are further supplemented for the 1975 crop of barley. The material previously appearing in these §§ 1421.72 through 1421.75 shall remain in full force and effect as to the crops to which it is applicable.

Sec.
1421.72 Purpose.
1421.73 Availability.
1421.74 Maturity of loans.
1421.75 Loan and purchase rates.

AUTHORITY: Secs. 4 and 5, 62 Stat. 1070, as amended (15 U.S.C. 714 b and c); Secs. 105, 401, 63 Stat. 1051, as amended (7 U.S.C. 1441 note, 1421).

§ 1421.72 Purpose.

This supplement contains additional program provisions which, together with the provisions of the General Regulations Governing Price Support for the 1970 and Subsequent Crops, the 1970 and Subsequent Crops Barley Loan and Purchase Program Regulations, and any amendments thereto, apply to loans on and purchases of the 1975 crop of barley.

§ 1421.73 Availability.

(a) *Loans.* A producer desiring to participate in the program through loans must request a loan on his 1975 crop of eligible barley on or before March 31, 1976.

(b) *Purchases.* Producers desiring to offer eligible 1975 crop barley not under loan for purchase must execute and deliver to the county ASCS office on or before February 28, 1977, a purchase agreement (Form CCC-614) indicating the approximate quantity of 1975 crop barley they will sell to CCC.

§ 1421.74 Maturity of loans.

Loans mature on the last day of the eleventh calendar month following the month in which the loan is disbursed or upon such earlier date as CCC may make demand for payment.

§ 1421.75 Loan and purchase rates.

(a) *Basic loan rates (counties).* Basic county rates (marketing area for Alaska) for loan and settlement purposes for barley (except mixed barley) grading U.S. No. 2 or better are established as follows:

ALABAMA

County	Rate per bushel
All counties	$0.90

ALASKA

Delta*	$1.54
Fairbanks*	1.53
Glenallen*	1.63
Homer*	1.59
Kenai-Sold*	1.66
Palmer	1.72
Talkeetna*	1.72

ARIZONA

All counties	$1.08

ARKANSAS

All counties	$0.90

CALIFORNIA

County	Rate per bushel	County	Rate per bushel
Alameda	$1.26	Inyo	$1.08
Alpine	1.09	Kern	1.21
Amador	1.22	Kings	1.19
Butte	1.17	Lake	1.16
Calaveras	1.22	Lassen	1.06
Colusa	1.21	Los Angeles	1.26
Contra Costa	1.23	Madera	1.22
El Dorado	1.21	Marin	1.23
Fresno	1.20	Mariposa	1.20
Glenn	1.18	Mendocino	1.10
Humboldt	1.06	Merced	1.22
Imperial	1.20	Modoc	1.04
Monterey	$1.18	Santa Clara	$1.22
Napa	1.21	Santa Cruz	1.19
Orange	1.26	Shasta	1.06
Placer	1.19	Sierra	1.08
Plumas	1.09	Siskiyou	1.04
Riverside	1.21	Solano	1.23
Sacramento	1.26	Sonoma	1.21
San Benito	1.18	Stanislaus	1.24
San Bernardino	1.22	Sutter	1.20
San Diego	1.26	Tehama	1.17
San Francisco	1.26	Tulare	1.18
San Joaquin	1.26	Tuolumne	1.20
San Luis Obispo	1.18	Ventura	1.21
San Mateo	1.23	Yolo	1.23
Santa Barbara	1.17	Yuba	1.20

COLORADO

County	Rate per bushel
All counties	$0.94

CONNECTICUT

All counties	$0.90

DELAWARE

All counties	$0.90

FLORIDA

All counties	$0.92

GEORGIA

All counties	$0.92

IDAHO

County	Rate per bushel	County	Rate per bushel
Ada	$0.95	Gem	$0.95
Adams	.95	Gooding	.95
Bannock	.95	Idaho	.99
Bear Lake	.92	Jefferson	.91
Benewah	1.02	Jerome	.95
Bingham	.94	Kootenai	1.02
Blaine	.95	Latah	1.02
Boise	.95	Lemhi	.91
Bonner	.98	Lewis	1.01
Bonneville	.92	Lincoln	.95
Boundary	.97	Madison	.92
Butte	.94	Minidoka	.96
Camas	.95	Nez Perce	1.02
Canyon	.95	Oneida	.95
Caribou	.92	Owyhee	.95
Cassia	.94	Payette	.95
Clark	.91	Power	.95
Clearwater	1.01	Shoshone	.90
Custer	.95	Teton	.92
Elmore	.95	Twin Falls	.96
Franklin	.96	Valley	.95
Fremont	.92	Washington	.95

ILLINOIS

County	Rate per bushel
Alexander	$0.96
Cook	.91
Madison	.95
Saint Clair	.95
All other counties	.86

INDIANA

All counties	$0.86

IOWA

Pottawattamie	$0.93
All other counties	.89

KANSAS

Wyandotte	$0.93
All other counties	.89

KENTUCKY

All counties	$0.87

LOUISIANA

County	Rate per bushel
East Baton Rouge	$1.09
Jefferson	1.09
Orleans	1.09
Saint Charles	1.09
West Baton Rouge	1.09
All other counties	.93

MAINE

All counties	$0.90

MARYLAND

Baltimore City	$1.09
All other counties	.90

MASSACHUSETTS

All counties	$0.90

MICHIGAN

All counties	$0.82

MINNESOTA

County	Rate per bushel	County	Rate per bushel
Aitkin	$0.93	Martin	$0.95
Anoka	.96	Meeker	.94
Becker	.84	Mille Lacs	.94
Beltrami	.86	Morrison	.91
Benton	.93	Mower	.95
Big Stone	.88	Murray	.92
Blue Earth	.96	Nicollet	.96
Brown	.94	Nobles	.92
Carlton	.97	Norman	.83
Carver	.97	Olmsted	.96
Cass	.89	Otter Tail	.85
Chippewa	.93	Pennington	.82
Chisago	.96	Pine	.97
Clay	.83	Pipestone	.89
Clearwater	.83	Polk	.82
Cottonwood	.93	Pope	.91
Crow Wing	.89	Ramsey	.97
Dakota	.97	Red Lake	.82
Dodge	.96	Redwood	.94
Douglas	.88	Renville	.93
Faribault	.95	Rice	.97
Fillmore	.93	Rock	.88
Freeborn	.96	Roseau	.80
Goodhue	.96	Saint Louis	.97
Grant	.86	Scott	.97
Hennepin	.97	Sherburne	.96
Houston	.92	Sibley	.96
Hubbard	.86	Stearns	.93
Isanti	.95	Steele	.97
Itasca	.92	Stevens	.88
Jackson	.93	Swift	.92
Kanabec	.94	Todd	.88
Kandiyohi	.93	Traverse	.86
Kittson	.78	Wabasha	.96
Koochiching	.90	Wadena	.87
Lac Qui Parle	.92	Waseca	.97
Lake of the Woods	.85	Washington	.97
Le Sueur	.97	Watonwan	.95
Lincoln	.89	Wilkin	.86
Lyon	.92	Winona	.94
McLeod	.96	Wright	.97
Mahnomen	.82	Yellow Medicine	.91
Marshall	.81		

MISSISSIPPI

County	Rate per bushel
All counties	$0.90

MISSOURI

County	Rate per bushel	County	Rate per bushel
Buchanan	$0.93	Saint Louis	$0.95
Clay	.93	All other counties	.91
Jackson	.93		

MONTANA

Beaverhead	$0.84	Blaine	$0.75
Big Horn	.80	Broadwater	.87

MONTANA—Continued

County	Rate per bushel	County	Rate per bushel
Carbon	$0.80	Meagher	$0.84
Carter	.72	Mineral	.92
Cascade	.83	Missoula	.92
Chouteau	.79	Musselshell	.79
Custer	.74	Park	.88
Daniels	.71	Petroleum	.77
Dawson	.74	Phillips	.72
Deer Lodge	.90	Pondera	.81
Fallon	.72	Powder River	.74
Fergus	.81	Powell	.90
Flathead	.95	Prairie	.74
Gallatin	.90	Ravalli	.88
Garfield	.75	Richland	.71
Glacier	.82	Roosevelt	.71
Golden Valley	.80	Rosebud	.75
Granite	.88	Sanders	.92
Hill	.78	Sheridan	.70
Jefferson	.90	Silver Bow	.90
Judith Basin	.80	Stillwater	.80
Lake	.88	Sweet Grass	.83
Lewis and Clark	.81	Teton	.81
Liberty	.80	Toole	.81
Lincoln	.95	Treasure	.75
McCone	.74	Valley	.72
Madison	.90	Wheatland	.81
		Wibaux	.72
		Yellowstone	.80

NEBRASKA

County	Rate per bushel
Douglas	$0.93
All other counties	.85

NEVADA

County	Rate per bushel
All counties	$1.08

NEW HAMPSHIRE

County	Rate per bushel
All counties	$0.90

NEW JERSEY

County	Rate per bushel
All counties	$0.90

NEW MEXICO

County	Rate per bushel
All counties	0.98

NEW YORK

County	Rate per bushel
Albany	$1.08
New York City	1.08
All other counties	.90

NORTH CAROLINA

County	Rate per bushel
All counties	$0.93

NORTH DAKOTA

County	Rate per bushel	County	Rate per bushel
Adams	$0.72	McKenzie	$0.69
Barnes	.80	McLean	.73
Benson	.75	Mercer	.72
Billings	.70	Morton	.72
Bottineau	.71	Mountrail	.70
Bowman	.70	Nelson	.77
Burke	.70	Oliver	.73
Burleigh	.75	Pembina	.77
Cass	.83	Pierce	.74
Cavalier	.75	Ramsey	.76
Dickey	.79	Ransom	.80
Divide	.70	Renville	.70
Dunn	.70	Richland	.83
Eddy	.76	Rolette	.72
Emmons	.72	Sargent	.83
Foster	.77	Sheridan	.74
Golden Valley	.70	Sioux	.72
Grand Forks	.80	Slope	.70
Grant	.70	Stark	.70
Griggs	.79	Steele	.80
Hettinger	.70	Stutsman	.80
Kidder	.75	Towner	.73
La Moure	.78	Traill	.80
Logan	.75	Walsh	.78
McHenry	.73	Ward	.71
McIntosh	.76	Wells	.76
		Williams	.70

OHIO

County	Rate per bushel
All counties	$0.84

OKLAHOMA

County	Rate per bushel
All counties	$0.92

OREGON

County	Rate per bushel	County	Rate per bushel
Baker	$1.00	Lake	$0.96
Benton	1.05	Lane	1.04
Clackamas	1.09	Lincoln	1.04
Clatsop	1.15	Linn	1.06
Columbia	1.15	Malheur	.94
Coos	.96	Marion	1.07
Crook	1.04	Morrow	1.03
Curry	.94	Multnomah	1.15
Deschutes	1.04	Polk	1.07
Douglas	.98	Sherman	1.10
Gilliam	1.09	Tillamook	1.10
Grant	1.04	Umatilla	1.05
Harney	.91	Union	1.03
Hood River	1.11	Wallowa	1.00
Jackson	.97	Wasco	1.11
Jefferson	1.07	Washington	1.11
Josephine	.97	Wheeler	1.06
Klamath	.97	Yamhill	1.09

PENNSYLVANIA

County	Rate per bushel
Philadelphia	$1.03
All other counties	.90

RHODE ISLAND

County	Rate per bushel
All counties	$0.90

SOUTH CAROLINA

County	Rate per bushel
Charleston	$1.08
All other counties	.93

SOUTH DAKOTA

County	Rate per bushel	County	Rate per bushel
Aurora	$0.80	Jackson	$0.73
Beadle	.83	Jerauld	.80
Bennett	.73	Jones	.78
Bon Homme	.83	Kingsbury	.86
Brookings	.87	Lake	.85
Brown	.82	Lawrence	.67
Brule	.78	Lincoln	.84
Buffalo	.80	Lyman	.78
Butte	.67	McCook	.80
Campbell	.76	McPherson	.80
Charles Mix	.81	Marshall	.83
Clark	.83	Meade	.70
Clay	.84	Mellette	.77
Codington	.86	Miner	.81
Corson	.73	Minnehaha	.84
Custer	.72	Moody	.85
Davison	.80	Pennington	.72
Day	.84	Perkins	.71
Deuel	.89	Potter	.80
Dewey	.75	Roberts	.87
Douglas	.81	Sanborn	.80
Edmunds	.80	Shannon	.72
Fall River	.68	Spink	.82
Faulk	.81	Stanley	.78
Grant	.89	Sully	.80
Gregory	.80	Todd	.77
Haakon	.73	Tripp	.78
Hamlin	.86	Turner	.84
Hand	.80	Union	.85
Hanson	.80	Walworth	.77
Harding	.69	Washabaugh	.73
Hughes	.79	Yankton	.84
Hutchinson	.81	Ziebach	.72
Hyde	.80		

TENNESSEE

County	Rate per bushel
Shelby	$0.96
All other counties	.90

TEXAS

County	Rate per bushel	County	Rate per bushel
Chambers	$1.11	Nueces	$1.11
Galveston	1.11	San Patricio	1.11
Harris	1.11	All other counties	.95
Jefferson	1.11		

UTAH

County	Rate per bushel
All counties	$0.98

VERMONT

County	Rate per bushel
All counties	$0.90

VIRGINIA

County	Rate per bushel	County	Rate per bushel
Chesapeake (Norfolk)	$1.03	All other counties	$0.90

WASHINGTON

County	Rate per bushel	County	Rate per bushel
Adams	$1.05	Lewis	$1.09
Asotin	1.05	Lincoln	1.04
Benton	1.07	Mason	1.02
Chelan	1.09	Okanogan	1.03
Clallam	.95	Pacific	1.04
Clark	1.15	Pend Oreille	.93
Columbia	1.06	Pierce	1.15
Cowlitz	1.15	San Juan	1.03
Douglas	1.04	Skagit	1.03
Ferry	1.00	Skamania	1.10
Franklin	1.06	Snohomish	1.03
Garfield	1.06	Spokane	1.02
Grant	1.05	Stevens	.99
Grays Harbor	1.04	Thurston	1.09
Island	1.03	Wahkiakum	1.12
Jefferson	1.00	Walla Walla	1.06
King	1.15	Whatcom	1.01
Kitsap	1.03	Whitman	1.04
Kittitas	1.07	Yakima	1.06
Klickitat	1.03		

WEST VIRGINIA

County	Rate per bushel
All counties	$0.90

WISCONSIN

County	Rate per bushel	County	Rate per bushel
Douglas	$0.97	All other counties	$0.87

WYOMING

County	Rate per bushel
All counties	$0.92

(b) *Discounts.* The basic county rate shall be adjusted as applicable by discounts as follows:

	Discount (cents per bushel)
Class—Mixed barley	2
Grade:	
U.S. No. 3	3
U.S. No. 4	6
U.S. No. 5	15
Garlicky	10
Weed Control Law (where required by § 1421.25)	10

Other factors. Amounts determined by CCC to represent market discounts for quality factors not specified above which affect the value of the barley, such as (but not limited to) thin barley, moisture, foreign material, test weight, heat damage, musty, sour, smutty, stained, weevily, ergoty, and bleached. Such discounts will be established not later than the time delivery of barley to CCC begins and will thereafter be adjusted from time to time as CCC determines appropriate to reflect changes in market conditions. Producers may obtain schedules of such factors and discounts at county ASCS offices approximately 1 month prior to the loan maturity date.

NOTE.—Discounts are cumulative except only one grade discount shall be applied. For the purpose of applying discounts, factors which cause barley of the subclass Malting Barley or Blue Malting Barley to have a lower numerical grade than if the barley were

graded under a different subclass shall be disregarded.

Effective date: March 21, 1975.

Signed at Washington, D.C., on March 17, 1975.

GLENN A. WEIR,
Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc.75-7460 Filed 3-20-75;8:45 am]

[CCC Grain Price Support Reg. 1975 Crop Oats Supplement]

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

Subpart—1975 Crop Oats Loan and Purchase Program

On July 17, 1974, notice of proposed rulemaking regarding loan and purchase rates for 1975 crop oats and operating provisions to carry out the 1975 crop oats loan and purchase program was published in the FEDERAL REGISTER (39 FR 26159).

Six responses were received from interested individual producers, a farm organization, and other interested parties. These responses included requests ranging from an increase in price support to the elimination of the price support program. Recommendation was also received to change the loan maturity date to the anniversary date of the loan.

After consideration of all responses, it has been determined that loan and purchase rates for 1975 crop oats on a national average will remain the same as in 1974. Support rates at the county level reflect adjustments necessary to reflect changes in rail freight rate structure and historical prices received by farmers by State and districts. Loans will no longer have identical maturity dates but will mature 12 months from the first day of the month in which the loan is made. Other operating provisions for the 1975 crop remain the same as those for the 1975 crop.

The General Regulations Governing Price Support for 1970 and Subsequent Crops, published at 35 FR 7363 and 7781 and any amendments thereto and the 1970 and Subsequent Crops Oats Loan and Purchase Regulations, published at 35 FR 8340 and any amendments to such regulations are further supplemented for the 1975 crop of oats. The material previously appearing in these §§ 1421.270 through 1421.274 shall remain in full force and effect as to the crops to which it is applicable.

Sec.
1421.270 Purpose.
1421.271 Availability.
1421.272 Maturity of loans.
1421.273 Loan and purchase rates.

AUTHORITY: Secs. 4 and 5, 62 Stat. 1070, as amended (15 U.S.C. 714 b and c); Secs. 105, 401, 63 Stat. 1051, as amended (7 U.S.C. 1441 note, 1421).

§ 1421.270 Purpose.

This supplement contains additional program provisions which, together with the provisions of the General Regulations Governing Price Support for the 1970 and Subsequent Crops, the 1970 and Subsequent Crops Oats Loan and Purchase Program Regulations, and any amendments thereto, apply to loans on and purchases of the 1975 crop of oats.

§ 1421.271 Availability.

(a) *Loans.* A producer desiring to participate in the program through loans must request a loan on his 1975 crop of eligible oats on or before March 31, 1976.

(b) *Purchases.* Producers desiring to offer eligible 1975 crop oats not under loan for purchase must execute and deliver to the county ASCS office on or before February 28, 1977, a purchase agreement (Form CCC-614) indicating the approximate quantity of 1975 crop oats they will sell to CCC.

§ 1421.272 Maturity of loans.

Loans mature on the last day of the eleventh calendar month following the month in which the loan is disbursed or upon such earlier date as CCC may make demand for payment.

§ 1421.273 Loan and purchase rates.

(a) *Basic loan and purchase rates.* County loan and purchase rates for oats and the schedule of premiums and discounts are shown below. The term "county" as used in this subpart with reference to the State of Alaska shall mean "marketing area". Marketing areas in Alaska shall be the areas established under the State small grain incentive program. Farm-stored loans will be made at the basic rate for the county where the grain is stored, adjusted only for the weed control discount where applicable. The loan and purchase rate for warehouse-stored oats loans shall be the basic rate for the county where the oats are stored, adjusted by the premiums and discounts shown in this section. Notwithstanding § 1421.23(c) settlement for oats delivered from other than approved warehouse storage shall be based (1) on the basic rate for the county in which the producer's customary delivery point is located, and (2) on the quality and quantity delivered as shown on the warehouse receipts and accompanying documents issued by an approved warehouse to which delivery is made, or if applicable, the quality and quantity delivered as shown on a form prescribed by CCC for this purpose. The basic rate applies to oats grading U.S. No. 3, having moisture not in excess of 14 percent.

ALABAMA

County	Rate per bushel
All counties	$0.65

ALASKA*

County	Rate per bushel	County	Rate per bushel
Delta	$1.01	Kenai-Soldotna	$1.09
Fairbanks	1.00	Palmer	1.13
Glenallen	1.07	Talkeetna	1.13
Homer	1.04		

ARIZONA

County	Rate per bushel
All counties	$0.70

ARKANSAS

County	Rate per bushel
All counties	$0.63

CALIFORNIA

County	Rate per bushel
All counties	$0.70

COLORADO

County	Rate per bushel
All counties	$0.61

CONNECTICUT

County	Rate per bushel
All counties	$0.64

DELAWARE

County	Rate per bushel
All counties	$0.64

FLORIDA

County	Rate per bushel
All counties	$0.68

GEORGIA

County	Rate per bushel
All counties	$0.65

IDAHO

County	Rate per bushel
All counties	$0.60

ILLINOIS

County	Rate per bushel	County	Rate per bushel
Adams	$0.57	Lee	$0.57
Alexander	.60	Livingston	.57
Bond	.58	Logan	.57
Boone	.57	McDonough	.57
Brown	.57	McHenry	.57
Bureau	.57	McLean	.57
Calhoun	.58	Macon	.57
Carroll	.57	Macoupin	.58
Cass	.57	Madison	.59
Champaign	.57	Marion	.59
Christian	.57	Marshall	.57
Clark	.58	Mason	.57
Clay	.59	Massac	.60
Clinton	.59	Menard	.57
Coles	.57	Mercer	.57
Cook	.59	Monroe	.60
Crawford	.59	Montgomery	.58
Cumberland	.58	Morgan	.57
De Kalb	.57	Moultrie	.57
De Witt	.57	Ogle	.57
Douglas	.57	Peoria	.57
Du Page	.57	Perry	.60
Edgar	.57	Piatt	.57
Edwards	.60	Pike	.57
Effingham	.58	Pope	.61
Fayette	.58	Pulaski	.60
Ford	.57	Putnam	.57
Franklin	.60	Randolph	.60
Fulton	.57	Richland	.59
Gallatin	.61	Rock Island	.57
Greene	.58	Saint Clair	.60
Grundy	.57	Saline	.61
Hamilton	.60	Sangamon	.57
Hancock	.57	Schuler	.57
Hardin	.61	Scott	.57
Henderson	.57	Shelby	.57
Henry	.57	Stark	.57
Iroquois	.57	Stephenson	.57
Jackson	.60	Tazewell	.57
Jasper	.59	Union	.60
Jefferson	.60	Vermilion	.57
Jersey	.58	Wabash	.60
Jo Daviess	.57	Warren	.57
Johnson	.60	Washington	.60
Kane	.57	Wayne	.60
Kankakee	.57	White	.60
Kendall	.57	Whiteside	.57
Knox	.57	Will	.58
Lake	.58	Williamson	.60
La Salle	.57	Winnebago	.57
Lawrence	.59	Woodford	.57

INDIANA

County	Rate per bushel	County	Rate per bushel
Adams	$0.61	Cass	$0.60
Allen	.61	Clark	.62
Bartholomew	.61	Clay	.60
Benton	.59	Clinton	.60
Blackford	.60	Crawford	.62
Boone	.60	Daviess	.62
Brown	.62	Dearborn	.63
Carroll	.60	Decatur	.61

INDIANA—Continued

County	Rate per bushel	County	Rate per bushel
De Kalb	$0.61	Morgan	$0.60
Delaware	.60	Newton	.59
Dubois	.62	Noble	.60
Elkhart	.61	Ohio	.63
Fayette	.60	Orange	.62
Floyd	.62	Owen	.60
Fountain	.59	Parke	.59
Franklin	.62	Perry	.62
Fulton	.60	Pike	.62
Gibson	.62	Porter	.60
Grant	.60	Posey	.62
Greene	.62	Pulaski	.60
Hamilton	.60	Putnam	.60
Hancock	.60	Randolph	.61
Harrison	.62	Ripley	.63
Hendricks	.60	Rush	.60
Henry	.60	Saint Joseph	.61
Howard	.60	Scott	.63
Huntington	.60	Shelby	.60
Jackson	.62	Spencer	.62
Jasper	.59	Starke	.60
Jay	.61	Steuben	.62
Jefferson	.63	Sullivan	.61
Jennings	.63	Switzerland	.63
Johnson	.60	Tippecanoe	.60
Knox	.62	Tipton	.60
Kosciusko	.60	Union	.61
Lagrange	.61	Vanderburgh	.62
Lake	.60	Vermillion	.59
La Porte	.61	Vigo	.60
Lawrence	.62	Wabash	.60
Madison	.60	Warren	.59
Marion	.60	Warrick	.62
Marshall	.60	Washington	.62
Martin	.62	Wayne	.61
Miami	.60	Wells	.60
Monroe	.62	White	.60
Montgomery	.60	Whitley	.60

IOWA

Adair	$0.57	Humboldt	$0.55
Adams	.57	Ida	.54
Allamakee	.54	Iowa	.57
Appanoose	.57	Jackson	.57
Audubon	.55	Jasper	.55
Benton	.57	Jefferson	.57
Black Hawk	.56	Johnson	.57
Boone	.55	Jones	.57
Bremer	.55	Keokuk	.57
Buchanan	.56	Kossuth	.53
Buena Vista	.55	Lee	.57
Butler	.55	Linn	.57
Calhoun	.55	Louisa	.57
Carroll	.55	Lucas	.57
Cass	.57	Lyon	.52
Cedar	.57	Madison	.57
Cerro Gordo	.54	Mahaska	.57
Cherokee	.55	Marion	.57
Chickasaw	.55	Marshall	.55
Clarke	.57	Mills	.57
Clay	.54	Mitchell	.53
Clayton	.55	Monona	.54
Clinton	.57	Monroe	.57
Crawford	.54	Montgomery	.57
Dallas	.55	Muscatine	.57
Davis	.58	O'Brien	.54
Decatur	.57	Osceola	.52
Delaware	.56	Page	.57
Des Moines	.57	Palo Alto	.55
Dickinson	.53	Plymouth	.53
Dubuque	.56	Pocahontas	.55
Emmet	.53	Polk	.55
Fayette	.55	Pottawattamie	.57
Floyd	.54	Poweshiek	.55
Franklin	.55	Ringgold	.57
Fremont	.57	Sac	.55
Greene	.55	Scott	.57
Grundy	.55	Shelby	.55
Guthrie	.55	Sioux	.53
Hamilton	.55	Story	.55
Hancock	.54	Tama	.55
Hardin	.55	Taylor	.57
Harrison	.55	Union	.57
Henry	.57	Van Buren	.57
Howard	.54		

IOWA—Continued

County	Rate per bushel	County	Rate per bushel
Wapello	$0.57	Winnebago	$0.53
Warren	.57	Winneshiek	.54
Washington	.57	Woodbury	.53
Wayne	.57	Worth	.53
Webster	.55	Wright	.55

KANSAS

Allen	$0.60	Linn	$0.60
Anderson	.60	Logan	.61
Atchison	.60	Lyon	.60
Barber	.63	McPherson	.61
Barton	.61	Marion	.61
Bourbon	.61	Marshall	.59
Brown	.59	Meade	.63
Butler	.62	Miami	.60
Chase	.61	Mitchell	.59
Chautauqua	.62	Montgomery	.62
Cherokee	.62	Morris	.60
Cheyenne	.60	Morton	.63
Clark	.63	Nemaha	.59
Clay	.59	Neosho	.61
Cloud	.59	Ness	.61
Coffey	.60	Norton	.59
Comanche	.63	Osage	.60
Cowley	.62	Osborne	.59
Crawford	.61	Ottawa	.59
Decatur	.59	Pawnee	.61
Dickinson	.60	Phillips	.58
Doniphan	.60	Pottawatomie	.59
Douglas	.60	Pratt	.62
Edwards	.61	Rawlins	.60
Elk	.61	Reno	.61
Ellis	.60	Republic	.58
Ellsworth	.60	Rice	.61
Finney	.62	Riley	.59
Ford	.62	Rooks	.59
Franklin	.60	Rush	.61
Geary	.60	Russell	.60
Gove	.61	Saline	.60
Graham	.60	Scott	.61
Grant	.62	Sedgwick	.62
Gray	.62	Seward	.63
Greeley	.61	Shawnee	.60
Greenwood	.61	Sheridan	.60
Hamilton	.62	Sherman	.60
Harper	.63	Smith	.58
Harvey	.61	Stafford	.61
Haskell	.62	Stanton	.62
Hodgeman	.61	Stevens	.63
Jackson	.60	Sumner	.63
Jefferson	.60	Thomas	.60
Jewell	.58	Trego	.60
Johnson	.61	Wabaunsee	.60
Kearny	.62	Wallace	.61
Kingman	.62	Washington	.58
Kiowa	.62	Wichita	.61
Labette	.62	Wilson	.61
Lane	.61	Woodson	.60
Leavenworth	.61	Wyandotte	.61
Lincoln	.59		

KENTUCKY

County	Rate per bushel
All counties	$0.65

LOUISIANA

All parishes	$0.65

MAINE

All counties	$0.64

MARYLAND

All counties	$0.65

MASSACHUSETTS

All counties	$0.64

MICHIGAN

County	Rate per bushel	County	Rate per bushel
Alcona	$0.58	Barry	$0.60
Alger	.59	Bay	.58
Allegan	.60	Benzie	.59
Alpena	.58	Berrien	.60
Antrim	.59	Branch	.61
Arenac	.58	Calhoun	.60
Baraga	.58	Cass	.60

MICHIGAN—Continued

County	Rate per bushel	County	Rate per bushel
Charlevoix	$0.59	Mackinac	$0.59
Cheboygan	.59	Macomb	.59
Chippewa	.59	Manistee	.60
Clare	.59	Marquette	.58
Clinton	.59	Mason	.60
Crawford	.58	Mecosta	.59
Delta	.58	Menominee	.58
Dickinson	.58	Midland	.58
Eaton	.59	Missaukee	.59
Emmet	.59	Monroe	.61
Genesee	.58	Montcalm	.59
Gladwin	.58	Montmorency	.58
Gogebic	.58	Muskegon	.60
Grand Traverse	.59	Newaygo	.60
Gratiot	.59	Oakland	.59
Hillsdale	.61	Oceana	.60
Houghton	.58	Ogemaw	.58
Huron	.58	Ontonagon	.58
Ingham	.59	Osceola	.59
Ionia	.59	Oscoda	.58
Iosco	.58	Otsego	.59
Iron	.58	Ottawa	.60
Isabella	.59	Presque Isle	.58
Jackson	.60	Roscommon	.58
Kalamazoo	.60	Saginaw	.58
Kalkaska	.59	Saint Clair	.59
Kent	.60	Saint Joseph	.60
Keweenaw	.58	Sanilac	.58
Lake	.60	Schoolcraft	.59
Lapeer	.58	Shiawassee	.58
Leelanau	.59	Tuscola	.58
Lenawee	.61	Van Buren	.60
Livingston	.59	Washtenaw	.60
Luce	.59	Wayne	.60
		Wexford	.60

MINNESOTA

Aitkin	$0.52	Marshall	$0.46
Anoka	.54	Martin	.51
Becker	.48	Meeker	.52
Beltrami	.48	Mille Lacs	.52
Benton	.52	Morrison	.51
Big Stone	.49	Mower	.52
Blue Earth	.52	Murray	.50
Brown	.51	Nicollet	.52
Carlton	.54	Nobles	.50
Carver	.53	Norman	.46
Cass	.50	Olmsted	.52
Chippewa	.50	Otter Tail	.49
Chisago	.54	Pennington	.46
Clay	.47	Pine	.53
Clearwater	.48	Pipestone	.50
Cook	.54	Polk	.46
Cottonwood	.51	Pope	.50
Crow Wing	.51	Ramsey	.54
Dakota	.53	Red Lake	.46
Dodge	.52	Redwood	.51
Douglas	.50	Renville	.51
Faribault	.52	Rice	.52
Fillmore	.53	Rock	.50
Freeborn	.53	Roseau	.46
Goodhue	.52	Saint Louis	.54
Grant	.49	Scott	.53
Hennepin	.54	Sherburne	.53
Houston	.53	Sibley	.52
Hubbard	.49	Stearns	.51
Isanti	.53	Steele	.52
Itasca	.52	Stevens	.49
Jackson	.51	Swift	.50
Kanabec	.53	Todd	.50
Kandiyohi	.51	Traverse	.48
Kittson	.45	Wabasha	.52
Koochiching	.49	Wadena	.50
Lac Qui Parle	.50	Waseca	.52
Lake	.54	Washington	.54
Lake of the Woods	.47	Watonwan	.51
Le Sueur	.52	Wilkin	.48
Lincoln	.50	Winona	.53
Lyon	.50	Wright	.53
McLeod	.52	Yellow Medicine	.50
Mahnomen	.47		

MISSISSIPPI

All counties	$0.65

MISSOURI

County	Rate per bushel
All counties	0.61

MONTANA

County	Rate per bushel	County	Rate per bushel
Beaverhead	$0.57	Madison	$0.55
Big Horn	.51	Meagher	.52
Blaine	.47	Mineral	.57
Broadwater	.53	Missoula	.56
Carbon	.52	Musselshell	.50
Carter	.47	Park	.54
Cascade	.52	Petroleum	.48
Chouteau	.49	Phillips	.47
Custer	.47	Pondera	.51
Daniels	.45	Powder River	.49
Dawson	.44	Powell	.55
Deer Lodge	.55	Prairie	.46
Fallon	.45	Ravalli	.56
Fergus	.49	Richland	.44
Flathead	.55	Roosevelt	.44
Gallatin	.54	Rosebud	.49
Garfield	.47	Sanders	.57
Glacier	.52	Sheridan	.44
Golden Valley	.51	Silver Bow	.55
Granite	.56	Stillwater	.52
Hill	.48	Sweet Grass	.53
Jefferson	.54	Teton	.51
Judith Basin	.50	Toole	.50
Lake	.56	Treasure	.50
Lewis and Clark	.54	Valley	.46
Liberty	.49	Wheatland	.52
Lincoln	.57	Wibeaux	.44
McCone	.45	Yellowstone	.52

NEBRASKA

County	Rate per bushel	County	Rate per bushel
Adams	$0.56	Jefferson	$0.57
Antelope	.53	Johnson	.58
Arthur	.54	Kearney	.56
Banner	.54	Keith	.55
Blaine	.53	Keya Paha	.51
Boone	.54	Kimball	.55
Box Butte	.53	Knox	.52
Boyd	.51	Lancaster	.57
Brown	.52	Lincoln	.55
Buffalo	.55	Logan	.54
Burt	.55	Loup	.53
Butler	.56	McPherson	.54
Cass	.57	Madison	.54
Cedar	.53	Merrick	.54
Chase	.57	Morrill	.54
Cherry	.52	Nance	.54
Cheyenne	.55	Nemaha	.58
Clay	.56	Nuckolls	.57
Colfax	.55	Otoe	.57
Cuming	.55	Pawnee	.58
Custer	.54	Perkins	.56
Dakota	.55	Phelps	.56
Dawes	.53	Pierce	.53
Dawson	.55	Platte	.54
Deuel	.55	Polk	.55
Dixon	.54	Red Willow	.57
Dodge	.56	Richardson	.58
Douglas	.57	Rock	.52
Dundy	.58	Saline	.57
Fillmore	.56	Sarpy	.57
Franklin	.57	Saunders	.57
Frontier	.56	Scotts Bluff	.54
Furnas	.57	Seward	.56
Gage	.58	Sheridan	.53
Garden	.54	Sherman	.54
Garfield	.53	Sioux	.53
Gosper	.56	Stanton	.54
Grant	.53	Thayer	.57
Greeley	.54	Thomas	.53
Hall	.55	Thurston	.55
Hamilton	.55	Valley	.54
Harlan	.57	Washington	.56
Hayes	.57	Wayne	.54
Hitchcock	.58	Webster	.57
Holt	.52	Wheeler	.53
Hooker	.53	York	.55
Howard	.54		

NEVADA

County	Rate per bushel
All counties	$0.70

NEW HAMPSHIRE

County	Rate per bushel
All counties	$0.64

NEW JERSEY

County	Rate per bushel
All counties	$0.63

NEW MEXICO

County	Rate per bushel
All counties	$0.68

NEW YORK

County	Rate per bushel
All counties	$0.66

NORTH CAROLINA

County	Rate per bushel
All counties	$0.65

NORTH DAKOTA

County	Rate per bushel	County	Rate per bushel
Adams	$0.44	McKenzie	$0.42
Barnes	.45	McLean	.41
Benson	.43	Mercer	.41
Billings	.42	Morton	.42
Bottineau	.41	Mountrail	.41
Bowman	.44	Nelson	.44
Burke	.41	Oliver	.42
Burleigh	.43	Pembina	.45
Cass	.46	Pierce	.42
Cavalier	.44	Ramsey	.44
Dickey	.45	Ransom	.46
Divide	.42	Renville	.41
Dunn	.41	Richland	.47
Eddy	.44	Rolette	.42
Emmons	.44	Sargent	.46
Foster	.44	Sheridan	.42
Golden Valley	.42	Sioux	.43
Grand Forks	.45	Slope	.43
Grant	.43	Stark	.41
Griggs	.44	Steele	.45
Hettinger	.42	Stutsman	.45
Kidder	.44	Towner	.43
La Moure	.45	Traill	.45
Logan	.44	Walsh	.45
McHenry	.41	Ward	.41
Mc Intosh	.44	Wells	.43
		Williams	.42

OHIO

County	Rate per bushel	County	Rate per bushel
Adams	$0.65	Henry	$0.63
Allen	.63	Highland	.65
Ashland	.64	Hocking	.65
Ashtabula	.66	Holmes	.65
Athens	.66	Huron	.64
Auglaize	.63	Jackson	.65
Belmont	.67	Jefferson	.67
Brown	.65	Knox	.64
Butler	.63	Lake	.65
Carroll	.66	Lawrence	.65
Champaign	.64	Licking	.64
Clark	.64	Logan	.64
Clermont	.65	Lorain	.65
Clinton	.65	Lucas	.63
Columbiana	.66	Madison	.64
Coshocton	.65	Mahoning	.66
Crawford	.64	Marion	.64
Cuyahoga	.65	Medina	.65
Darke	.62	Meigs	.66
Defiance	.62	Mercer	.61
Delaware	.64	Miami	.63
Erie	.64	Monroe	.67
Fairfield	.64	Montgomery	.63
Fayette	.64	Morgan	.66
Franklin	.64	Morrow	.64
Fulton	.63	Muskingum	.65
Gallia	.66	Noble	.66
Geauga	.65	Ottawa	.64
Greene	.64	Paulding	.62
Guernsey	.66	Perry	.65
Hamilton	.64	Pickaway	.64
Hancock	.63	Pike	.65
Hardin	.63	Portage	.65
Harrison	.66	Preble	.62

OHIO—Continued

County	Rate per bushel	County	Rate per bushel
Putnam	.63	Tuscarawas	.65
Richland	.64	Union	.64
Ross	.65	Van Wert	.62
Sandusky	.64	Vinton	.65
Scioto	.65	Warren	.64
Seneca	.64	Washington	.67
Shelby	.63	Wayne	.65
Stark	.65	Williams	.63
Summit	.65	Wood	.63
Trumbull	.66	Wyandot	.64

OKLAHOMA

County	Rate per bushel
All counties	$0.65

OREGON

County	Rate per bushel
All counties	$0.66

PENNSYLVANIA

County	Rate per bushel
All counties	$0.66

RHODE ISLAND

County	Rate per bushel
All counties	$0.64

SOUTH CAROLINA

County	Rate per bushel
All counties	$0.65

SOUTH DAKOTA

County	Rate per bushel	County	Rate per bushel
Aurora	$0.48	Jackson	$0.47
Beadle	.48	Jerauld	.48
Bennett	.48	Jones	.47
Bon Homme	.50	Kingsbury	.48
Brookings	.49	Lake	.48
Brown	.46	Lawrence	.46
Brule	.48	Lincoln	.51
Buffalo	.48	Lyman	.47
Butte	.46	McCook	.49
Campbell	.45	McPherson	.45
Charles Mix	.49	Marshall	.46
Clark	.47	Meade	.46
Clay	.52	Mellette	.48
Codington	.48	Miner	.48
Corson	.45	Minnehaha	.50
Custer	.49	Moody	.49
Davison	.48	Pennington	.47
Day	.47	Perkins	.45
Deuel	.49	Potter	.46
Dewey	.46	Roberts	.47
Douglas	.49	Sanborn	.48
Edmunds	.46	Shannon	.49
Fall River	.49	Spink	.47
Faulk	.46	Stanley	.47
Grant	.49	Sully	.47
Gregory	.48	Todd	.48
Haakon	.47	Tripp	.48
Hamlin	.48	Turner	.51
Hand	.47	Union	.52
Hanson	.48	Walworth	.46
Harding	.45	Washabaugh	.48
Hughes	.47	Yankton	.51
Hutchinson	.50	Ziebach	.46
Hyde	.47		

TENNESSEE

County	Rate per bushel
All counties	$0.65

TEXAS

County	Rate per bushel
All counties	$0.70

UTAH

County	Rate per bushel
All counties	$0.68

VERMONT

County	Rate per bushel
All counties	$0.64

VIRGINIA

County	Rate per bushel
All counties	$0.65

WASHINGTON

County	Rate per bushel
All counties	$0.62

WEST VIRGINIA

All counties $0.65

WISCONSIN

County	Rate per bushel	County	Rate per bushel
Adams	$0.57	Marathon	$0.57
Ashland	.57	Marinette	.58
Barron	.55	Marquette	.57
Bayfield	.56	Menominee	.57
Brown	.56	Milwaukee	.59
Buffalo	.54	Monroe	.56
Burnett	.54	Oconto	.57
Calumet	.56	Oneida	.58
Chippewa	.56	Outagamie	.56
Clark	.56	Ozaukee	.58
Columbia	.56	Pepin	.54
Crawford	.57	Pierce	.54
Dane	.58	Polk	.54
Dodge	.57	Portage	.57
Door	.56	Price	.57
Douglas	.54	Racine	.59
Dunn	.55	Richland	.56
Eau Claire	.55	Rock	.58
Florence	.58	Rusk	.56
Fond du Lac	.56	Saint Croix	.54
Forest	.58	Sauk	.58
Grant	.57	Sawyer	.56
Green	.58	Shawano	.57
Green Lake	.57	Sheboygan	.57
Iowa	.58	Taylor	.57
Iron	.58	Trempealeau	.55
Jackson	.56	Vernon	.55
Jefferson	.58	Vilas	.58
Juneau	.57	Walworth	.58
Kenosha	.59	Washburn	.55
Kewaunee	.56	Washington	.58
LaCrosse	.55	Waukesha	.59
Lafayette	.58	Waupaca	.57
Langlade	.57	Waushara	.57
Lincoln	.57	Winnebago	.56
Manitowoc	.56	Wood	.57

WYOMING

All counties $0.59

(b) *Premiums and discounts.*

	Cents per bushel
Premiums:[1]	
Grade U.S. No. 1	2
Grade U.S. No. 2	1
Test weight:	
Heavy	1
Extra heavy	2

[1] Premiums shall not be applicable to "badly stained or materially weathered" oats.

Discounts:	
Grade U.S. No. 4 on the factor of test weight only but otherwise U.S. No. 3 or better	3
Grade U.S. No. 4 because of being "badly stained or materially weathered"	7
Garlicky	3
Weed control discount (where required by § 1421.25)	10

Other factors. Amounts determined by CCC to represent discounts for quality factors not specified above which affect the value of the oats, such as (but not limited to) low test weight, foreign material, heat damage, percent of sound cultivated oats, wild oats, moisture, sour, stones, musty, ergoty, weevily, smutty, and bleached. Such discounts will be established not later than the time delivery of oats to CCC begins and will thereafter be adjusted from time to time as CCC determines appropriate to reflect changes in market conditions. Producers may obtain schedules of such factors and discounts at county ASCS offices approximately 1 month prior to the loan maturity date.

Effective Date. March 21, 1975.

Signed at Washington, D.C., on March 17, 1975.

GLENN A. WEIR,
Acting Executive Vice President,
Commodity Credit Corporation.

[FR Doc.75-7459 Filed 3-20-75;8:45 am]

proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE INTERIOR

National Park Service

[36 CFR Part 7]

YOSEMITE NATIONAL PARK, CALIF.

Camping Requirements

Notice is hereby given that pursuant to the authority contained in section 3 of the Act of August 25, 1916 (39 Stat. 535 (16 U.S.C. 3)), as amended, and the Act of June 2, 1920 (41 Stat. 732 (16 U.S.C. 61)), as amended, National Park Service Order 77 (38 FR 7478), as amended, Regional Director, Western Region Order No. 7 (37 FR 6326), it is proposed to change § 7.16 of Title 36 of the Code of Federal Regulations.

The purpose of this amendment is to introduce a new regulation for Yosemite National Park. The result should be better safeguarding of foods from wildlife in the Park's campgrounds, particularly from the American black bear.

It is the policy of the Department of the Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections on this proposal to the Superintendent, Yosemite National Park, P.O. Box 577, Yosemite National Park, Calif. 95389, on or before April 21, 1975.

Paragraph (e) of § 7.16 is amended with the addition of subparagraph (3) as follows:

§ 7.16 Yosemite National Park.

* * * * *

(e) Camping.—* * *

(3) All food or similar organic material, must be kept completely sealed in a vehicle or camping unit that is constructed of solid, nonpliable material, or must be suspended at least 10 feet above the ground and 4 feet horizontally from any post or tree trunk. This restriction does not apply to food that is being eaten or is being prepared for eating.

LESLIE P. ARNBERGER,
Superintendent,
Yosemite National Park.

[FR Doc.75-7424 Filed 3-20-75;8:45 am]

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

[7 CFR Parts 271, 275]

[Amdt. No. 57]

FOOD STAMP PROGRAM

Proposed Rulemaking

Pursuant to the authority contained in the Food Stamp Act of 1964, as amended (78 Stat. 703, as amended; (7 U.S.C. 2011-2026)), notice is hereby given that the Food and Nutrition Service, Department of Agriculture intends to revise its regulations governing the operation of the Food Stamp Program for the purpose of implementing the reporting requirements of Pub. L. 93-347 which amended section 15(b) of the Food Stamp Act to read as follows:

(b) The Secretary is authorized to pay to each State agency an amount equal to 50 percentum of all administrative costs, including, but not limited to, the cost of (1) the certification of households; (2) the acceptance, storage, and protection of coupons after their delivery to receiving points within the States; (3) the issuance of such coupons to eligible households; (4) the outreach and fair hearing requirements of section 10 of this Act; and (5) the control and accounting of coupons: *Provided,* That each State shall, from time to time at the request of the Secretary, report to the Secretary on the effectiveness of its administration of the program and no such payment shall be made to any State unless the Secretary is satisfied pursuant to regulations which he shall issue that an adequate number of qualified personnel are employed by the State in the program to administer the program efficiently and effectively.

(Regulations implementing 50 percent payment of States' administrative costs were published in the FEDERAL REGISTER on December 17, 1974; 39 FR 43692.)

The legislative history of Pub. L. 93-347 indicates the requirement that States report on the effectiveness of their administration of the Food Stamp Program was added to assure that the States employ an adequate staff to handle the program and to strengthen the administration of the program. Achievement of this second purpose was considered to be particularly important because of the amount of Federal money provided to the States through the Food Stamp Program. Because of this legislative history the "adequate number of qualified personnel" language in Pub. L. 93-347 is not to be narrowly interpreted. The number of personnel required is directly related to other program requirements and should not provide an absolute measurement which would guarantee payment to a State where serious deficiencies other than number of qualified employees imperil prudent administration.

Therefore, in order to implement the intent of Congress in amending the Food Stamp Act and to permit the Secretary to make the required determination of the efficiency and effectiveness of each State's administration of the program in an appropriate manner, this section establishes requirements for the reporting of uniform data on the entire administration of the program as well as the conditions for continued funding by FNS.

State agencies will be required to continue the quality control review procedures in accordance with FNS instructions and, in addition, to perform annual reviews of State level program management and operations and of project level operations for project areas with a bonus issuance of $500,000 or more a month. All other project areas must be reviewed once every two years.

On a semi-annual basis, State agencies will be required to report to FNS on the findings of their semi-annual quality control reviews and those reviews of State and project level management and operations performed during the preceding semi-annual period. Such report shall include corrective action plans for resolving deficiencies noted during the reviews and status reports on pending corrective action plans. Because quality control is a vital part of this system the regulatory language has been moved from an earlier section of the regulations to this section.

In recognition of the States' need for a reasonable period of time in which to secure the funds and staff necessary to assume their responsibilities under Section 275.10, FNS will assist State agencies in the data collection responsibilities from July 1, 1975 until January 1, 1976.

FNS will submit to each State agency by July 1, 1975, a profile summarizing program deficiencies which will be developed from information available to FNS. Within 120 days of receipt of the profile, the State agency must submit a corrective action plan covering the findings contained in the profile and the quality control findings for the period January-June 1975.

During the period July 1 to December 31, 1975, FNS will develop and test procedures for reviewing State and project area level management and operations. The results of such reviews will be transmitted to the State agency on or before March 1, 1976. This information and the quality control findings for the period July-December 1975 will provide the basis for the second corrective action plan which will be due May 1, 1976. Beginning January 1, 1976, the State agency will assume total responsibility for data gathering and reporting.

Pub. L. 93-347 provides that payment shall be made to a State for the Federal share of its administrative costs to the extent that it is administering the program efficiently and effectively. Accordingly, FNS will take action to suspend all or a portion of the State agency's letter of credit if the State fails to submit the reports required by the system

on a timely basis. In addition, if FNS determines that the State has knowingly submitted an incorrect report on its operations, failed to implement its corrective action plan, or substantially failed to comply with Food Stamp Regulations, FNS will take action to either suspend or cancel all or a portion of the State agency's letter of credit. However, the emphasis throughout the proposed regulations is to encourage State improvement rather than to penalize States by stopping administrative funds. Therefore, in determining the extent to which a State meets the standards for proper administration established in current regulations and instructions, FNS will judge a State primarily on the effectiveness and timeliness of its actions to discover and correct deficiencies.

Interested persons may submit written comments, suggestions, or objections regarding the proposed changes to P. Royal Shipp, Director, Food Stamp Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C., 20250. In order to be sure of consideration, all submissions must be received no later than April 21, 1975. All comments, suggestions or objections received by April 21, 1975 will be considered before the final regulations are issued.

Comments, suggestions, or objections will be open to public inspection pursuant to 7 CFR 1.27(b) at the Office of the Director during regular business hours (8:30 a.m.–5 p.m.).

Parts 271 and 275 of Chapter II of Title 7 of the Code of Federal Regulations are amended as follows:

PART 271—PARTICIPATION OF STATE AGENCIES AND ELIGIBLE HOUSEHOLDS

1. In Section 271.1, paragraph (h) is amended to read as follows:

§ 271.1 General Terms and Conditions for State Agencies.

* * * * *

(h) Administrative financing. Except as provided in § 271.2, each State agency shall finance or cause to be financed, from funds available to the State or political subdivisions thereof, the costs of carrying out the administrative responsibilities assigned to it under the provisions of this subchapter, including providing adequate qualified staff and facilities to process applicant households within 30 days of receipt of an affidavit or an Application for Participation and to carry out in an efficient and effective manner other administrative tasks required by this subchapter.

* * * * *

§ 271.4 [Amended]

2. Section 271.4 is amended by deleting paragraph (a)(5) and renumbering paragraphs (a)(6) through (a)(8) as paragraphs (a)(5) through (a)(7), respectively.

PART 275—PAYMENT OF CERTAIN ADMINISTRATIVE COSTS OF STATE AGENCIES

3. Section 275.10 is revised to read as follows:

§ 275.10 Monitoring and Reporting Program Performance.

(a) *Purpose.* Under the Food Stamp Act, the State agency is responsible for the effective administration of the program and for reporting on such administration to the Department. The Food Stamp Act assigns to the Department the responsibility for ensuring that the State's administration is effective and efficient prior to continuing the payment of funds for costs incurred in the administration of the program. Effective and efficient administration of the program means administration by the State agency of its program responsibilities in a manner which substantially complies with the Food Stamp Act, this subchapter, FNS Instructions and the State Agency's Plan of Operation. To enable the accomplishment of these mandates, this section: (1) Requires that each State agency have a system for monitoring and improving its administration of the program, (2) establishes requirements for reports which FNS will use in determining the extent to which a State meets the standards for proper administration established in this subchapter and in FNS instructions in order to continue Federal payments for administrative costs, and (3) sets forth conditions under which FNS will suspend or cancel such payments.

(b) *Definitions.* *"Annual"* means the 12-month period from January 1 through December 31.

"Biennial" means the 24-month period from January 1 of an even-numbered year through December 31 of the following year.

"Project area" means the political subdivision within a State which has been approved for participation in the program by the Department. However, for the review and reporting purposes of this section, the State agency may, with FNS approval, establish a different administrative unit as its project area.

"Semi-annual" means the six-month period either from January 1 through June 30 or July 1 through December 31.

(c) *State responsibilities for monitoring and improving program performance.* The State agency shall provide for a continuing system of data collection, evaluation and action which will allow for a determination of the efficiency and effectiveness of program administration and improvement in program operations. To ensure the successful operation of such system, the State agency shall designate a person to coordinate these activities. The State agency shall submit to FNS for approval an amendment to the State Plan of Operation containing the name and title of the person so designated. Further the State shall provide adequate staff to keep the program review process current within established reporting dates and at a level of quality which ensures valid findings, adequate program analysis and effective corrective action. The components of the State agency's system shall be:

(1) Data collection through the following: (i) A quality control system (a method of continuing review on a sampling basis) to validate the accuracy of determinations of program eligibility and determine the extent to which households are paying the proper purchase requirements and receiving the coupon allotments to which they are entitled. The State agency's system of quality control shall be implemented through:

(A) Application of sampling methods prescribed by FNS;

(B) Use of FNS-prescribed schedules and instructions or schedules which provide for identical information; and

(C) Field investigations including personal interviews with all households which fall within the sample of participating households, and as necessary, with households that have been denied participation or whose eligibility has been terminated.

(ii) Reviews of project area management and operations including, but not necessarily limited to, information concerning internal management procedures, staff training and utilization, caseload data, certification and issuance procedures, timeliness and accuracy of reports, outreach efforts, fair hearing procedures, coupon management and security, fiscal controls, and service to recipients. Such information shall at a minimum be collected as follows:

(A) On an annual basis for project areas with monthly bonus of $500,000 or more in the last month of the preceding Federal fiscal year.

(B) On a biennial basis for project areas with monthly bonus of less than $500,000; one quarter to be completed in each semi-annual period unless otherwise approved by FNS.

(iii) Reviews of State management and operations, including, but not necessarily limited to, information concerning internal management practices and controls, system for program control and evaluation, quality control, corrective action planning, staff training and utilization, coordination of outreach efforts, overall program supervision, fair hearing procedures, fiscal controls, timeliness and accuracy of reports, and any functions relating to the certification of households or issuance and management of coupons performed at the State level. Such information shall at a minimum be collected on an annual basis.

(2) Data analysis and evaluation which will result in: (i) A comprehensive review of information collected in paragraph (c)(1) of this section; (ii) A review of results of past corrective action; (iii) An identification of problems; and (iv) A determination of probable causal factors.

(3) Corrective action planning. (i) The development of corrective action plans should involve the coordinated efforts of persons in the area of data analysis, quality control, operations, policy development and management, in identifying causal factors and determining a course of action which will serve to either substantially reduce or eliminate program deficiencies. Such corrective action plans shall include an identification of the problem, the name of the person who is responsible for resolving the problem, and a timetable for its resolution. The coordinator, established in

paragraph (c) of this section, will be responsible for insuring both the preparation of the corrective action plan and its approval by the head of the State agency.

(ii) Timing. (A) Project area corrective action plans shall be prepared no later than 60 days following the completion date of the review activity.

(B) State corrective action plans shall be prepared no later than 120 days after the end of the semi-annual period. Such plans shall be based on the quality control findings, State management and operations, information, and pertinent information gathered during project area reviews.

(4) Corrective action implementation and monitoring. The State agency Coordinator shall ensure the effectiveness and timely completion of corrective actions through monitoring the completion of corrective action plans and assessing the results.

(d) *Responsibilities for reporting on program performance.* States shall report to FNS on their administration of the program through the following reports:

(1) *Personnel.* Such report shall be submitted on July 1 of each year and shall contain the following information on equivalent full-time food stamp positions as of May 15 of the same year: (i) number of nonassistance certification workers, (ii) number of first line nonassistance certification supervisors, (iii) number of quality control reviewers, (iv) number of first line quality control supervisors, (v) number of second line quality control supervisors, (vi) number of quality control statisticians, (vii) number of fair hearing officials, (viii) number of State employed outreach workers and/or the cost of contracted outreach workers, (ix) number of State employed issuance workers and/or the cost of contractual issuance, (x) number of support workers, and (xi) number of unpaid workers.

(2) Quality control reports as prescribed.

(3) Timetable for performance of reviews required under paragraph (c) (1) (ii) and (iii) of this section. The timetable shall cover two years of review activity and shall be submitted to FNS for approval 60 days prior to each biennial period. Any adjustments to the timetable must have prior FNS approval.

(4) Project area corrective action plans and review findings for project areas with monthly bonus of $500,000 or more shall be submitted to FNS within 60 days following the completion of the review.

(5) Semi-annual Performance Report. Such report shall be due no later than 120 days following the end of the semi-annual period and shall consist of the following:

(i) Project area corrective action plans and review findings for project areas with monthly bonus of less than $500,000. Such corrective action plans shall be developed in accordance with paragraph (c) (3) (ii) of this section, and shall reflect all progress made toward completion at the time of submission.

(ii) State corrective action plan based on:

(A) Statewide quality control findings; and

(B) Review of State management and operations, if such review was conducted during the semi-annual period. The results of such review shall also be included.

(iii) Corrective Action Status Report. Such report shall indicate the completion of or progress made on previously submitted corrective action plans. FNS may require more frequent or more detailed status reporting during the correction of serious deficiencies.

(e) *FNS determination of effectiveness and efficiency of State operations.* FNS shall make a determination on the efficiency and effectiveness of State operations on the basis of State reports and other information available such as Federal audits and investigations and unit cost data referred to in § 275.8(b) (4) as it relates to the general criteria under section (c) (1) (a) of Appendix A which requires that allowable costs be necessary and reasonable for proper administration of the program. As part of the determination, FNS will review State reports and corrective action plans for completeness and timeliness. In addition, FNS will conduct reviews of the State's system for data collection and evaluation in order to:

(1) Assess the operation of the State food stamp quality control system, the State management and operations review system, and the project area management and operations review system;

(2) Provide a basis for assisting the State in improving its system; and

(3) Test the validity of the data collected by the States.

(f) *Suspension or cancellation of FNS funding.* Effective July 1, 1975, FNS may take action to suspend or cancel funding as provided in Section 275.13. Such action will be preceded by a formal warning to the State that suspension or cancellation is being considered. Nothing in this section shall be construed as abrogating the State's recourse to further review by the Federal court system. Suspension or cancellation may take place under the following conditions:

(1) FNS may suspend all or any portion of the State agency's letter of credit if the State fails to submit on a timely basis any of the following completed reports:

(i) Personnel.

(ii) Statistical portion of semi-annual quality control report.

(iii) Timetable for performance of reviews.

(iv) Project area corrective action plans and review findings for project areas with a bonus of $500,000 or more.

(v) Semi-annual Performance Report which includes the review of State management and operations, reviews of project area management and operations performed during the applicable semi-annual period, the required corrective action plans, and Corrective Action Status Report.

(2) FNS may suspend or cancel all or any portion of the State agency's letter of credit if FNS determines that the State agency has:

(i) Failed to substantially comply with the provisions of this subchapter, or,

(ii) Knowingly submitted an incorrect report on its administration of the program, or

(iii) Failed to take the necessary action contained in its FNS approved corrective action plan.

(g) *Implementation.* In order to provide the necessary time for States to secure State level funds and adequate staff to assume the total responsibilities under this section, the implementation will be accomplished in two phases. Under phase one, which is the interim period, FNS will assist State agencies in the data collection responsibilities. This period will end on January 1, 1976, at which time State agencies will assume full responsibility for data collection and reporting under this section. FNS will consider extending this period until June 30, 1976, if a State agency demonstrates, to the satisfaction of FNS, that it is unable to fully implement this provision.

(1) Phase one interim procedures.

(i) FNS will submit to each State agency by July 1, 1975, a profile summarizing program deficiencies which will be developed from information available to FNS. Upon receipt of the profile, the State agency must submit a corrective action plan for FNS approval within 120 days. Such corrective action plans shall incorporate quality control findings for the period January–June 1975.

(ii) During the period July 1 to December 31, 1975, FNS will develop and test procedures for State management and operation reviews and project area management and operations reviews. The results of such reviews will be transmitted to the State agency on or before March 1, 1976. This information and the quality control findings for the period July–December 1975 will provide the basis for a second corrective action plan which will be due May 1, 1976. The State agency will, at the same time, submit a status report on progress made toward the completion of the previously submitted corrective action plan.

(2) Phase two final implementation. Beginning January 1, 1976, the State agency will assume total responsibility for data gathering and reporting. Prior to the actual commencement of the reporting period, the State agency shall submit on November 1, 1975 a timetable for performance of reviews as specified in paragraph (d) (3) of this section. If FNS has given the State agency approval to delay implementation, the State agency shall submit instead a schedule which will ensure assumption of its responsibilities by July 1, 1976.

(78 Stat. 703, as amended; (7 U.S.C. 2011–2026))

(Catalog of Federal Domestic Assistance Programs No. 10.551, National Archives Reference Services)

Dated: March 17, 1975.

JOHN M. DAMGARD,
Deputy Assistant Secretary.

[FR Doc.75-7404 Filed 3-20-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 3]

STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses

The Commissioner of Food and Drugs proposes to close the transition period allowed for the changeover from nonimpact-resistant lenses to impact-resistant lenses. To protect the public from unsafe eyeglass and sunglass lenses, to provide for development of an adequate supply of impact-resistant lenses for use in eyeglasses and sunglasses, and to facilitate an orderly changeover to these lenses, the Commissioner specified in a regulation (21 CFR 3.84) published in the FEDERAL REGISTER of February 2, 1972 (37 FR 2503) that the transition to impact-resistant lenses must be completed as promptly as possible and that all lenses manufactured after January 31, 1972 must be impact-resistant, except when a physician or optometrist found that impact-resistant lenses would not fulfill the visual requirements of a particular patient.

In June 1972 the Food and Drug Administration prepared a publication, "Question and Answer Pamphlet No. 1 on Impact-Resistant Lenses" ((FDA) 72-4002, June 1972), to help interested persons understand the regulation on impact-resistant lenses and to deal with frequently asked questions concerning the regulation and transition period. The pamphlet is on display in the office of the Hearing Clerk, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

It was pointed out in the pamphlet that finished nonimpact-resistant lenses manufactured before January 31, 1972 could be sold after that date, although an effort should be made to render those lenses impact-resistant before sale, and that finished nonimpact-resistant lenses manufactured prior to that date would be permitted to be imported to facilitate the orderly changeover to impact-resistant lenses.

The Commissioner urged during the proposal stage of the regulation, as published in the FEDERAL REGISTER of November 6, 1970 (35 FR 17116), that the transition period start and be completed as promptly as possible. He now finds that a sufficient period of time has elapsed since January 31, 1972 to allow for a smooth uninterrupted transition to the manufacture of impact-resistant lenses and concludes there is no longer any reason to permit use of nonimpact-resistant lenses, except in special cases.

The Commissioner proposes to revise the regulations to close the transition period. The change will delete the provision allowing use of nonimpact-resistant lenses manufactured before January 31, 1972 and will provide that lenses manufactured for use in eyeglasses and sunglasses be impact-resistant, except when a physician or optometrist finds that these lenses will not fulfill visual requirements. An importer for resale is regarded as a manufacturer.

Because of the time allowed for the transition period, the Commissioner proposes that the revised regulation be effective 30 days after date of publication of the final order in the FEDERAL REGISTER. He anticipates that this action will not have a significant effect on the environment and, therefore, an environmental impact statement, pursuant to section 102(2)(c) of the National Environmental Policy Act, will not be required.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502(j), 701(a), 52 Stat. 1051, 1055; (21 U.S.C. 352(j), 371(a))) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 3 be amended in § 3.84 by revising paragraph (h) to read as follows:

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

1. Section 3.84(h) is revised as set forth below:

§ 3.84 Use of impact-resistant lenses in eyeglasses and sunglasses.

* * * * *

(h) All lenses must be impact-resistant; except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.

* * * * *

Interested persons are invited to submit their comments regarding this proposal in writing (preferably in quintuplicate, except single copies of comments may be submitted by individuals), on or before May 20, 1975. Comments should be addressed to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: March 17, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7387 Filed 3-20-75;8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 39]

[Docket No. 14455]

McDONNELL DOUGLAS MODEL DC-10 SERIES, LOCKHEED MODEL L-1011 SERIES, AND BOEING MODEL B-747 SERIES AIRPLANES

Proposed Airworthiness Directive

The Federal Aviation Administration is considering amending Part 39 of the Federal Aviation Regulations by adding an airworthiness directive applicable to McDonnell Douglas Model DC-10, Lockheed Model L-1011, and Boeing Model B-747 airplanes. There has been service experience that indicates that the rapid in-flight depressurization of any of these airplanes caused by a sudden large opening in a lower cargo compartment can result in the airplane becoming incapable of continued safe flight and landing. Since this condition is likely to exist or develop in other airplanes of the same type designs, the proposed airworthiness directive would require modifications that would significantly improve the capability of these airplanes to continue safe flight and landing following a sudden in-flight depressurization. It would be required that the modifications be approved by the Chief, Aircraft Engineering Division, FAA Western Region, for the Lockheed Model L-1011 and McDonnell Douglas Model DC-10 airplanes and by the Chief, Engineering and Manufacturing Branch, FAA Northwest Region, for the Boeing Model B-747 airplane.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Information on the economic impact that might result because of the adoption of the proposed rule is requested. Communications should identify the docket number and be submitted in duplicate to the Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, AGC-24, 800 Independence Avenue, SW., Washington, D.C. 20591. All communications received on or before May 22, 1975, will be considered by the Administrator before taking action upon the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments will be available both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

This amendment is proposed under the authority of sections 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, and 1423) and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

In consideration of the foregoing, it is proposed to amend § 39.13 of Part 39 of the Federal Aviation Regulations by adding the following new airworthiness directive:

McDONNELL DOUGLAS, LOCKHEED, AND BOEING. Applies to all McDonnell Douglas Model DC-10 Series, Lockheed Model L-1011 Series, and Boeing Model B-747 Series airplanes certificated in all categories.

Compliance is required on or before July 1, 1977, unless already accomplished.

To improve the capability of the passenger and crew compartment floors to withstand, without collapse, an in-flight depressurization caused by the sudden opening of a large hole in a lower deck cargo compartment, comply with paragraphs (a) and (b):

(a) Incorporate the modification specified in paragraph (a)(1), taking into consideration the factors specified in paragraphs (a)(2) and (a)(3):

(1) Provide additional venting capability or an increase in floor strength, or both, as necessary, to prevent floor collapse caused

by the decompression effects resulting from a sudden large in-flight opening in any portion of any lower deck cargo compartment.

(2) The size of openings to be considered must include the maximum size opening expected in service, but the maximum size opening considered may not have an area of less than 20 square feet.

(3) Each compartment and ambient condition pressure differential expected in service must be considered.

(b) The modifications and determinations required under paragraph (a) of this AD must be approved by the Chief, Aircraft Engineering Division, FAA Western Region, for McDonnell Douglas Model DC-10 Series and Lockheed Model L-1011 Series airplanes; and by the Chief, Engineering and Manufacturing Branch, FAA Northwestern Region, for Boeing Model B-747 Series airplanes.

Issued in Washington, D.C. on March 20, 1975.

R. P. SKULLY,
Director,
Flight Standards Service.

[FR Doc.75-7675 Filed 3-20-75;12:00 am]

[14 CFR Part 71]

[Airspace Docket No. 74-NW-26]

BOISE, IDAHO

Alteration of Control Zone

The Federal Aviation Administration (FAA) is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the description of the Boise, Idaho Control Zone.

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Chief, Operations, Procedures and Airspace Branch, Northwest Region, Federal Aviation Administration, FAA Building, King County International Airport, Seattle, Washington 98108. All communications received on or before April 21, 1975, will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

A public docket will be available for examination by interested persons in the office of the Regional Counsel, Northwest Region, Federal Aviation Administration, FAA Building, King County International Airport, Seattle, Washington 98108.

A review of the airspace requirements at Boise, Idaho disclosed that additional Control Zone airspace is required to provide controlled airspace for flights executing the Boise VORTAC Rwy 28L Approach.

In consideration of the foregoing, the FAA proposes the following airspace action:

In § 71.171 (40 FR 354) the description of the Boise, Idaho Control Zone is amended to read as follows:

BOISE, IDAHO

With a 5-mile radius of the Boise Air Terminal (Latitude 43°33'55" N., Longitude 116°13'30" W.); within 2 miles each side of the Boise VORTAC 304° radial, extending from the 5-mile radius zone to 12 miles northwest of the VORTAC; within 2 miles each side of the Boise VORTAC 319° radial, extending from the 5-mile radius zone to 12 miles northwest of the VORTAC, within 5 miles each side of the Boise VORTAC 114° radial, extending from the 5-mile radius area to 12 miles southeast of the VORTAC; and within 2 miles west and 5 miles east of the Boise VORTAC 179° radial extending from the 5-mile radius area to 7 miles south of the VORTAC.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958, as amended, (49 U.S.C. 1348(a)), and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Seattle, Washington on March 13, 1975.

C. B. WALK, Jr.,
Director, Northwest Region.

[FR Doc.75-7358 Filed 3-20-75;8:45 am]

[14 CFR PART 71

[Airspace Docket No. 74-NW-20]

HILLSBORO, OREGON

Alteration of Control Zone

The Federal Aviation Administration (FAA) is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the description of the Hillsboro, Oregon, Control Zone.

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Chief, Operations, Procedures, and Airspace Branch, Northwest Region, Federal Aviation Administration, FAA Building, Boeing Field, Seattle, Washington, 98108. All communications received within on or before April 21, 1975, will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

A public docket will be available for examination by interested persons in the office of the Regional Counsel, Northwest Region, Federal Aviation Administration, FAA Building, King County International Airport, Seattle, Washington 98108.

An ILS Rwy 12 Standard Instrument Approach Procedure for the Portland-Hillsboro Airport, Hillsboro, Oregon, has been established to be effective upon commissioning of the Instrument Landing System. The description of the Hillsboro Control Zone needs to be altered to provide additional controlled airspace to contain the new ILS procedure to Runway 12.

In consideration of the foregoing, the FAA proposes to amend Part 71 of the Federal Aviation Regulations as follows:

In § 71.171 (40 FR 354) the description of the Hillsboro, Oregon, Control Zone is amended to read as follows:

HILLSBORO, OREGON

Within a 5-mile radius of Portland-Hillsboro Airport (Latitude 45°32'15" N, Longitude 122°56'46" W); within 2 miles each side of the Newburg VORTAC 007° radial, extending from the 5-mile radius area to 8 miles south of the airport; within 2 miles each side of the 039° bearing from the airport reference point, extending from the 5-mile radius area to 9.5 miles northeast of the airport; and within 3.5 miles each side of the 323° bearing from the airport reference point, extending from the 5-mile radius area to 16 miles northwest. This control zone will be effective during the time established in advance by a Notice to Airmen and continuously published in the Airmen's Information Manual.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958 as amended (49 U.S.C. 1348(a)) and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Seattle, Washington, on March 13, 1975.

C. B. WALK, Jr.,
Director, Northwest Region.

[FR Doc.75-7360 Filed 3-20-75;8:45 am]

[14 CFR PART 71

[Airspace Docket No. 75-SO-26]

JACKSON, MISSISSIPPI

Alteration of Transition Area

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would alter the Jackson, Miss., transition area.

Interested persons may submit such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Federal Aviation Administration, Southern Region, Air Traffic Division, P.O. Box 20636, Atlanta, Ga. 30320. All communications received on or before April 21, 1975, will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Chief, Airspace and Procedures Branch. Any data, views or arguments presented during such conferences must also be submitted in writing in accordance with this

notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Administration, Southern Region, Room 645, 3400 Whipple Street, East Point, Ga.

The Jackson transition area described in § 71.181 (40 FR 441) would be amended as follows:

"* * * north of the runway end * * *" would be deleted and "* * * north of the runway end; within 3 miles each side of the Bruce RBN (Lat. 32°26'28" N., Long. 90° 06'19" W.), extending from the 5.5-mile radius area to 8.5 miles north of the RBN * * *" would be substituted therefor.

The proposed alteration is required to provide controlled airspace protection for IFR aircraft executing the new NDB RWY 17 Instrument Approach Procedure to Bruce Campbell Field, utilizing the Bruce (private) Nondirectional Radio Beacon.

This amendment is proposed under the authority of sec. 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on March 12, 1975.

PHILLIP M. SWATEK,
Director, Southern Region.

[FR Doc.75-7361 Filed 3-20-75;8:45 am]

[14 CFR PART 71

[Airspace Docket No. 75-NW-01]

PORT ANGELES, WASHINGTON

Establish Control Zone

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would include the description of the Port Angeles, Washington, Control Zone.

Interested persons may participate in the proposed rule making by submitting such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Chief, Operations, Procedures and Airspace Branch, Northwest Region, Federal Aviation Administration, FAA Building, King County International Airport, Seattle, Washington 98108. All communications received on or before April 21, 1975, will be considered before action is taken on the proposed amendment. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Regional Air Traffic Division Chief. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

A public docket will be available for examination by interested persons in the office of the Regional Counsel, Northwest Region, Federal Aviation Administration, FAA Building, King County International Airport, Seattle, Washington 98108.

The control zone would accommodate the published instrument approach procedure for the William R. Fairchild International Airport, Port Angeles, Washington.

In consideration of the foregoing, the Federal Aviation Administration proposes the following airspace action:

In § 71.171 (40 FR 354), add the following description:

PORT ANGELES, WASHINGTON

Within a 5-mile radius of William R. Fairchild International Airport (latitude 48°07'-10" N, longitude 123°29'44" W), excluding that airspace within a 1-mile radius of latitude 48°08'28" N, longitude 123°24'45" W.

This control zone is effective during specific dates and times established in advance by a Notice to Airmen. Effective date and time will thereafter be continuously published in the Airman's Information Manual.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958, as amended, (49 U.S.C. 1348(a)), and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in Seattle, Washington, on March 13, 1975.

C. B. WALK, Jr.,
Director, Northwest Region.

[FR Doc.75-7359 Filed 3-20-75;8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Ch. II]

CHILDREN'S SLEEPWEAR

Sizes 7 Through 14 (FF 5-74); Affirmative Labeling

The purpose of this notice is to amend the Standard for the Flammability of Children's Sleepwear, sizes 7 through 14 (FF 5-74), issued by the Consumer Product Safety Commission on May 1, 1974 (39 FR 15210), under the Flammable Fabrics Act (15 U.S.C. 1191, et seq.).

The Standard applies to all children's sleepwear garments in sizes 7 through 14, and all fabric or related material intended or promoted for use in such sleepwear. The Standard requires all items of children's sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975 to comply with the Standard.

The amendment issued in this notice requires each such item of children's sleepwear manufactured on or after May 1, 1975, through May 1, 1978 to be affirmatively labeled with a prescribed statement that the item complies with the Standard. The label need not be permanently affixed to the item of children's sleepwear, but it must be prominent, conspicuous, legible and readily visible at the point of sale to ultimate consumers. The label statement may be attached to the item itself, on a hang tag attached to the item, or on a package enclosing the item.

Background. In the FEDERAL REGISTER of May 1, 1974 (39 FR 15228) the Commission published a Notice of Possible Need for Amendment of the Standard. The possible need to require affirmative labeling for items subject to the Standard was one of four issues the Commission listed in that Notice.

In the FEDERAL REGISTER of January 20, 1975 (40 FR 3276), the Commission proposed to amend the Standard to require affirmative labeling of items subject to the Standard for a period of three years from the effective date of the Standard. In addition, the Commission withdrew its notice of possible need for amendment as to the remaining three issues mentioned in that notice. The Commission invited public comment on the proposed amendment regarding affirmative labeling.

Comments. A total of eleven comments were received in response to the January 20, 1975 notice of possible need for amendment. Ten comments were generally in support of the Standard and the proposed affirmative labeling amendment to the Standard. One comment, from a consumer, objected to the Standard itself, and other comments objected to certain portions of the Standard.

1. *Content of label.* Five of the comments addressed the content of the proposed affirmative labels. A retailer states that the label to be required for all items of sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975 through May 1, 1978 should read "Flame-retardant. U.S. Standard FF 5-74" rather than "Flame-resistant. U.S. Standard FF 5-74" as proposed. The comment states that the words "flame retardant" would be consistent with descriptive wording used by retailers for over ten years and that to change the wording could cause confusion among consumers. This commenter states that the words "flame retardant" more correctly describe the properties of items of children's sleepwear which comply with the Standard, since the fabric does not readily ignite or propagate flame and self-extinguishes when removed from a flame. The comment states that the term "flame resistant" may imply a more protective property than is the case under the Standard.

Another comment suggests that the labels should clearly indicate to parents that the garments which comply with the Standard are not fireproof, but that they afford a significant degree of protection.

One comment, from a member of the National Advisory Committee for the Flammable Fabrics Act, states that the wording "Flame-resistant. U.S. Standard FF 5-74" is ill-advised because the term "flame-resistant" is subjective and not yet adequately defined and that an opinion survey shows that the term implies substantially more protection than the term "flame retardant." In addition the comment states the term could erroneously impart a sense of "protective clothing" or could invite experimentation by children. The comment also

states that the proposed terminology is in connection with a test method which has not been related to real life fire situations and would seem to require the type of labeling that led the Federal Trade Commission to take action against the cellular plastics industry. Thus the comment suggests alternate wording that uses neither the term "flame resistant" nor the term "flame retardant."

Another comment concurs with the proposed label statement but suggests that research be performed to determine more universally meaningful language than "flame resistant."

Discussion. The Commission believes it is necessary to prescribe language for affirmative labels to briefly describe the properties of items that comply with the standard so that consumers will understand the effect of the standard. Therefore, the Commission believes affirmative labels should contain some language as to the flammability of items complying with the Standard.

Although the Commission has not conducted surveys regarding consumer understanding of the meanings of the terms "flame resistant" and "flame retardant", the Commission believes that the public can be informed of the purposes of flammability standards for children's sleepwear. The use of consistent flammability labeling should further this effort.

The Commission has learned that the Committee on Textiles of the American Society for Testing and Materials (ASTM) has been considering a set of uniform flammability definitions which specify use of the term "flame resistant" to describe material which does not readily ignite and propagate a flame. The term "flame retardant" would describe substances applied to fabric to make it "flame resistant". The Commission has learned that the proposed definitions have received a majority affirmative vote of that Committee, and are expected to be adopted. The Commission believes that it will help to eliminate confusion among consumers by adopting this generally accepted terminology regarding the flammability of textiles.

The Commission has no evidence that the use of the terminology will invite experimentation by children. The Commission believes that the Standard does prescribe a test method that relates to the major flammability hazard of children's sleepwear in sizes 7 through 14, and believes the term "flame resistant" does describe the properties of items complying with the Standard. Therefore the Commission issues this amendment to the Standard to require affirmative labeling that states "Flame-resistant. U.S. Standard FF 5–74".

2. *Permanency of the label.* One comment from a consumer requests that the Commission require labeling "that remains on flammable products". One other comment, from a retailer, expressly agrees with the proposal to allow nonpermanent hang tags or stickers to be used for labeling.

Discussion. The major purposes of requiring affirmative labeling are to allow consumers to distinguish complying from noncomplying items of children's sleepwear at the point of sale, and to assist the Commission in its efforts to enforce compliance with the Standard. The Commission believes consumers will be able to make an informed choice between items which comply with the Standard and items which do not comply with the Standard if the prescribed statements are prominent, conspicuous, legible and readily visible to the ultimate consumer at the point of sale. Thus the Commission does not believe it is necessary to require that the affirmative labels be permanently affixed to the items of children's sleepwear in sizes 7 through 14.

3. *Effective date of amendment.* One comment from a retailer states that the Commission should announce the exact wording to be required on the affirmative labels as soon as possible and estimates that at least 45 days will be required to procure labels and distribute them to manufacturers. Therefore, the comment recommends that 45 days be allowed between the date of publication of the final amendment and the mandatory compliance date for labeling.

Discussion. The Commission agrees that it should specify the exact wording of the label statement and therefore the amendment to the Standard prescribes the required wording to be used on labels.

The Commission explained in the January 20, 1975 notice of proposed amendment to the Standard (40 FR 3276) its intention that any final amendment as to labeling would become effective on May 1, 1975, the effective date of the Standard. In this notice of amendment, below, the Commission finds for good cause that the amendment requiring affirmative labeling of items of children's sleepwear in sizes 7 through 14 should become effective on May 1, 1975.

The Commission believes that publication of this notice provides sufficient time for compliance with the amendment. Additionally, the Commission issued a press release announcing its decision to issue the amendment to become effective May 1, 1975 and describing the requirements of the amendment.

4. *Miscellaneous.* A number of comments addressed issues that are not the subject of this rule-making proceeding. One comment objects to the Standard itself as being unnecessary and causing additional expense. Other comments object to the Commission decision, published in the FEDERAL REGISTER of January 20, 1975 (40 FR 3276) to withdraw the May 1, 1974 notice of possible need for amendment of the Standard (39 FR 15228) as to allowing testing exemptions and defining the terms "manufactured" and "in inventory or with the trade" as part of the Standard. One comment suggests that the two Commission flammability standards for children's sleepwear (DOC FF 13–71 and FF 5–74) should be combined to provide one standard for sleepwear in sizes 0 through 14.

Discussion. Because these comments are outside this proceeding, they will not be addressed. However, in issuing the Standard on May 1, 1974 (39 FR 15210) and withdrawing the notice of possible need for amendment to the Standard on January 20, 1975 (40 FR 3276), the Commission explained its actions. In addition, on January 20, 1975, the Commission published a policy statement clarifying the way it defines the terms "manufactured" and "in inventory or with the trade" for the purpose of the Standard, and invited comment on the policy statement. Elsewhere in the FEDERAL REGISTER today, the Commission has published the final policy statement. The Commission also points out that section .1(c) of the Standard provides that items that meet all the requirements of the Standard for the Flammability of Children's Sleepwear (DOC FF 3–71), sizes 0 through 6X, are in compliance with the standard for sizes 7 through 14.

Findings. On the basis of the comments received, additional investigation by the staff of the Commission, and other relevant information the Commission has determined to issue the following amendment to the Standard. The National Advisory Committee for the Flammable Fabrics Act was consulted as to the amendment to the Standard at a meeting on January 28, 1975.

5. *Items in Compliance with DOC FF 3–71.* Section .1(c) of the Standard provides that items of children's sleepwear in sizes 7 through 14 that meet all the requirements of the Standard for the Flammability of Children's Sleepwear for sizes 0–6X (DOC FF 3–71) are in compliance with FF 5–74, the Standard for sizes 7–14. The preamble to the Standard for sizes 7 through 14 (39 FR 15210, May 1, 1974) states that this provision is included in the Standard because all the test criteria of the Standard for sizes 7 through 14 are set forth in identical language in the Standard for sizes 0 through 6X. No reduction in the the stringency of the Standard for sizes 7 through 14 occurred when the Commission included section .1(c) in the Standard. The preamble to the Standard for sizes 7 through 14 states that section .1(c) was therefore "added to the final Standard to provide that fabrics and garments which meet all the test criteria of the Standard for the Flammability of Children's Sleepwear (DOC FF 3–17) are in compliance with this Standard."

Informal discussion with some members of industry indicates that they interpret section .1(c) of the Standard to mean that items of children's sleepwear in sizes 7 through 14 that comply with DOC FF 3–71 need not meet the affirmative labeling requirement which is issued in this Notice.

This interpretation is inaccurate. The amendment to the Standard requires that all items of children's sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975, through May 1, 1978, must be affirmatively labeled. This requirement is applicable if the item of

children's sleepwear in sizes 7 through 14 complies with the Standard by meeting the test criteria of DOC FF 3–71, in addition to the test criteria of FF 5–74, or if the item complies solely with FF 5–74.

In order to clarify any possible ambiguity as to the extent of the requirement for affirmative labeling in the amendment to the Standard, the Commission has included language in the amendment to indicate that all complying items of sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975, through May 1, 1978, must be affirmatively labeled with the prescribed statement. Although this clarifying language was not included in the January 20, 1975, notice of proposed amendment, it merely clarifies the Commission's intention as to the coverage of the affirmative labeling requirement.

The Consumer Product Safety Commission finds that the affirmative labeling amendment to the Standard for the Flammability of Children's Sleepwear; Sizes 7 through 14 (FF 5–74) is:

1. Needed for children's sleepwear in sizes 7 through 14 to protect the public against unreasonable risk of the occurrence of fire leading to death, personal injury, or significant property damage; and

2. Reasonable, technologically practicable, and appropriate, and stated in objective terms; and

3. Limited to items of children's sleepwear in sizes 7 through 14 which currently present unreasonable risks of the occurrence of fire leading to death, personal injury, or significant property damage.

The affirmative labeling amendment to the Standard will become effective May 1, 1975, the effective date of the Standard. Section 4(b) of the Flammable Fabrics Act (15 U.S.C. 1193) provides that any amendment to a flammability standard shall become effective twelve months from the date on which it is promulgated unless the Commission finds for good cause and publishes the finding that an earlier or later effective date is in the public interest. The Commission hereby finds that it is in the public interest to require that the amendment to require affirmative labeling of items of children's sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975 through May 1, 1978 become effective on May 1, 1975. To allow a later effective date for this amendment would not enable consumers to distinguish complying from noncomplying items of children's sleepwear in sizes 7 through 14 at the point of sale. Noncomplying items of such sleepwear may be sold but not manufactured, on or after May 1, 1975. Particularly during the time period immediately after the Standard becomes effective it is likely that both complying and noncomplying items of sleepwear will be available to consumers. Thus, it is necessary that affirmative labeling be required immediately upon the effectiveness of the standard.

Therefore, pursuant to provisions of the Flammable Fabrics Act (sec. 4, 67 stat. 112, as amended 81 Stat. 569–70; 15 U.S.C. 1193) and under authority vested in the Consumer Product Safety Commission by the Consumer Product Safety Act (Pub. L. 92–573, sec. 30(b), 86 Stat. 1231; (15 U.S.C. 2079(b))), the Standard for the Flammability of Children's sleepwear; sizes 7 through 14 (FF5–74) (39 FR 15210, May 1, 1974) is amended as follows:

The provision of section .6 of the Standard appearing after the title *Labeling reqirements* is designated as .paragraph (a).

A new paragraph is added to section .6, paragraph (b), to read as follows:

(b) All items of children's sleepwear Standard (including those items that comply with DOC FF 3–71) and manufactured on or after May 1, 1975 through May 1, 1978, shall bear a label which states: "Flame-resistant. U.S. Standard FF 5–74." The label must be prominent, conspicuous, legible and readily visible at the point of sale to ultimate consumers. The label statement may be attached to the item itself, on a hang tag attached to the item, or on a package enclosing the item. The label need not be affixed permanently.

Effective date. This amendment becomes effective on May 1, 1975.

(Sec. 4, 67 Stat. 112, as amended 81 Stat. 569–70; (15 U.S.C. 1193))

Dated: March 18, 1975.

SADYE E. DUNN,
Secretary,
Consumer Product Safety Commission.

[FR Doc.75-7455 Filed 3-20-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

[FRL 347-1]

IMPLEMENTATION PLANS

Iowa: Approval of Compliance Schedules

On May 31, 1972 (37 FR 10842), pursuant to section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved portions of State plans for implementation of the national ambient air quality standards. The State of Iowa submitted to the Environmental Protection Agency compliance schedules to be considered as proposed revisions to the approved plans pursuant to 40 CFR 51.6. 40 CFR 51.8 requires the Administrator to approve or disapprove compliance schedules submitted by the states. Therefore, the Administrator proposes the approval of the compliance schedules listed below.

The approvable schedules were adopted by the State and submitted to the Environmental Protection Agency after notice and public hearings in accordance with the procedural requirements of 40 CFR 51.4 and 51.6 and the substantive requirementss of 40 CFR 51.15 pertaining to compliance schedules. The compliance schedules have been reviewed and determined to be consistent with the approved control strategies of Iowa. Each approved revision establishes a new date by which the individual source must comply with the applicable emission limitation in the federally-approved State Implementation Plan. This date is indicated in the table below, under the heading "Final Compliance Date." In all cases, the schedules include incremental steps toward compliance with the applicable emission limitations. While the tables below do not include these interim dates, the actual compliance schedules do.

Under Iowa law, the compliance schedule is not enforceable after the date on which the associated variance expires and variances cannot extend for more than one year. Therefore, to the extent that the schedules extend past the variance expiration date, they are not legally enforceable at this time. For this reason, EPA's approval of each compliance schedule will be unconditional only as to that part of the schedule covered by the initial variance. Approval of the remainder of the schedule will be conditioned upon the State's renewal of the variance in identical form and substance to that included in the schedule submitted to the Environmental Protection Agency and approved herein. If the variance is renewed in this manner, the condition precedent will be satisfied and the approval of the next segment of the schedule would not require further action by the State or this Agency. If the variance is not renewed, or is modified from the version that had been federally approved, the condition will not be fulfilled, the approval of the remainder of the schedule would not be effective, and the State's immediately-effective regulation would again become federally enforceable.

Provisional approval of final compliance dates and extensions of variances is justifiable only because of the one-year variance limitation in the law of Iowa. Since there will be no substantive changes in the schedules set forth below and public hearings were held on the complete schedule, there is no reason to require compliance with 40 CFR 51.6 procedures at the time Iowa renews each variance. The schedules were immediately effective on the date of adoption. An "Effective Date" is not indicated on the table. The "Variance Expiration Date" is included instead.

In the indication of proposed approval of individual compliance schedules, the individual schedules are included by reference only. In addition, since the large number of compliance schedules preclude setting forth detailed reasons for approval of individual schedules in the FEDERAL REGISTER, an evaluation report has been prepared for each individual compliance schedule. Copies of these evaluation reports are available for public inspection at the Environmental Protection Agency Regional Office, 1735 Baltimore, Kansas City, Missouri. The compliance schedules and the State Implementation Plans are available for public inspection

at the Environmental Protection Agency Regional Office; the Environmental Protection Agency, Division of Stationary Source Enforcement, 401 M Street, Washington, D.C.; and the Iowa Department of Environmental Quality, 3920 Delaware, Des Moines, Iowa.

Interested persons may participate in this rulemaking by submitting written comments in triplicate to the Region VII office at the above address. All comments submitted on or before April 21, 1975, will be considered. Receipt of comments will be acknowledged but substantive responses will not be provided. All comments received, as well as copies of the applicable implementation plans, will be available for inspection during normal business hours at the Regional Office.

The proposed rulemaking is issued under authority of section 110(a) of the Clean Air Act, as amended, (42 U.S.C. 1857c-5).

Dated: March 6, 1975.

JEROME H. SVORE,
Regional Administrator.

It is proposed to amend Part 52 of Chapter I, Title 40 of the Code of Federal Regulations as follows:

Subpart Q—Iowa

1. In § 52.825, the table in subparagraph (c) is amended as follows:

§ 52.825 Compliance Schedules.

* * * * * *

(c) * * *

IOWA

Source	Location	Regulation involved	Date adopted	Variance expiration date	Final compliance date
* * * *					
Scoville Manufacturing Co., caredco window and door division, grinding system (item No. 3).	Dubuque	4.3(2)a	Nov. 14, 1974	June 30, 1975	June 30, 1975
Katelman Foundry, Inc., Cupola	Council Bluffs	4.4(4)	Feb. 13, 1975	Mar. 13, 1975	Mar. 13, 1975
Armour & Co. (the Greyhound Corp.), boilers Nos. 1, 3, 4, and 5.	Mason City	4.3(2)b	do	July 31, 1975	July 31, 1975
Headford Brothers & Hitchins Foundry Co., cupola.	Waterloo	4.4(4)	Aug. 8, 1974	June 1, 1975	June 1, 1975
Green Products Co., alfalfa dehydrating plant.	Conrad	4.3(2)a	Feb. 13, 1975	May 1, 1975	May 1, 1975
Gra-Iron Foundry Corp., cupola	Marshalltown	4.4(4)	do	Mar. 15, 1975	Mar. 15, 1975
Progressive Foundry, Inc., cupola	Perry	4.4(4)	do	Apr. 23, 1975	Apr. 23, 1975
Farmers Mutual Cooperative Co., cyclone on headhouse.	Alton	4.4(6)	do	June 15, 1975	June 15, 1975
Wapsie Valley Creamery, Inc., whey spray dryer.	Independence	4.3(2)a	do	July 29, 1975	July 29, 1975
Houdaille Industries, Inc., viking pump division, sand silo.	Cedar Falls	4.3(2)a	do	June 3, 1975	June 3, 1975
Rohlin Construction Co., asphaltic concrete plant D.	LaPorte	4.4(2)	do	May 20, 1975	May 20, 1975
Spencer Municipal Hospital, incinerator.	Spencer	4.4(2)	do	July 31, 1957	July 31, 1975
Norris Construction Co., asphaltic concrete plant No. 250.	Ottumwa	4.4(2)	do	May 16, 1975	May 16, 1975
Iowa Road Builders Co., asphaltic concrete plant.	Ames	4.4(2)	do	July 31, 1975	July 31, 1975
Cessford Construction Co., asphaltic concrete plant No. 1.	LeGrand	4.4(2)	do	Apr. 15, 1975	Apr. 15, 1975

[FR Doc.75-7217 Filed 3-20-75;8:45 am]

[40 CFR Part 52]

[FRL 347-2]

IMPLEMENTATION PLANS

Kansas: Approval and Disapproval of Compliance Schedules

On May 31, 1972 (37 FR 10842), pursuant to section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved portions of State plans for implementation of the national ambient air quality standards, and on September 22, 1972, in the FEDERAL REGISTER (37 FR 19809), the Administrator promulgated § 52.876 Compliance Schedules as a part of the Kansas Implementation Plan.

The State of Kansas submitted to the Environmental Protection Agency compliance schedules as variances and enforcement orders to be considered as proposed revisions to the approved plans pursuant to 40 CFR 51.6 and 40 CFR 51.7 (d) (2). 40 CFR 51.8 requires the Administrator to approve or disapprove compliance schedules submitted by the States. Therefore, the Administrator proposes the approval and disapproval of the compliance schedules listed below.

The approvable schedules were adopted by the States and submitted to the Environmental Protection Agency after notice and public hearings in accordance with the procedural requirements of 40 CFR 51.4, 51.6, and 51.7(d) (2), and the substantive requirements of 40 CFR 51.15 pertaining to compliance schedules. The compliance schedules have been reviewed and determined to be consistent with the approved control strategies of Kansas.

Each approved revision establishes a new date by which the individual source must comply with the applicable emission limitation in the federally approved State Implementation Plan. This date is indicated in the table below, under the heading "Final Compliance Date."

The following schedules are amendments to previously proposed compliance schedules: Colt Industries, Kansas City; Kiowa District Hospital, Kiowa; Kansas State University Health Center, Manhattan; Minneola District Hospital, Minneola; North Central Foundry, Enterprise; U.S.D. #247, Cherokee; and Walton Foundry, Iola.

The following are Orders issued to sources on previously approved variances: McPherson County Highway Department, McPherson; and Sherwin-Williams Chemicals, Coffeyville.

The schedules proposed to be disapproved in this notice fail to meet the requirements of 40 CFR 51.15(b) (1), in that the compliance schedules extend beyond the attainment date in the State Implementation Plan.

In the indication of proposed approval and disapproval of individual compliance schedules, the individual schedules are included by reference only. In addition, since the large number of compliance schedules preclude setting forth detailed reasons for approval or disapproval of individual schedules in the FEDERAL REGISTER, an evaluation report has been prepared for each individual compliance schedule. Copies of these evaluation reports are available for public inspection at the Environmental Protection Agency Regional Office, 1735 Baltimore, Kansas City, Missouri. The compliance schedules proposed to be approved or disapproved, and the State Implementation Plans are available for public inspection at the Environmental Protection Agency Regional Office; the Environmental Protection Agency, Division of Stationary Source Enforcement, 401 M Street, Washington, D.C.; and the Kansas State Department of Health and Environment, Forbes Air Force Base, Building 740, Topeka, Kansas.

Interested persons may participate in this rulemaking by submitting written comments in triplicate to the Region VII Office at the above address. All comments submitted on or before April 21, 1975, will be considered. All comments received, as well as copies of the applicable implementation plans, will be available for inspection during normal business hours at the Regional Office.

This proposed rulemaking is issued under the authority of section 110(a) of the Clean Air Act, as amended, 42 U.S.C. 1857c-5.

Dated: March 16, 1975.

JEROME H. SVORE,
Regional Administrator.

It is proposed to amend Part 52 of Chapter I, Title 40 of the Code of Federal Regulations as follows:

Subpart R—Kansas

1. In § 52.876, the table in subparagraph (c) (1) is amended by adding the following:

§ 52.876 Compliance Schedules.

* * * * * *

(c) * * *

KANSAS

Source	Location	Regulation involved	Date adopted	Effective date	Final compliance date
American Walnut Co., teepee incinerator.	Kansas City	28-19-41B	Jan. 24, 1975	Immediately	June 1, 1975
Heckert Construction Co., rotary dryer.	Pittsburg	28-19-50A	do	do	Do.
McPherson County Highway Department, asphalt plant.	McPherson	28-19-50 28-19-20	do	do	Jan. 1, 1975
National Alfalfa Dehydrating & Milling, pellet mill lift cyclone.	LeRoy	28-19-50A	do	do	Apr. 15, 1975
Service Iron Foundry, cupola	Wichita	28-19-20 28-19-50	do	do	June 1, 1975
Colt Industries, cupola	Kansas City	28-19-20 28-19-50	do	do	Feb. 15, 1975
Cross Alfalfa Products, Hammermill	Lewis	28-19-50A	do	Immediately	July 1, 1975
Kiowa District Hospital, incinerator	Kiowa	28-19-40 28-19-41	do	do	Do.
Kansas State University Health Center, incinerator.	Manhattan	28-19-40	do	do	Mar. 15, 1975
Minneola District Hospital, incinerator.	Minneola	28-19-40 28-19-41	do	do	July 31, 1975
North Central Foundry, Inc., gray iron foundry cupola.	Enterprise	28-19-20	do	do	July 1, 1975
S. & F. Sales, Inc. open burning	Bonner Springs	28-19-45	do	do	July 31, 1975
Walton Foundry, Inc., cupola	Iola	28-19-20	do	do	July 1, 1975
U.S.D. No. 247, Cherokee grade school incinerator.	Cherokee	28-19-40	do	do	July 31, 1975
McCune school incinerator		28-19-40	do	do	Do.
Southeast high incinerator		28-19-40	do	do	Do.
West mineral grade incinerator		28-19-40	do	do	Do.
Weir attendance center incinerator		28-19-40	do	do	Do.

2. In § 52.876, the table in subparagraph (c)(2) is amended by adding the following:

§ 52.876 Compliance Schedules.

(c) * * *

KANSAS

Source	Location	Regulation involved	Date adopted
Kansas Army Ammunition Plant, open burning	Parsons	28-19-45	Jan. 24, 1975
Reid Grain, headhouse	Goodland	28-19-50	Do.
Sherwin-Williams Chemicals, black ash kiln	Colleyville	28-19-50A	Do.

[FR Doc.75-7218 Filed 3-20-75;8:45 am]

[40 CFR Part 52]

[FRL 347-3]

IMPLEMENTATION PLANS

Missouri: Approval of Compliance Schedules

On May 31, 1972 (37 FR 10842), pursuant to section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved portions of State plans for implementation of the national ambient air quality standards.

During January 1975, the State of Missouri submitted to the Environmental Protection Agency compliance schedules to be considered as proposed revisions to the approved plans pursuant to 40 CFR 51.6. 40 CFR 51.8 requires the Administrator to approve or disapprove compliance schedules submitted by the States. Therefore, the Administrator proposes the approval of the compliance schedules listed below.

The approvable schedules were adopted by the States and submitted to the Environmental Protection Agency after notice and public hearings in accordance with the procedural requirements of 40 CFR 51.4 and 51.6 and the substantive requirements of 40 CFR 51.15 pertaining to compliance schedules. The compliance schedules have been reviewed and determined to be consistent with the approved control strategies of Missouri.

Each approved revision establishes a new date by which the individual source must comply with the applicable emission limitation in the federally approved States Implementation Plan. This date is indicated in the table below under the heading "Final Compliance Date." In all cases, the schedules include incremental steps toward compliance with the applicable emission limitations. While the tables below do not include these interim dates, the actual compliance schedules do. The "Effective Date" column in the table indicates the date the compliance schedules become effective for purposes of federal enforcement.

The schedule for CPC International, North Kansas City, is an amendment to a schedule previously published as a final approval on January 23, 1975 (40 FR 3566).

In the indication of proposed approval of individual compliance schedules, the individual schedules are included by reference only. In addition, since the large

number of compliance schedules preclude setting forth detailed reasons for approval of individual schedules in the FEDERAL REGISTER, an evaluation report has been prepared for each individual compliance schedule. These evaluation reports are available for public inspection at the Environmental Protection Agency Regional Office, 1735 Baltimore, Kansas City, Missouri. The compliance schedules proposed to be approved and the State Implementation Plans are available for public inspection at the Environmental Protection Agency Regional Office; the Environmental Protection Agency, Division of Stationary Source Enforcement, 401 M Street, Washington, D.C.; and the Missouri Department of Natural Resources, State Office Building, Jefferson City, Missouri

Interested persons may participate in this rulemaking by submitting written comments in triplicate to the Region VII office at the above address. All comments submitted on or before April 21, 1975, will be considered. All comments received, as well as copies of the applicable implementation plans, will be available for inspection during normal business hours at the Regional Office.

This proposed rulemaking is issued under authority of section 110(a) of the Clean Air Act, as amended, 42 U.S.C. 1857c-5.

Dated: March 6, 1975.

JEROME H. SVORE,
Regional Administrator.

It is proposed to amend Part 52 of Chapter I, Title 40 of the Code of Federal Regulations as follows:

Subpart AA—Missouri

1. In § 52.1335, the table in subparagraph (a) is amended by adding the following:

§ 52.1335 Compliance Schedules.

* * * * * *

(a) * * *

MISSOURI

Source	Location	Regulation involved	Date adopted	Effective date	Final compliance date
Gardner-Denver, Cupola Furnaces	LaGrange	S-V	Jan. 22, 1975	Immediately	May 1, 1975
CPC International, wet corn fed rotary dryers.	North Kansas City.	(1)	do	do	Apr. 3, 1975
Empire District Electric, coal-fired-boilers.	Asbury	S-VI, S-VIII	do	do	June 15, 1975

[1] Regulation V and VI, air pollution control regulations for the Kansas City metropolitan area.

[FR Doc.75-7219 Filed 3-20-75;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 21, 43 & 61]

[Docket No. 18920]

DOMESTIC RADIO SERVICE

Further Notice of Inquiry and Proposed Rule Making

In the matter of establishment of policies and procedures for consideration of applications to provide specialized common carrier services in the domestic public point-to-point microwave radio service and proposed amendments to Parts 21, 43 and 61 of the Commission's rules.

1. In this proceeding the Commission has promulgated rules and policy dealing with the establishment of competitive common carrier facilities for the provision of private line or specialized communications (Issues A and B), the development of frequency conservation rules to prepare for the increased use of the radio spectrum (Issue C),[1] and local distribution facilities and frequencies (Issue E).[2] The only remaining issue as yet unresolved in this proceeding involves the quality and reliability of service (Issue D). In context with competition among carriers for specialized services, the question here is whether some measure of protection to the subscribers is called for in the area of quality and reliability of service.

2. In the Notice of Inquiry to Formulate Policy, Notice of Proposed Rule Making and Order (at paragraphs 62-65), 24 FCC 2d 318 (1970), the Commission tentatively decided against prescribing minimum standards of technical performance, but proposed to require of all carriers providing such services:

(1) That the applicant specify in standard terminology in his microwave application the proposed reliability of service to the customer, to the extent that the nature of the proposed service is known;

(2) That the carrier be required to specify in his tariff, and notify the customer of, the precise reliability factors applicable to the particular service;

(3) That the carrier make refunds on a reasonable proportionate basis where the service rendered fails to meet the specified reliability standards; and

(4) That the carrier make periodic reports to the Commission concerning the reliability actually achieved, service complaints and refunds.

The Commission also requested comments on the development of standard statements of reliability quality factors for the various types of service, and on the contents of the proposed quarterly reports (paragraph 65).

3. In response to that proposal there were no comments that addressed the matter in any depth, and at the time of the First Report and Order we noted that the issue had apparently been overshadowed by Issues A and B. While we subsequently indicated plans to establish an industry advisory committee to consider Issue D, 30 FCC 2d 888 (1971), no further action was taken due to the higher priorities given to the resolution of Issue E and the processing and consideration of some 2500 applications for specialized common carrier microwave authorizations. However, now that many of these competing systems have been authorized and are in operation, the questions posed in Issue D have become more timely and in need of early resolution.[3] Now that competitive systems are in actual operation, we should be provided with valuable experience and insight not heretofore available.

4. Under these circumstances, we believe that the most appropriate method for moving forward toward resolution of Issue D is to seek additional comments, but more suitably focused by a number of questions. These questions are not intended to be all-inclusive, and where they lead to other questions, we hope those commenting will address all relevant matters. We also wish to solicit the widest possible response, not only by carriers but by users and equipment suppliers as well. Upon receipt of the responses to these questions, the Common Carrier Bureau staff may hold one or more informal conferences to discuss various aspects of these matters with interested persons.[4]

5. While the concept of an advertised level of quality and reliability would seem to be straight forward, we realize that developing specific rules and standards will be anything but simple. However, our goal is not to impose over-complicated requirements but to arrive at a reasonable policy designed to provide some indication to the potential customer of the performance that can be reasonably expected and thus to encourage fair competition among competing carriers.

6. Before proceeding to the questions it may be helpful to briefly discuss what is intended by the terms "quality and reliability." It is easy from a conceptual point of view to make a distinction between the two. Quality can be perceived of as being some amount—absolute or relative—of noise and/or error free transmission of information over a communications system,[5] whereas reliability may be thought of as the probability of a communications system performing its

[1] See *First Report and Order*, 29 FCC 2d 870 (1971).

[2] See *Second Report and Order*, 47 FCC 2d 737 (1974).

[3] See *American Telephone and Telegraph*, Docket No. 20288, released December 16, 1974 (FCC 74-1370).

[4] Public notice will be given of any such conferences.

[5] The term "quality" is also used on occasion to refer to a characteristic of a communication channel related to size or capacity, e.g. a 4 KHz channel offers more quality in the transmission of a voice signal than a 3 KHz channel. This measure of quality is not within our concern in this proceeding.

intended functions at the prescribed quality level. While these terms can be distinguished, they are closely interdependent. One cannot easily apply a quality standard if a system reliability standard has not been met. On the other hand, a reliability standard becomes largely useless if the quality of service is extremely poor. Therefore, as a practical matter we propose to treat these terms more or less as one concept for the purpose of discussing system performance.

7. Responses to the following questions are solicited:

(a) In what terms should quality and reliability be expressed, for analog and digital signals? (e.g. percent reliability, signal to noise ratio, bit error rate, error free seconds, etc.?) On what length of time should a reliability measurement be based?

(b) Assuming that the terms differ for analog and digital, should they be a function of the type of transmission facilities, the type of use, or both? (For example, if digital facilities are used for voice transmission as well as data, should the quality and reliability be expressed in terms appropriate for both voice and data?)

(c) To what extent is it advisable or necessary to standardize the methods for determining quality and reliability on a system-wide basis? How difficult would it be to establish standards for calculation? What factors should be taken into consideration? What standardized methods could be adopted?

(d) Once quality and reliability standards are established for a given system, what methods are available to the carrier to monitor the operation of the system to estimate its actual performance?

(e) How practical would it be for a customer to determine what quality and reliability he is actually receiving on an end to end circuit? Are there any inexpensive devices available that can monitor performance on a circuit?

(f) When two or more systems with different performance standards are interconnected, what is the effect on the end to end service rendered to the customer? What is the effect of interconnecting analog and digital facilities, of cable and radio?

(g) What are the most important system parameters that effect end to end performance on two or more interconnected systems? How can overall performance be calculated and represented to the customer on such interconnected systems? Would the method of monitoring the performance of such interconnected facilities be any more difficult than it would for an integrated system?

(h) Where refunds for inferior service are appropriate, what should be the standard therefor in the case of voice transmission, data, or a combination of the two? Over what period of time should service be measured and refunds apply?

(i) What efforts are currently being made by carriers to establish system standards of quality and reliability, to measure system performance according to such standards, and to advise the customer of expected performance?

8. Authority for this inquiry and proposed rule making is contained in sections 4(i), 303 and 403 of the Communications Act of 1934, as amended. All interested persons are invited to file written comments on these proposed rules on or before May 23, 1975.[6] In reaching its decision in this matter the Commission may take into account any other relevant information before it in addition to the comments invited by this notice.

9. In accordance with the provision of § 1.419 of the Commission's rules, an original and 14 copies of all comments, replies, pleadings, briefs, or other documents shall be furnished to the Commission. Responses will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

Adopted: March 11, 1975.

Released: March 18, 1975.

FEDERAL COMMUNICATIONS COMMISSION,

[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7409 Filed 3-20-75;8:45 am]

FEDERAL POWER COMMISSION

[18 CFR Parts 3, 260]

[Docket No. RM75-24]

CONTINUING INVESTIGATION OF ACTIVITIES OF NATURAL GAS PRODUCERS AND PRODUCING AFFILIATES

Proposed Rulemaking

MARCH 13, 1975.

Notice is hereby given, pursuant to 5 U.S.C. 553 and sections 4, 5, 8, 10, 14, 15, and 16 of the Natural Gas Act (52 Stat. 822, 823, 825, 826, 828, 829, 830; 76 Stat. 72; (15 U.S.C. 717c, 717d, 717g, 717l, 717m, 717n, 717o)), that the Federal Power Commission is considering the adoption of rules and regulations providing for the systematic collection of data and information concerning producer and producing affiliate expenditures, exploration and development activities, reserve additions, production and revenues. All persons found by the Commission to be a "natural-gas company" within the meaning of the Natural Gas Act, and their jurisdictional affiliates and subsidiaries as defined in 18 CFR 157.40(a)(2) of the Commission's regulations, would be required to complete, file and attest to the information solicited in the proposed report (Attachment A, proposed FPC Form 64[1]).

The proposed form (Attachment A) consists of three schedules, with attachments. Schedule No. 1 includes the total expenditures made by producers for the entire United States and various production areas for exploration and development of oil and gas by type of reservoir. Schedule No. 2 requests data on exploration and development activity for both the entire United States and certain specific production areas. Schedule No. 3 details production, revenue, royalty and non-associated gas reserve data for the United States and the various production areas.

The proposed form, FPC Form 64, is designed to provide information which will assist the Commission in the biennial review of the nationwide rate established in Opinion No. 699-H, and for all future such reviews. It will also aid the Commission in monitoring both gas producer expenditures, and revenue, leasing and drilling activity on an annual basis and it will also be of great value in determining future adjustments to flowing gas prices.

The starting point for any producer ratemaking determination made by this Commission is a consideration of the costs involved.[2] The importance of this element of a just and reasonable rate and the components thereof is set forth in our latest determination of the nationwide rate.[3] The form proposed herein is specifically designed to provide the Commission with an independently verifiable source of information on producer expenditures, revenues, and leasing and drilling activity. Collection of this data, in conjunction with the material to be submitted on Forms 40[4] and 45,[5] will permit the Commission, in its biennial review of the nationwide rate, to rely, primarily, on information submitted directly to us and auditable by us, rather than to be forced to rely upon published data not open to close scrutiny.

The proposed form requires the submission of certain reserve data for the past ten years. The importance of this type of information to a determination of productivity, which is a vital component of the costing methodology employed in Opinion No. 699-H,[6] was set forth in our order promulgating Form 40.[7] The proposed form requires information for the past ten years, while Form 40 would include only the initial reporting year. Since the definitions to be employed will be the same for both forms, the proposed form will not increase the burden placed on respondents by Form 40, and the resultant information will be invaluable in providing the Commission with reliable data on productivity.

Schedule No. 3 of the proposed form would include reserve addition data for

---

[6] Due to the preliminary nature of this Notice and our desire to proceed promptly in this matter, we are not providing for reply comments in order to allow additional time for the preparation of more comprehensive comments. If any person believes that reply comments are especially important, they will be considered if they are filed within 15 days of the date for filing comments.

[1] Filed as part of the original document.

[2] *Texaco Inc.* v. *F.P.C.*, 417 U.S. 380 (1974).

[3] Opinion No. 699-H, Opinion And Order On Rehearing Affirming In Part And Modifying In Part Opinion No. 699 And Granting In Part And Denying In Part Petitions For Rehearing, Docket No. R-389-B, —— F.P.C. ——, mimeo at 13-34 (issued December 4, 1974). (hereinafter Opinion No. 699-H)

[4] Order No. 526, Natural Gas Companies Annual Report Of Proved Domestic Gas Reserves: FPC Form No. 40, Docket No. RM74-16, —— F.P.C. —— (issued February 25, 1975). (hereinafter Order No. 526)

[5] Order No. 521, Investigation Of Rates Charged For Nonjurisdictional Sales of Natural Gas By Natural Gas Companies Subject To The Jurisdiction Of The Federal Power Commission, Docket No. RM74-12, —— F.P.C. —— (issued January 9, 1975).

[6] Opinion No. 699-H, mimeo at 19-27.

[7] Order No. 526, mimeo at 8-9.

the entire United States and also for six production areas: (1) Appalachian and Illinois Basins, (2) Rocky-Mountain Areas, (3) Offshore Federal Domain, (4) wells drilled in water greater than 250 feet deep, (5) wells drilled onshore below 15,000 feet, and (6) Alaska.

The deepening national crisis and shortage of alternate domestic energy sources compels the Commission to undertake continuing, broadly based investigations of all facts and circumstances surrounding and underlying the Commission's ratemaking functions established in sections 4 and 5 of the Natural Gas Act. Natural gas is a vital element in the nation's energy base, accounting for over forty percent of domestic energy production and over fifty percent of industrial energy consumption. Because natural gas is the cleanest burning fossil fuel, it is a premium fuel having minimal adverse effect on the physical environment. The deepening natural gas shortage and critical shortages of alternative fuels require the Commission to pursue any and all steps necessary to insure that the public has an adequate supply of natural gas available at the lowest price consistent with providing the necessary incentives to elicit that supply.[8]

A determination of the nature and scope of information collection by the Commission is necessary and appropriate to the fullfilment of the statutory obligations prescribed by sections 4 and 5 of the Act to establish just and reasonable rates for natural gas sales.[9]

Timely information on natural gas producer and producer affiliate expenditures, exploration and developmental activities, reserve additions, and revenues is not collected by any government agency on a comprehensive and correlated basis. The proposed rules and regulations established herein are designed to provide the Commission with a continuous flow of current information to be used in evaluating the efficacy and consequences of rates established by the Commission.

Any information submitted to the Commission pursuant to this rulemaking, if adopted, would be subject to audit by the Commission staff upon reasonable notice by the Commission. Upon such grounds as the Commission may determine as prudent and necessary, the requirement of notice may be waived by the Commission on an ex parte basis, and company books, papers, records, and related material shall be produced upon demand by properly identified Commission representatives. All schedules submitted pursuant to this rulemaking would be sworn to by an appropriately authorized officer of the firm submitting the questionnaire as a true, complete, and accurate response to the data requested to the best of that officer's and firm's information, knowledge, and belief.

The information solicited under this rulemaking for propcsed rules and regulations would be made on FPC Form No. 64, which the Commission also proposes to adopt in order to insure uniformity and completeness in the reporting of information on producer and producer affiliate expenditures, exploration and developmental activities, reserve additions, production and revenue. The specific data that would be acquired by the Commission is set forth in Attachment A attached hereto in schedule Nos. 1, 2, and 3 thereof, along with definitions and procedures to be employed in completing these schedules.

The definitions to be employed in this survey are those in common usage in the natural gas industry. Reserve additions, for example, would be defined as that term is used by the American Gas Association, which collects such data for the publication of its annual surveys.

The utilization in the proposed survey of well established definitions commonly employed in the industry decreases the possibility of a misunderstanding of the directions, thereby avoiding a variation in results. The purpose of this procedure is so that little or no modification of business recordkeeping would be required.

Any interested person may submit to the Federal Power Commission, Washington, D.C. 20426, not later than April 30, 1975, data, views, and comments or suggestions in writing concerning the proposed form. Written submittals will be placed in the Commission's public files and will be available for public inspection at the Commission's Office of Public Information, Washington, D.C. 20426, during regular business hours. The Commission will consider all such written submittals before acting on the matters herein proposed. An original and 14 conformed copies should be filed with the Secretary of the Commission. Submissions to the Commission should indicate the name, title, and mailing address of the person to whom correspondence in regard to the proposal should be addressed and whether the person filing them requests a conference with the Staff of the Federal Power Commission to discuss the proposed form. The Staff, in its discretion, may grant or deny requests for conference.

The proposed amendments to Parts 3 and 260 would be issued under the authority granted the Federal Power Commission by the Natural Gas Act, as amended, particularly sections 4, 5, 8, 10, 14, 15, and 16 (52 Stat. 822, 823, 825, 826, 828, 829, 830; 76 Stat. 72; (15 U.S.C. 717c, 717d, 717g, 717i, 717m, 717n, 717o)).

1. Accordingly, the Federal Power Commission proposes to amend Part 260, Statements and Reports (Schedules), in Subchapter G—Approved Forms, Natural Gas Act, Chapter I, Title 18 of the Code of Federal Regulations by adding new Section 260. —. prescribing new FPC Report Form No. 64, Report of Producer Expenditures, Exploration and Development Activity, and Production and Revenues in the form set out in Attachment hereto. New Section 260. —. will read:

§ 260.— Form No. 64, Report Of Producer Expenditures, Exploration And Development Activity, Production And Revenues.

(a) The form of Report of Producer Expenditures, Exploration and Development Activity, Production and Revenues as FPC Form No. 64, is prescribed.

(b) Each person found by the Commission to be a "natural-gas company" within the meaning of the Natural Gas Act, and their jurisdictional affiliates and subsidiaries as defined in 18 CFR 157.40 (a) (2) of the Commission's regulations, shall annually prepare and file with the Commission an original and three copies of Report of Producer Expenditures, Exploration and Development Activity, Production and Revenues, FPC Form No. 64. The report for the calendar year ending December 31, 1974, shall be filed by June 30, 1975, and the report for each calendar year thereafter ending December 31 shall be filed by March 31 of the following year.

2. Further, it is proposed to amend § 3.170(a) (27) of Part 3, Organization; operation; information and requests; miscellaneous charges; ethical standards, Subchapter A—General Rules, Chapter I, Title 18 of the Code of Federal Regulations to read as follows:

§ 3.170 Approved forms, etc.

(a) The following is a list of approved forms, statements, and reports, under the Natural Gas Act, descriptions of which have been published in subchapter G, parts 250 and 260 of this chapter.

* * * * * * *

(27) Form No. 64, Report of Producer Expenditures, Exploration and Development Activity, Production and Revenues of each person found by the Commission to be a "natural-gas company" within the meaning of the Natural Gas Act, and their jurisdictional affiliates and subsidiaries as defined in 18 CFR 157.40(a) (2) of the Commission's regulations. (Section 260. —. of this Chapter)

The Secretary shall cause prompt publication of this notice to be made in the FEDERAL REGISTER.

By direction of the Commission.

MARY B. KIDD,
Acting Secretary.

[FR Doc.75-7378 Filed 3-20-75;8:45 am]

[18 CFR Part 141]

[Docket No. RM75-18]

ELECTRIC UTILITY QUESTIONNAIRE

Plans and Costs for Meeting Current Air Pollution Standards

FEBRUARY 21, 1975.

Take notice that, pursuant to 5 U.S.C. 553 and sections 202, 301, 304(a), 309

[8] The natural gas shortages have been judicially recognized, *e.g., F.P.C.* v. *Louisiana Power & Light Co.*, 406 U.S. 621 (1972); *Placid Oil Company, et al.* v. *F.P.C.*, 483 F.2d 880 (5th Cir. 1973), *certiorari granted sub nom. Mobil Oil Corporation, et al.* v. *F.P.C.*, Nos. 73-437, *et al.*, January 14, 1974; *Shell Oil Company* v. *F.P.C.* 484 F.2d 469 (1973).

[9] The Commission regulates sales of natural gas in interstate commerce for resale. *Phillips Petroleum Co.* v. *Wisconsin*, 347 U.S. 672 (1954).

and 311 of the Federal Power Act (49 Stat. 848, 849, 854, 855–856, 858, 859; 67 Stat. 461; 16 U.S.C. 824a, 825, 825c(c), 825h, 825j), the Federal Power Commission proposes to enact FPC Form No. 67A, a questionnaire to be filed annually by appropriate utilities in order to create a comprehensive source of information and body of data on the existence, operation and cost of pollution control equipment for the removal of particulate matter and sulfur oxides at utility plants, and on the probable cost of alternative methods for meeting National Ambient Air Quality Standards.

The proposed amendment to Part 141 of the Commission's Approved Forms under the Federal Power Act would be issued under the authority granted the Federal Power Commission by the Federal Power Act, as amended, particularly sections 202, 301, 304(a), 309, and 311 (49 Stat. 848, 849, 854, 855–856, 858, 859; 67 Stat. 461; 16 U.S.C. 824a, 825, 825c (c), 825h, 825j).

Accordingly, it is proposed to amend Part 141, Statements and Reports (Schedules), in Subchapter D—Approved Forms, Federal Power Act, Chapter I, Title 18 of the Code of Federal Regulations by adding a new § 141.62 prescribing new FPC Form No. 67A, Plans and Costs for Meeting Current Air Pollution Standards, in the form set out in attachment A hereto. New § 141.62 will read:

§ 141.62 Steam-electric air quality control data for meeting current standards.

(a) This Form is designed to secure information on the existence, operation and cost of pollution control equipment for removal of particulate matter and sulfur oxides at utility plants, and on the probable cost of alternative methods for meeting National Air Quality Standards.

(b) Each steam electric utility plant at least 25 megawatts capacity which burns coal oil and which will commence operation before January 1, 1981 shall submit in sextuplet this form before May 1, 1975.

Declining supplies of natural gas available for electric utility boiler use, electric utility industry inability to develop nuclear power plant capacity in accordance with previously published schedules, and our national need to decrease our dependence upon foreign oil imports have led to increased industry reliance upon coal as a fuel source to meet demands. Inadequate supplies of low-sulfur coal have resulted in increased electric utility industry consumption and utilization of coal with higher sulfur content, necessitating the implementation of particulate matter and sulfur oxide emission control and removal plans and hardware by electric utilities in order to comply with National Ambient Air Quality Standards and State Implementation Plans on a timely basis.

Review of data responses gathered from various diverse sources suggests that the existing information at hand on the existence, operation and cost of such equipment and planning is fragmentary, incomprehensive and incomplete, thereby underscoring the need for development of a comprehensive source of information and body of data to examine future utility emission control plans and costs. In addition to the Commission, the Environmental Protection Agency, the Federal Energy Administration, and other Federal, State and local government agencies will have full access to information submitted in response to FPC Form 67 A, encompassing all steam-electric plans of at least 25 megawatts capacity which burn coal and oil, and are presently in operation or will commence operation before January 1, 1981. Completed forms are to be submitted in sextuplet to the Commission before May 1, 1975.

Any interested person may submit to the Federal Power Commission, Washington, D.C. 20426, not later than April 7, 1975, data, views, comments or suggestions in writing concerning all or part of the amendments proposed herein. Written submittals will be placed in the Commission's public files and will be available for public inspection at the Commission's Office of Public Information, Washington, D.C. 20426, during regular business hours. An original and 14 conformed copies should be filed with the Secretary of the Commission. Submittals to the Commission should indicate the name, title, mailing address and telephone number of the person to whom communications concerning the proposal should be addressed, and whether the person filing them requests a conference with the Staff of the Federal Power Commission to discuss the proposed amendments. The Staff, in its discretion, may grant or deny requests for conference. The Commission will consider all such written submittals before acting on the matters herein proposed.

The Secretary shall cause prompt publication of this notice to be made in the FEDERAL REGISTER.

By direction of the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7503 Filed 3-19-75;10:54 am]

NATIONAL SCIENCE FOUNDATION

[45 CFR Part 650]

DISPOSITION OF RIGHTS IN INVENTIONS

Notice of Proposed Rule Making

Notice is hereby given that Part 650 of Title 45 of the Code of Federal Regulations is proposed to be amended as set forth below.

The proposed amendment provides for certain limitations on the use of Foundation funds for further development of inventions made in the course of or under Foundation awards in cases where the inventing organization has been allowed to retain pricipal rights in such inventions.

Interested persons are invited to submit written comments on these regulations to the Director, National Science Foundation, ATTN: Office of the General Counsel, Washington, D.C. 20550, by May 30, 1975.

It is proposed that Chapter VI, Part 650 of Title 45 of the Code of Federal Regulations be amended as follows:

PART 650—PATENTS

1. Section 650.8(c) is amended by adding the following after subsection (5) and renumbering subsection (6) as subsection (7).

§ 650.8 [Amended]

* * * * *

(c) * * *

(6) include a provision similar to that set forth in § 650.9(c)(2); and

* * * * *

2. Paragraphs (2) and (3) of § 650.9 (c) are renumbered (3) and (4) respectively. A new paragraph (2) is added as follows:

§ 650.9 [Amended]

* * * * *

(c) * * *

(2) The willingness of a grantee to assume the costs and risks associated with the bringing of an invention to the point of practical application is a significant factor influencing most determinations that the grantee should be allowed to retain principal rights in an invention made under the award. Consequently, a provision limiting the use of Foundation funds for further development of such inventions will normally be included as a condition of each such determination. For this purpose, a provision such as the following shall be used:

(i) Unless specifically approved by the Grants and Contracts Officer, the grantee shall not use funds provided by the Foundation for performing development, engineering, or design work directed toward a commercial embodiment of the invention.

(ii) Paragraph (c)(2)(i) of this section shall not apply to efforts made to improve the invention for the primary purpose of enhancing its utility in connection with scientific research conducted by the grantee. Further to the extent that the work statement in the award or proposal upon which the award was based clearly specifies a line of research to be pursued, paragraph (c)(2)(i) of this section shall not apply to the pursuance of such research.

3. In the last paragraph of § 650.9(c)(4) (previously § 650.9(c)(3)) delete (2) and substitute (3) therefor.

Dated: March 14, 1975.

H. GUYFORD STEVER,
Director.

[FR Doc.75-7391 Filed 3-20-75;8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF DEFENSE

Department of the Air Force

USAF SCIENTIFIC ADVISORY BOARD

Meeting

MARCH 18, 1975.

The USAF Scientific Advisory Board Study Group on Management and Support of Air Force Command, Control, and Communications will hold a meeting at Andrews Air Force Base, Maryland. The dates and times are as follows.

April 2, 1975, 8:30 a.m.–6:00 p.m.
April 3, 1975, 8:30 a.m.–2:30 p.m.

The Study Group will receive classified briefings, conduct internal planning, and review proprietary information on matters listed in 5 U.S.C. 552(b) (1), (4), and (5) on April 2, 1975, and on April 3, 1975, from 8:30 a.m. to 12:00 p.m. From 1:15 p.m. to 2:30 p.m. on April 3, 1975, the Study Group will receive unclassified informational briefings, and this session will be open to the public. Persons wishing to attend the open session must make reservations with Miss Hall, 301–981–4215, by March 31, 1975. Written statements may be filed with the Study Group Secretariat by interested individuals at the meeting on April 3, 1975.

The requirement for the study was established by the Secretary of the Air Force on March 12, 1975, with a request for completion within 45 calendar days. In order to hold approximately four separate meetings and to have all individuals who are serving on the Study Group be able to attend, it is necessary to give less than 15 days notice for this meeting.

For further information, contact the USAF Scientific Advisory Board Secretariat on 202–697–4811.

JAMES E. DAGWELL,
Chief, Documentation Management Branch, Directorate of Administration.

[FR Doc.75–7421 Filed 3–20–75;8:45 am]

Department of the Navy

NAVY RESALE SYSTEM ADVISORY COMMITTEE

1974 Report of Closed Meeting

Under section 10(d) of the Federal Advisory Committee Act, the Navy Resale System Advisory Committee filed its 1974 Reports of Closed Meetings of the Navy Resale System Advisory Committee with the Library of Congress pursuant to the requirements of section 13 of the Federal Advisory Committee Act (5 U.S.C. App. I).

Any person desiring to review the Report may visit the Library of Congress, Exchange and Gift Division, Federal Advisory Committee Desk, Washington, D.C. Copies of the Reports and additional information may be obtained by addressing requests as follows:

Navy Resale System Advisory Committee Coordinator (Code: PL)
Navy Resale System Office
29th Street and 3rd Avenue
Brooklyn, New York 11232

Dated: March 17, 1975.

WILLIAM O. MILLER,
Rear Admiral, JAGC, U.S. Navy, Deputy Judge Advocate General.

[FR Doc.75–7362 Filed 3–20–75;8:45 am]

Office of the Secretary

DEFENSE SCIENCE BOARD TASK FORCE ON "SPECIFICATIONS AND STANDARDS IMPROVEMENT"

Advisory Committee Meeting

Pursuant to the provisions of Pub. L. 92–463, effective January 5, 1973, notice is hereby given that the Defense Science Board Task Force on "Specifications and Standards Improvement" will meet in open session on Thursday and Friday 17–18 April 1975 in Room 203A, Building 45, Defense Electronics Supply Center, Wilmington Pike, Dayton, Ohio.

The mission of the Defense Science Board is to advise the Secretary of Defense and Director of Defense Research and Engineering on overall research and engineering and to provide long range guidance in these areas to the Department of Defense.

The primary responsibility of the Task Force is to provide an evaluation of current DoD Specifications and Standards and the related DoD organization, system and procedures to serve as a basis for DoD policy decisions to reduce costs in systems/equipment design and acquisition.

At this meeting, the Task Force will devote discussions to Parts Standardization in Weapons Systems. Discussion will include parts specifications and standards, their impact on weapon system costs; parts control programs; nonstandard parts approval; industry/company parts standardization programs; and DoD parts organization involved in development, maintenance and issuance of parts specifications and standards.

Attendees outside of Task Force members will be admitted as observers to the proceedings. With time permitting and at the discretion of the Chairman, a specified but limited time will be allotted so as to permit observers to comment, make recommendations, take issue, or otherwise speak with respect to the subjects. Observers will be asked to leave during executive sessions.

Due to the limited time and space availability, it is requested that persons interested in attending the DSB Task Force meeting provide written notice to the address listed below. Notice should include information with respect to interest and degree of participation.

Mr. Lester Fox, Director
Defense Materiel Specifications and Standards Office
Cameron Station
Alexandria, Virginia 22314

Telephone inquiries may also be made to Mr. Fox at (202) 274–7061

MAURICE W. ROCHE,
Director, Correspondence and Directives, OASD (Comptroller).

MARCH 18, 1975.

[FR Doc.75–7444 Filed 3–20–75;8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Nev–051742]

NEVADA

Proposed Withdrawal of a Portion of the Sheldon Antelope Range from Mineral Entry

Correction

In FR Doc. 75–5253 appearing at page 8368, in the issue for Thursday, February 27, 1975 the first line of the coordinates under Mount Diablo Meridian was omitted, it should read "T. 45., R. 22 E.".

[INT FES—75–37]

OUTER CONTINENTAL SHELF OFFSHORE CENTRAL GULF OF MEXICO

Availability of Final Environmental Impact Statement Regarding Possible Oil and Gas Lease Sale

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a final environmental impact statement relating to a possible Outer Continental Shelf general oil and gas lease sale of 594 tracts of submerged lands on the Outer Continental Shelf in the Central Gulf of Mexico.

Single copies of the final environmental statement can be obtained from the Office of the Manager, Gulf of Mexico Outer Continental Shelf Office, Bureau of Land Management, Suite 3200, The Plaza Tower, 1001 Howard Avenue, New Orleans, Louisiana 70113, and from the Office of Public Affairs, Bureau of Land Management (130), Washington, D.C. 20240.

Copies of the final environmental statement will also be available for pub-

lic review in the main libraries in the following cities: New Orleans, Baton Rouge, and Lafayette, Louisiana; Galveston and Houston, Texas; Mobile, Alabama; and Gulfport, Mississippi.

CURT BERKLUND,
Director,
Bureau of Land Management.

Approved: March 19, 1975.

ROLAND G. ROBINSON, Jr.
Deputy Assistant Secretary of the Interior.

[FR Doc.75-7610 Filed 3-20-75;8:45 am]

Fish and Wildlife Service

ENDANGERED SPECIES PERMIT

Receipt of Application

Notice is hereby given that the following application for a permit is deemed to have been received under section 10 of the Endangered Species Act of 1973 (Pub. L. 93-205).

Applicant: Mr. Stephen A. M. Jovicich, 1658 W. Main (Apt. #1), Houston, Texas 77006.

OMB NO. 43-R1670

DEPARTMENT OF THE INTERIOR
U.S. FISH AND WILDLIFE SERVICE

FEDERAL FISH AND WILDLIFE LICENSE/PERMIT APPLICATION

1. APPLICATION FOR (*Indicate only one*)
☐ IMPORT OR EXPORT LICENSE ☒ PERMIT

2. BRIEF DESCRIPTION OF ACTIVITY FOR WHICH REQUESTED LICENSE OR PERMIT IS NEEDED.
I wish to take and import two St. Lucia parrots (Amazona versicolor) for the purpose of propagation.

3. APPLICANT. (*Name, complete address and phone number of individual, business, agency, or institution for which permit is requested*)
Stephen A. M. Jovicich
1658 W. Main (apt. #1)
Houston, Texas 77006
713-523-2696

4. IF "APPLICANT" IS AN INDIVIDUAL, COMPLETE THE FOLLOWING:
☒ MR. ☐ MRS. ☐ MISS ☐ MS.
HEIGHT: 6' 0" WEIGHT: 155 lbs
DATE OF BIRTH: August 8, 1953
COLOR HAIR: black COLOR EYES: brown
PHONE NUMBER WHERE EMPLOYED: 713-222-3196
SOCIAL SECURITY NUMBER: 463-96-9496
OCCUPATION: Aviculturist
ANY BUSINESS, AGENCY, OR INSTITUTIONAL AFFILIATION HAVING TO DO WITH THE WILDLIFE TO BE COVERED BY THIS LICENSE/PERMIT:
Save Animals From Extinction (SAFE)

5. IF "APPLICANT" IS A BUSINESS, CORPORATION, PUBLIC AGENCY, OR INSTITUTION, COMPLETE THE FOLLOWING:
EXPLAIN TYPE OR KIND OF BUSINESS, AGENCY, OR INSTITUTION
NAME, TITLE, AND PHONE NUMBER OF PRESIDENT, PRINCIPAL OFFICER, DIRECTOR, ETC.
IF "APPLICANT" IS A CORPORATION, INDICATE STATE IN WHICH INCORPORATED

6. LOCATION WHERE PROPOSED ACTIVITY IS TO BE CONDUCTED
I propose to import from St. Lucia to Houston possibly laying over in Miami depending on flight connections.

7. DO YOU HOLD ANY CURRENTLY VALID FEDERAL FISH AND WILDLIFE LICENSE OR PERMIT? ☐ YES ☒ NO
(*If yes, list license or permit number*)

8. IF REQUIRED BY ANY STATE OR FOREIGN GOVERNMENT, DO YOU HAVE THEIR APPROVAL TO CONDUCT THE ACTIVITY YOU PROPOSE? ☒ YES ☐ NO
(*If yes, list jurisdiction and type of document*)
St. Lucia government letter

9. CERTIFIED CHECK OR MONEY ORDER (*if applicable*) PAYABLE TO THE U.S. FISH AND WILDLIFE SERVICE ENCLOSED IN AMOUNT OF: $

10. DESIRED EFFECTIVE DATE: July 1975

11. DURATION NEEDED: July 1- August 31

12. ATTACHMENTS. THE SPECIFIC INFORMATION REQUIRED FOR THE TYPE OF LICENSE/PERMIT REQUESTED (*See 50 CFR [illegible]*) MUST BE ATTACHED. IT CONSTITUTES AN INTEGRAL PART OF THIS APPLICATION. LIST SECTIONS OF 50 CFR UNDER WHICH ATTACHMENTS ARE PROVIDED.
50 CFR 17.23

CERTIFICATION

I HEREBY CERTIFY THAT I HAVE READ AND AM FAMILIAR WITH THE REGULATIONS CONTAINED IN TITLE 50, PART 11, OF THE CODE OF FEDERAL REGULATIONS AND THE OTHER APPLICABLE PARTS IN SUBCHAPTER B OF CHAPTER I OF TITLE 50, AND I FURTHER CERTIFY THAT THE INFORMATION SUBMITTED IN THIS APPLICATION FOR A LICENSE/PERMIT IS COMPLETE AND ACCURATE TO THE BEST OF MY KNOWLEDGE AND BELIEF. I UNDERSTAND THAT ANY FALSE STATEMENT HEREIN MAY SUBJECT ME TO THE CRIMINAL PENALTIES OF 18 U.S.C. 1001.

SIGNATURE (*In Ink*) [signature] DATE 11/15/74

3-200
10-74

Stephen A. M. Jovicich

165 W. MAIN, APT. NO. 1,
HOUSTON, TEX. 77006,
November 15, 1974.

DIRECTOR, BUREAU OF SPORT FISHERIES AND WILDLIFE, *U.S. Department of the Interior, Washington, D.C. 20240.*

DEAR SIR: I am requesting a permit to import two individual St. Lucia parrots (*Amazona versicolor*), one male and one female for the purpose of propagation.

Permission to export these birds has been received from the St. Lucia government, a copy of which was sent to you in Mrs. Nichols' letter of 18 October 1974. The birds will be nestlings taken during the 1975 breeding season. They will be removed from the wild in the manner suggested in Dr. Nichols' letter to Mr. Compton.

These birds will be part of the U.S. phase of the SAFE project for the propagation of endangered Lesser Antillean birds. Provisions must be made in the event that they are not a true pair, male and female, or in case of the death of one of them. If no additional *A. versicolor* can be found in the U.S., the parrots will be sent to Jersey Wildlife Preservation Trust which is responsible for the European phase of this SAFE project.

The birds will be kept in the facilities described to you in Mrs. Nichols' letter of 18 October 1974. Care for these birds will be performed by Mrs. Nichols, her husband, and myself. They have worked with *Amazona guildingii* (from St. Vincent) for several years and are responsible for the first breeding of these birds at the Houston Zoological Gardens. Their other qualifications have been noted in their letters to you. I have worked with parrots for much of my three years at the Houston Zoological Gardens some of this time spent specifically caring for the *A. guildingii* there. Mrs. Nichols and her husband will be responsible for all decisions concerning the care of these parrots and for keeping a studbook for the species. All effort will be made to co-operate with any other owners of *A. versicolor* (who we are seeking at present) in a manner which will best benefit the species.

Once captured on the island the parrots will ride with me to Houston in a stout carrier in the seat next to me, insofar as airline regulations permit. Depending on flight connections the birds and I may lay over on the way back, spending the night in a room of the Miami Airport Hotel. The birds will have seeds available to them inside their compartments at all times except when coming through U.S. Customs, and would be offered water at all transfers between planes, and when lack of air turbulence permits while on the airplane. I will be responsible for seeing that the birds undergo proper U.S. Agriculture quarantine. Once completed the birds will then be kept in the facilities described in the Nichols' letter which I mentioned earlier.

Any parrots which might be raised from these two *A. versicolor* will be the property of Dr. and Mrs. Nichols and will be either:

1) Kept for them to work with,
2) Sent to Jersey Wildlife Preservation Trust,
3) Placed with appropriately qualified co-operating zoos or private aviculturists, or
4) Returned to St. Lucia for the repopulation efforts as Dr. and Mrs. Nichols decide insofar as is allowed by your regulations.

In any event no first generation offspring will be sold.

I stated in my letter of 28 September 1974 that in case of my death the parrots will become the property of Mrs. Nichols or her husband. In case of the death of all three of us or in case Dr. and Mrs. Nichols should not be able to care for the parrots they will have made arrangements that the parrots will either be:

1) Returned to the wild on St. Lucia,
2) Returned to aviculturists in the Lesser Antilles, or
3) Sent to zoos or private aviculturists prepared to care for them, most probably Jersey Wildlife Preservation Trust.

Sincerely.

STEPHEN A. M. JOVICICH.

Documents and other information submitted in connection with this application are available for public inspection during normal business hours at the Service's office in Suite 600, 1612 K Street NW., Washington, D.C.

Interested persons may comment on this application by submitting written data, views, or arguments, preferably in triplicate, to the Director (FWS/LE),

Fish and Wildlife Service, Post Office Box 19183, Washington, D.C. 20036. All relevant comments received within 30 days of the date of publication will be considered.

Dated: March 17, 1975.

C. R. BAVIN,
Chief, Division of Law Enforcement, U.S. Fish and Wildlife Service.

[FR Doc.75-7295 Filed 3-20-75;8:45 am]

ENDANGERED SPECIES PERMIT

Receipt of Application

Notice is hereby given that the following application for a permit is deemed to have been received under section 10 of the Endangered Species Act of 1973 (Pub. L. 93-205).

Applicant: Mr. Gregory Scott Gray, 7710 Valley View Lane, Houston, Texas 77036.

OMB NO. 42-R1670

DEPARTMENT OF THE INTERIOR
U.S. FISH AND WILDLIFE SERVICE

FEDERAL FISH AND WILDLIFE LICENSE/PERMIT APPLICATION

1. APPLICATION FOR (Indicate only one)
☐ IMPORT OR EXPORT LICENSE ☒ PERMIT

2. BRIEF DESCRIPTION OF ACTIVITY FOR WHICH REQUESTED LICENSE OR PERMIT IS NEEDED.
Importation of two Amazona imperialis, Imperial Parrots, an endangered species from Dominica.

3. APPLICANT. (Name, complete address and phone number of individual, business, agency, or institution for which permit is requested)
Gregory Scott Gray
7710 Valley View La.
Houston, Texas 77036
713-7742810

4. IF "APPLICANT" IS AN INDIVIDUAL, COMPLETE THE FOLLOWING:

	HEIGHT	WEIGHT
☒ MR. ☐ MRS. ☐ MISS ☐ MS.	5' 6"	125 lbs.
DATE OF BIRTH: July 6, 1949	COLOR HAIR: Blond.	COLOR EYES: Hazel
PHONE NUMBER WHERE EMPLOYED: 713-222-3195	SOCIAL SECURITY NUMBER: 462-80-9554	

OCCUPATION: Aviculturist-Ornithologist

5. IF "APPLICANT" IS A BUSINESS, CORPORATION, PUBLIC AGENCY, OR INSTITUTION, COMPLETE THE FOLLOWING:
EXPLAIN TYPE OR KIND OF BUSINESS, AGENCY, OR INSTITUTION

ANY BUSINESS, AGENCY, OR INSTITUTIONAL AFFILIATION HAVING TO DO WITH THE WILDLIFE TO BE COVERED BY THIS LICENSE/PERMIT
Save Animals From Extinction is supporting the research and capture of Amazona imperialis.

NAME, TITLE, AND PHONE NUMBER OF PRESIDENT, PRINCIPAL OFFICER, DIRECTOR, ETC.

IF "APPLICANT" IS A CORPORATION, INDICATE STATE IN WHICH INCORPORATED

6. LOCATION WHERE PROPOSED ACTIVITY IS TO BE CONDUCTED
Parrots will be captured on Dominica and imported through Miami, Fla.

7. DO YOU HOLD ANY CURRENTLY VALID FEDERAL FISH AND WILDLIFE LICENSE OR PERMIT? ☐ YES ☒ NO
(If yes, list license or permit numbers)

8. IF REQUIRED BY ANY STATE OR FOREIGN GOVERNMENT, DO YOU HAVE THEIR APPROVAL TO CONDUCT THE ACTIVITY YOU PROPOSE? ☒ YES ☐ NO
(If yes, list jurisdictions and type of documents)
Export permit will be issued by Dominica. (see enclosed copy)

9. CERTIFIED CHECK OR MONEY ORDER (If applicable) PAYABLE TO THE U.S. FISH AND WILDLIFE SERVICE ENCLOSED IN AMOUNT OF: $ 50.00

10. DESIRED EFFECTIVE DATE: 1 July 1975

11. DURATION NEEDED: 2 months

12. ATTACHMENTS. THE SPECIFIC INFORMATION REQUIRED FOR THE TYPE OF LICENSE/PERMIT REQUESTED (See 50 CFR 13.12(b)) MUST BE ATTACHED, IT CONSTITUTES AN INTEGRAL PART OF THIS APPLICATION. LIST SECTIONS OF 50 CFR UNDER WHICH ATTACHMENTS ARE PROVIDED.
50 CFR 17.23 (a7) 50 CFR 17.11

CERTIFICATION

I HEREBY CERTIFY THAT I HAVE READ AND AM FAMILIAR WITH THE REGULATIONS CONTAINED IN TITLE 50, PART 13, OF THE CODE OF FEDERAL REGULATIONS AND THE OTHER APPLICABLE PARTS IN SUBCHAPTER B OF CHAPTER I OF TITLE 50, AND I FURTHER CERTIFY THAT THE INFORMATION SUBMITTED IN THIS APPLICATION FOR A LICENSE/PERMIT IS COMPLETE AND ACCURATE TO THE BEST OF MY KNOWLEDGE AND BELIEF. I UNDERSTAND THAT ANY FALSE STATEMENT HEREIN MAY SUBJECT ME TO THE CRIMINAL PENALTIES OF 18 U.S.C. 1001.

SIGNATURE (In ink): Gregory D. Gray — DATE: 4 January 1975

3-200 (6/74) Gregory S. Gray

INT-41780-74

7710 VALLEY VIEW LANE,
HOUSTON, TEX. 77036.
November 7, 1974.

DIRECTOR, BUREAU OF SPORT FISHERIES AND WILDLIFE, U.S. DEPARTMENT OF THE INTERIOR, WASHINGTON, D.C. 20240.

DEAR SIR: I request permission to import two individuals of an endangered species, *Amazona imperialis* of Dominica, for purposes of propagation.

I have read Pub. L. 93-205, 50 CFR Part 10, 50 CFR Part 13, 50 CFR 17, and Prohibitions and Permits under the Endangered Species Act of 1973 and believe that all information required for a permit has already been sent to you by Holly A. J. Nichols or will be contained in this letter.

I have been a Keeper at the Bird Department of the Houston Zoological Gardens for three years. Much of this time has been spent working with parrots.

Next spring and summer I will be on Dominica for three to four months studying the ecology of *Amazona imperialis* and *Amazona arausiaca* as a participant in the SAFE project on the Lesser Antillean amazons under the direction of Holly A. J. Nichols. I believe that on Monday, 23 September Mrs. Nichols personally gave Mr. Earl B. Baysinger some information in the form of a letter dated 23 September, about this project and my request. I believe most of the questions about my application should be answered in Mrs. Nichols' letter and the supporting material she included with her letter, of which I have copies and believe is accurate.

The parrots would be taken from the wild in the manner mentioned in Dr. Nichols' letter to the Chief Forestry Officer of Dominica, a copy of which was included with Mrs. Nichols' letter of 23 September. They would ride back to Houston with me, caged in a stout wood and wire carrier which I will have a Dominican carpenter construct. In so far as airline regulations permit they would ride in the cabin in their own seat next to me. Depending on flight connections the birds and I might lay over on the way back, spending the night in a room of the Miami Airport Hotel. The birds would have seeds available to them inside their compartments at all times except when coming through U.S. Customs, and would be offered water at all transfers between planes and when lack of air turbulence permits while on the planes.

I will be responsible for seeing that the birds undergo proper U.S. Agriculture and HEW quarantine. Upon completion of quarantine I will keep the parrots in the facilities previously described to you by Mrs. Nichols. She and her husband will be responsible for all decisions concerning the care of these parrots. She will be responsible for keeping a studbook for the species and cooperating with other owners of *A. imperialis* in a manner which will be best for the species.

In case of my death the parrots will become the property of Mrs. Nichols and her husband. In case of the death of all three of us or in case Dr. and Mrs. Nichols should not be able to care for the parrots, they will have made arrangements that the parrots will be either

1. Returned to the wild on Dominica,
2. Sent to aviculturists in the Lesser Antilles, or
3. Sent to zoos or private aviculturists prepared to care for them, most probably Jersey Wildlife Preservation Trust.

Any parrots which might be raised from these *A. imperialis* will be the property of Dr. and Mrs. Nichols and will be either

1. Kept for them to work with.
2. Sent to Jersey Wildlife Preservation Trust.
3. Placed with appropriately qualified cooperating zoos or private aviculturists, or
4. Returned to St. Lucia for repopulation efforts, as Dr. and Mrs. Nichols decide in so far as is allowed by your regulations. In any case no first generation offspring will be sold.

I am 65 inches tall, weigh 125 lb., have blonde hair and hazel irises.

I believe all other information has been sent to you by Mrs. Nichols.

As she indicated I may return with two *Amazona arausiaca* instead of two *A. imperialis*. I believe that *A. arausiaca* is not now regulated as an endangered species by USDI. In any case I will be returning with the birds in July or August 1975.

I hereby certify that I have read and am familiar with the regulations contained in Title 50, Part 13, of the Code of Federal Regulations and the other applicable parts in Sub-chapter B of Chapter I of Title 50, and I further certify that the information submitted in this application for a permit is complete and accurate to the best of my knowledge and belief. I understand that any

false statement hereon may subject me to the criminal penalties of 18 U.S.C. 1001.

Sincerely,

GREGORY SCOTT GRAY.

Documents and other information submitted in connection with this application are available for public inspection during normal business hours at the Service's office in Suite 600, 1612 K Street NW., Washington, D.C.

Interested persons may comment on this application by submitting written data, views, or arguments, preferably in triplicate, to the Director (FWS/LE), Fish and Wildlife Service, Post Office Box 19183, Washington, D.C. 20036. All relevant comments received on or before April 21, 1975 will be considered.

Dated: March 17, 1975.

C. R. BAVIN,
Chief, Division of Law Enforcement, U.S. Fish and Wildlife Service.

[FR Doc.75-7296 Filed 3-20-75;8:45 am]

Office of Hearings and Appeals

[Docket No. M 75-58]

DUQUESNE LIGHT CO.

Amendment to Petition for Modification of Application of Mandatory Safety Standard[1]

Notice is hereby given that in accordance with the provisions of section 301 (c) of the Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. 861(c) (1970), Duquesne Light Company has filed an amended petition to modify the application of 30 CFR 75.1405 to its Warwick Mine, Portal No. 3, Greensboro, Pennsylvania.

30 CFR 75.1405 provides:

All haulage equipment acquired by an operator of a coal mine on or after March 30, 1971, shall be equipped with automatic couplers which couple by impact and uncouple without the necessity of persons going between the ends of such equipment. All haulage equipment without automatic couplers in use in a mine on March 30, 1970, shall also be so equipped within 4 years after March 30, 1970.

To be read concurrently with § 75.1405 is 30 CFR 75.1405-1 which provides:

The requirement of § 75.1405 with respect to automatic couplers applies only to track haulage cars which are regularly coupled and uncoupled.

Petitioner amends its original petition as follows:

In lieu of automatic couplers, Petitioner proposes to install on the present link-and-pin couplings, mechanical guiding devices, so that the link can be remotely guided into position in case of misalignment and also a mechanical device so that the pin can be remotely engaged and disengaged. By the use of these mechanical devices, the cars can be coupled or uncoupled and the link aligned without having a worker go in between the cars. This system will thus eliminate the hazards of automatic couplers and still provide a means whereby a worker does not have to go in between cars while coupling or uncoupling or aligning the link.

Persons interested in this petition may request a hearing on the petition or furnish comments on or before April 21, 1975. Such requests or comments must be filed with the Office of Hearings and Appeals, Hearings Division, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

JAMES R. RICHARDS,
Director,
Office of Hearings and Appeals.

MARCH 14, 1975.

[FR Doc.75-7432 Filed 3-20-75;8:45 am]

[Docket No. M 75-87]

LITTLE "T" COAL, INC.

Petition for Modification of Application of Mandatory Safety Standard

Notice is hereby given that in accordance with the provisions of section 301(c) of the Federal Coal Mine Health and Safety Act of 1969, 30 U.S.C. 861(c) (1970), Little "T" Coal, Inc. has filed a petition to modify the application of 30 CFR 77.1605(k) to its Mine #1, Ten Mile, Tennessee.

30 CFR 77.1605(k) provides:

Berms or guards shall be provided on the outer bank of elevated roadways.

In support of its petition, Petitioner states:

Petitioner feels that the installation of either guardrails or berms would have the effect of lessening the safe condition of its haulage road for the following reasons:

1. Berms and, to a certain extent, guardrails, would create a drainage hazard. It would be impossible to maintain proper drainage, and wash-outs and hazardous conditions would result in wet weather.

2. Berms and guardrails would hamper snow removal and would cause the road to ice over during winter months.

3. The grader now used for road maintenance could no longer be used.

4. Additional man-hours and equipment would be needed for road maintenance, particularly during the winter months. This, in itself, would result in increased accident potential during snow or ice conditions.

5. The haulage road is of insufficient width to build berms. Solid rock would have to be blasted, and the resulting highwall along the road would present a new hazard.

6. Guardrails would have to be installed on fill material which would not provide sufficient anchorage.

7. Fully 75 percent of haulage time is spent on county and state roads which are no safer than Petitioner's haulage road.

Petitioner proposes to implement the following alternate method:

1. Signs and traffic controls will be installed as follows:

a. Where the road is more than 20 feet wide passing zones will be established.

b. Where the road is less than 20 feet wide it will be marked for one-lane traffic.

c. Signs will be posted stating that loaded trucks have the right-of-way.

d. Stop signs will be placed where needed.

e. Other traffic control measures will be implemented as needed.

2. Petitioner's contract haulers will be notified that they are responsible for seeing that all drivers are instructed on the rules of the road. Contractors will see to it that all trucks are equipped with the necessary safety features and are inspected and maintained as required.

Inasmuch as the subject road was in existence before Petitioner put in its mines, Petitioner feels that the above course of action is a feasible alternative to the requirements of this § 77.1605(k). Petitioner also believes that its alternate method will afford the miners at the subject mine no less than the same measure of protection as the application of the mandatory standard.

Persons interested in this petition may request a hearing on the petition or furnish comments on or before April 21, 1975. Such requests or comments must be filed with the Office of Hearings and Appeals, Hearings Division, U.S. Department of the Interior, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

JAMES R. RICHARDS,
Director,
Office of Hearings and Appeals.

MARCH 14, 1975.

[FR Doc.75-7433 Filed 3-20-75;8:45 am]

Geological Survey

[Power Site Cancellation 331]

COLUMBIA RIVER BASIN, WASHINGTON

Power Site Cancellation

Pursuant to authority under the Act of March 3, 1879 (20 Stat. 394; 43 U.S.C. 31), and 220 Departmental Manual 6.1, Power Site Classification 349 of June 22, 1944 is hereby cancelled to the extent that it affects the following described land:

WILLAMETTE MERIDIAN, WASHINGTON

T. 30 N., R. 24 E.,
Sec. 21, lot 5.

The area described aggregates 4.30 acres.

The effective date of this cancellation is July 14, 1975.

Dated: March 13, 1975.

HENRY W. COULTER,
Acting Director.

[FR Doc.75-7431 Filed 3-20-75;8:45 am]

[1] The original petition was published in 39 FR 42699 on December 6, 1974.

National Park Service

GOLDEN GATE NATIONAL RECREATION AREA ADVISORY COMMISSION

Relocation of Meeting

The location of the meeting of the Golden Gate National Recreation Area Advisory Commission scheduled for April 8 to be held at the Fort Mason Officer's Club, the notice of which was previously published on page 11921 in the FEDERAL REGISTER on Friday, March 14, 1975 (40 FR 11921) has been changed to 6th Army Conference Room, Building 35, Mesa Street, Presidio of San Francisco, at 7:30 p.m.

Dated: March 18, 1975.

ROBERT M. LANDAU,
Deputy Associate Director, Legislation.

[FR Doc.75-7443 Filed 3-20-75;8:45 am]

Office of the Secretary

[INT DES 75-13]

SHERWOOD URANIUM PROJECT ON THE SPOKANE INDIAN RESERVATION

Availability of Draft Environmental Statement

Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared an environmental impact statement for approval of a lease between the Spokane Tribe of Indians and Western Nuclear Inc. The environmental impacts of developing a uranium mine and processing facilities on 580 acres of the Spokane Indian Reservation near Wellpinit, Washington are presented.

Written comments are invited before May 5, 1975. Copies are available for inspection at the following locations:

Bureau of Indian Affairs
Environmental Quality Services
Room 3429, Department of Interior Bldg.
Washington, D.C. 20245
Telephone (202) 343-2139

Bureau of Indian Affairs
Portland Area Office
Room 409 Loyd Plaza
1425 Irving Street, NE.
Portland, Oregon 97208
Telephone (503) 234-3361 Ext. 4257

Bureau of Indian Affairs
Spokane Indian Agency
Wellpinit, Washington 99040
Telephone (509) 258-4466

Copies of the draft statement may be obtained without cost from the Portland Area Office, Bureau of Indian Affairs, Room 409 Loyd Plaza, 1425 Irving Street NE., Portland, Oregon 97208.

Dated: March 17, 1975.

STANLEY D. DOREMUS,
Deputy Assistant Secretary of the Interior.

[FR Doc.75-7263 Filed 3-20-75;8:45 am]

DEPARTMENT OF COMMERCE

Domestic and International Business Administration

ELECTRONIC INSTRUMENTATION TECHNICAL ADVISORY COMMITTEE

Partially Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I (Supp. III, 1973), notice is hereby given that a meeting of the Electronic Instrumentation Technical Advisory Committee will be held on Tuesday, May 6, 1975, Room 3708, 9:30 a.m., Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C.

The Committee was established on October 23, 1973 to advise the Office of Export Administration, Bureau of East-West Trade, with respect to questions involving technical matters, world-wide availability and actual utilization of production and technology, and licensing procedures which may affect the level of export controls applicable to electronic instrumentation, including technical data related thereto, and including those whose export is subject to multilateral (COCOM) controls.

The Committee meeting agenda has five parts:

GENERAL SESSION

(1) Opening remarks by the Chairman.
(2) Presentation of papers or comments by the public.
(3) Review of application of microprocessors to instrumentation.
(4) Review of digital filter and time compression techniques.

EXECUTIVE SESSION

(5) Discussion of matters properly classified under Executive Order 11652, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The public will be permitted to attend the General Session, at which a limited number of seats will be available to the public. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (5), the Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 16, 1974, pursuant to section 10(d) of the Federal Advisory Committee Act that the matters to be discussed in the Executive Session should be exempt from the provisions of the Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552(b)(1), i.e., it is specifically required by Executive Order 11652 that they be kept confidential in the interest of the national security. All matters have been properly classified under the Executive Order. All Committee members have appropriate security clearances.

Minutes of the open portion of the meeting will be available upon written request addressed to the Central Reference and Records Inspection Facility, Room 7043, U.S. Department of Commerce.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Domestic and International Business Administration, Room 1620, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202/967-4196.

In accordance with paragraph (4) of the Order of the United States District Court for the District of Columbia in *Aviation Consumer Action Project, et al., v. C. Langhorne Washburn, et al.*, September 10, 1974, as amended, September 23, 1974 (Civil Action No. 1838-73), the Complete Notice of Determination to close portions of the series of meetings of the Electronic Instrumentation Technical Advisory Committee and of any subcommittees thereof, was published in the FEDERAL REGISTER (40 FR 5547, appearing in the issue of February 6, 1975).

Dated: March 13, 1975.

RAUER H. MEYER,
Director, Office of Export Administration, Bureau of East-West Trade, U.S. Department of Commerce.

[FR Doc.75-7406 Filed 3-20-75;8:45 am]

MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE, ET AL.

Applications for Duty-Free Entry of Scientific Articles

Correction

In FR Doc. 75-6266 appearing at page 11376 in the issue of Tuesday, March 11, 1975 the following correction should be made: In the first column, the third full paragraph, the first line should read "Docket number: 75-00355-33-19095".

National Oceanic and Atmospheric Administration

COASTAL ZONE MANAGEMENT

Notice of Public Hearing on Draft Environmental Impact Statement

Notice is hereby given that the Office of Coastal Zone Management, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, will hold a public hearing for the purpose of receiving comments on the draft environmental impact statement pertaining to the coastal zone management program of the State of Washington which has been submitted to the Secretary of Commerce for approval

under the Coastal Zone Management Act of 1972, as amended. The hearing will be held in the Nisqually Room, Seattle Center, 305 Harrison, Seattle, Washington 98109, between the hours of 7 p.m. and midnight, on April 22, 1975. The views of members of the public and interested organizations are invited. Both written and oral statements will be accepted. Presentations will be scheduled on a first-come, first-served basis; but priority will be given to those who have prepared statements. Time will be alloted at the end of the meeting for those without statements who wish to be heard. In order that the maximum opportunity be afforded all those who wish to be heard, presentations may be limited to a maximum of ten minutes or as otherwise appropriate. No audio-visual equipment will be available. Office of Coastal Zone Management staff may wish to question speakers.

Persons or organizations wishing to be heard on this matter should contact the Office of Coastal Zone Management as soon as possible in order that an appearance schedule may be drawn up and definite times established for presentations. The address is: Office of Coastal Zone Management, National Oceanic and Atmospheric Administration, Rockville, Maryland 20852, 301/496-8896.

Written comments may also be submitted by mail to the Office of Coastal Zone Management. Such written comments must be received before May 5, 1975, in order to be considered for inclusion in the final environmental impact statement.

Copies of the draft environmental impact statement may be obtained from the Office of Coastal Zone Management, and copies of the statement as well as of the Washington coastal zone management program, with supporting documents, are also available for inspection by the public at the following locations:

CLALLAM COUNTY

North Olympic Library System, 2210 S. Peabody Street, Port Angeles 98362, 206/457-4464—James H. Kirks, Jr.

GRAYS HARBOR

Aberdeen Timberland Library, 121 E. Market Street, Aberdeen 98520, 206/533-2360—Rosalie Spellman.

ISLAND COUNTY

Snow Isle Regional Library, P.O. Box 148, Marysville 98270, 206/259-8177—Mae L. Schoenrock.

JEFFERSON COUNTY

Port Townsend Public Library, 1228 Lawrence Street, Port Townsend 98368, 206/385-3181—Madge M. Wallin.

KING COUNTY

King County Library System, 300 8th Ave., North, Seattle 98109, 206/344-7465—Herbert F. Mutschler.

KITSAP COUNTY

Kitsap Regional Library, 612 5th Street, Bremerton 98310, 206/377-3955—Irene Heninger.

MASON COUNTY

Timberland South Mason Library, Rt. 5, Box 35, Shelton 98584—Doris Whitmarsch.

PACIFIC COUNTY

Raymond Public Library, 507 Duryea, Raymond 98577, 206/942-2403—Jay Windisch.

PIERCE COUNTY

Pierce County Library, 2356 Tacoma Ave., S., Tacoma 98402, 206/572-6760—Carolyn J. Else.

SAN JUAN COUNTY

Eastsound (Moyers) Library, Orcas Island, P.O. Box 165, Eastsound 98245—Polly Klauder.

SKAGIT COUNTY

Anacortes Public Library, 1209 9th Street, Anacortes 98221, 206/293-2700—G. Douglas Everhart.

SNOHOMISH CO.

See Island Co.

THURSTON CO.

Olympia Public Library, 7th and Franklin, Olympia 98501, 206/352-0595—Margaret Coopinger.

WAHKIAKUM CO.

Cathlamet Public Library, P.O. Box 337, Cathlamet 98612, 206/795-3254—Eleanor A. Taylor.

WHATCOM CO.

Whatcom County Library, 5205 N.W. Road, Bellingham 98225, 206/733-1250—Linda Hellyer.

THE WASHINGTON DEPARTMENT OF ECOLOGY

Olympia, Washington 98504, 206/753-2800—Rodney Mack.

and

DEPARTMENT OF COMMERCE

Main Commerce Building, 14th & Constitution, NW., Room 7046, Washington, D.C. 20230.

Comments should address the adequacy of the draft environmental impact statement as well as the desirability of the proposed program.

No verbatim transcript of the hearing will be maintained, but staff present will record the general thrust of remarks.

Following consideration of the comments received at this hearing, as well as written comments submitted to the Office of Coastal Zone Management, the Office of Coastal Zone Management will prepare the final environmental impact statement pursuant to the National Environmental Policy Act of 1969 and implementing CEQ guidelines.

R. H. HAGEMEYER,
Acting Assistant Administrator for Administration.

[FR Doc.75-7491 Filed 3-20-75;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control

COAL MINE DUST PERSONAL SAMPLER UNITS

Notice of Hearing To Revoke Certificates of Approval of Bendix Corporation Units

Section 202(a) of the Federal Coal Mine Health and Safety Act of 1969 (30 U.S.C. 842(a)) provides that accurate samples of respirable dust in coal mine atmospheres shall be taken and that such samples shall be taken by a device approved by both the Secretary of the Interior and the Secretary of Health, Education, and Welfare. In 1970, the Secretaries jointly adopted the regulations in Part 74 of Title 30, Code of Federal Regulations which set forth the requirements for approval of coal mine dust personal sampler units and the procedures for applying for such approval (35 FR 4327). The regulations provide for the issuance of a certificate of approval to applicants whose sampler units meet the prescribed tests and specifications. The testing and approval program is administered by the Secretary of the Interior, through the Mining Enforcement and Safety Administration (MESA) and by the Secretary of Health, Education, and Welfare, through the National Institute for Occupational Safety and Health (NIOSH).

Pursuant to 30 CFR 74.7, NIOSH has issued certificates of approval to the Bendix Corporation under approval numbers TC-74-012, TC-74-016, and TC-74-017 for Bendix coal mine dust personal sampler units. 30 CFR 74.11 provides that a certificate of approval for a coal mine dust personal sampler unit issued under Part 74 may be revoked for cause by NIOSH.

Research conducted by MESA has revealed that with the passage of time and when the cassettes are subjected to increased temperatures, a weight loss occurs in the cassettes used in the Bendix Corporation approved sampler units. Therefore, the units do not comply with the requirements of Part 74 and determinations of compliance based on dust samples collected with the Bendix units using such cassettes are unreliable.

Notice is hereby given that a public hearing will begin at 9:30 a.m. on April 1, 1975, in Conference Room F of the Department of Health, Education, and Welfare's Parklawn Building, 5600 Fishers Lane, Rockville, Maryland for the purpose of receiving relevant evidence concerning whether the certificates of approval issued for the Bendix Corporation personal sampler units should be revoked.

Dr. Elliott Harris, Director of the Division of Laboratories and Criteria Development, NIOSH, is designated as Chairman of the hearing, which will be conducted in an informal manner in accordance with the following procedures:

Appropriate representatives of NIOSH and MESA will present their evidence as to why the Bendix Corporation certificates of approval should be revoked. The Chairman and Bendix Corporation will be able to question those representatives. Bendix Corporation will then have an opportunity to make its presentation and to respond to questions from the Chairman, and from representatives of NIOSH and MESA. Parties making presentations will be given the opportunity to make supplementary statements which may include comments on or rebuttal of other persons' views and an opportunity to make recommendations concerning the issues in any of the statements. Any party may appear in person or by counsel. Copies of the technical data which

serve as the basis for this hearing may be examined at, or obtained from NIOSH, 5600 Fishers Lane, Rockville, Maryland 20852.

A verbatim record of the proceedings of the hearing session will be maintained. All relevant written statements, charts, tabulations and other data will be received in the record. The Chairman will submit to the Director, NIOSH, the transcript of the hearing and all material submitted for the record together with his recommendations on the issues. Thereafter, the Director, NIOSH, will make a decision in writing concerning the Bendix Corporation certificates of approval at issue and announce such decision.

Dated: March 17, 1975.

EDWARD J. BAIER,
Acting Director, National Institute for Occupational Safety and Health.

[FR Doc.75-7380 Filed 3-20-75;8:45 am]

Food and Drug Administration

[FDA-225-75-4026]

ARTX TELECOMMUNICATION EQUIPMENT

Memorandum of Understanding With the Virginia Department of Agriculture and Commerce

Pursuant to the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697), stating that future memoranda of understanding between the Food and Drug Administration and others would be published in the FEDERAL REGISTER, the Commissioner of Food and Drugs issues the following notice:

The Food and Drug Administration executed a Memorandum of Understanding with the Virginia Department of Agriculture and Commerce on January 27, 1975. The purpose of the memorandum is to establish the procedures and guidelines for the operation, maintenance, and protection of FDA-rented ARTX Telecommunication Equipment. It reads as follows:

MEMORANDUM OF UNDERSTANDING BETWEEN THE VIRGINIA DEPARTMENT OF AGRICULTURE AND COMMERCE AND THE FOOD AND DRUG ADMINISTRATION

I. *Purpose.* To establish the procedures and guidelines for the operation, maintenance and protection of FDA-rented ARTX Telecommunication Equipment located in the Division of Product & Industry Regulations, P.O. Box 1163, Richmond, Virginia.

II. *Background.* The FDA, Assistant Secretary for Health, Department of HEW, and the General Services Administration have approved a program to install full telecommunication transmit and receive terminals in a number of prime state food and drug agencies. Although terminals will be placed in a number of prime food and drug regulatory agencies, there are a number of other agencies with food and drug responsibilities in each state, where no terminal will be installed. Therefore, your agency, being one that received a terminal, must agree to share the terminal with other food and drug agencies in your state to assure that the communication system is accessible to all agencies with food and drug related responsibilities.

In addition to terminal-sharing, it is necessary for our two agencies to assure that proper operation and necessary supporting requirements for the equipment is maintained and proper security is provided for the equipment.

III. *Substance of Agreement.* A. The Food and Drug Administration agrees:

1. To arrange for the installation of the equipment in the location designated by your agency.
2. To support financially the cost of initial installation of the equipment and pay directly to GSA and Western Union the monthly rental cost. After the initial installation, the state will be responsible for relocation installation cost, unless relocation is in conjunction with a major move of the terminal agency to a new location address.
3. To identify for you those units in your state on which terminal-sharing must be accomplished.
4. To require that the terminal location agency (your agency) submit to FDA a terminal-sharing plan to be developed by you and other sharing units in your state.
5. To arrange through Western Union for training of terminal operators.
6. To provide operation instruction manual.
7. To withdraw financial support for the terminal if gross misuse of the terminal is practiced after due notice.

B. The State Terminal Agency agrees:

1. To provide suitable physical location for equipment with adequate security protection.
2. To provide and pay for electric power source to operate the terminal. (110 volts)
3. To provide for paper, tape and other material necessary for the operation of the equipment.
4. To share the terminal with other food and drug agencies in the state according to a terminal-sharing plan agreed to by each potential user.
5. To submit to the FDA Regional Office monthly traffic log. (Form to be furnished by FDA)
6. To submit promptly all messages received for addressees other than your agencies. Transmit promptly messages to FDA received from other appropriate agencies.
7. Maintain operator coverage for the terminal between normal working hours of your agency.
8. Notify vendor (Western Union) of any breakdown of the equipment or other needs for maintenance.
9. Notify FDA (Regional or Headquarters) of periods that the equipment is out-of-service.
10. That the system will be used only for communication between your state and FDA (Regional, District, or Headquarters Office). It is understood that the equipment is not to be used for communication between state agencies.

IV. *Name and Address of Terminal Agency.* Virginia Department of Agriculture & Commerce, Division of Product & Industry Regulation, P.O. Box 1163, Richmond, Virginia 23209.

V. *Liaison Officers.* For Virginia Department of Agriculture and Commerce: Ray E. Vanhuss, Jr., Supr., Food Inspection.

Address: Same as agency.
Telephone No.: (804) 770-3520.

For FDA: J. Donald Sherry, Director, Investigations Branch.

Address: Baltimore District FDA, 900 Madison Avenue, Baltimore, Md. 21201.
Telephone No.: (301) 962-4099.

VI. *Period of Agreement.* This agreement, when accepted by both parties, will have an effective period of performance three (3) years from date of signature and may be modified by mutual consent by both parties or may be terminated by either party upon a thirty (30) day advance written notice to the other.

Approved and accepted for the Virginia Department of Agriculture and Commerce:

Dated: January 27, 1975.

S. MASON CARBAUGH,
Commissioner.

Approved and accepted for the Food and Drug Administration:

Dated: January 21, 1975.

T. C. MARAVIGLIA,
Regional Food and Drug Director, Region III.

Effective date. This Memorandum of Understanding became effective January 27, 1975.

Dated: March 17, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7389 Filed 3-20-75;8:45 am]

[DESI 11792]

CARISOPRODOL IN COMBINATION WITH PHENACETIN AND CAFFEINE

Drugs for Human Use; Drug Efficacy Study Implementation; Follow-Up Notice

A notice (DESI 11792) was published in the FEDERAL REGISTER of September 1, 1970 (35 FR 13854), pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, in which the Commissioner of Food and Drugs announced his conclusion that the combination drug product described below is possibly effective and lacking substantial evidence of effectiveness for its various labeled indications. The product has been used in the treatment of conditions related to muscle pain and stiffness. On the basis of new evidence and reevaluation of previous information, such products are now regarded as less-than-effective (probably effective) for certain uses. This notice announces that conclusion.

Other products included in the notice of September 1, 1970 are not affected by this notice, having been previously dealt with. The single active ingredient products containing carisoprodol have been reevaluated as effective (39 FR 29399; August 15, 1974). The combination product containing carisoprodol, phenacetin, caffeine, and codeine phosphate was the subject of a proposal to withdraw approval of the new drug application (39 FR 23292; June 27, 1974) and a request for hearing is under review. Other "skeletal muscle relaxant"—analgesic combinations have previously been upgraded to less-than-effective (probably effective) and those reevaluations were published in the FEDERAL REGISTER on August 14, 1974 (39 FR 29210 for chlorzoxazone

with acetaminophen and 39 FR 29211 for methocarbamol with aspirin).

Soma Compound Tablets, containing carisoprodol 200 mg., phenacetin 160 mg., and caffeine 32 mg.; Wallace Pharmaceuticals, Division of Carter-Wallace, Inc., Half Acre Road, Cranbury, NY 08512 (NDA 12-365).

Combination products containing a so-called "skeletal muscle relaxant" and an analgestic were initially concluded to be either possibly effective or lacking substantial evidence of effectiveness, pursuant to the National Academy of Sciences-National Research Council, Drug Efficacy Study Group reviews. The Commissioner has determined that these combinations should be regarded as less-than-effective (probably effective) for the following reasons:

1. The NAS/NRC had serious doubts concerning the effectiveness of the "skeletal muscle relaxant" component of such combinations, and made it clear that these doubts were a major reason for the rating of the combinations as ineffective or possibly effective. Thus, the Panel on Neurological Drugs stated for Soma Compound:

> The Panel has evaluated Soma as "Possibly effective" as a peripheral muscle relaxant, with the statement that present studies are inconclusive and the suggestion that further studies be done. In view of this, the Panel feels it is not justifiable to add other ingredients to these preparations until the major product is proved efficacious.

The Commissioner has concluded that new evidence in the form of adequate and well-controlled studies has demonstrated that the so-called "skeletal muscle relaxants" are effective in the treatment of discomfort associated with acute, painful musculo-skeletal conditions.

This new finding has significant impact on the reasoning underlying the Panel's rating since it is rational and justifiable to add together two effective ingredients that act through different mechanisms to relieve musculo-skeletal pain and to carry out studies to determine whether such a combination is effective as a fixed combination. It now appears entirely possible that the analgesic-skeletal muscle relaxant combinations, if investigated appropriately, can be demonstrated to be effective and to meet the requirements of the combination drug policy (21 CFR 3.86).

2. The studies of these combinations completed to date have shown, in some cases, a trend in favor of the combination as compared with its components, but in no case has the trend reached the usual requirements for statistical significance.

The Commissioner finds that the clinical investigational techniques for the study of the drug class have been difficult to develop and that, despite extensive efforts, methods for measuring relevant therapeutic effects remain imperfect. In these circumstances, the failure at this point to observe statistically significant differences between the combinations and their components should not be considered strong evidence against the combination.

It should be emphasized that the present upgrading of these combinations to probably effective does not represent any conclusion that they are in fact in compliance with § 3.86, nor any commitment to promulgation of an effective rating in the future in the absence of the usual substantial evidence of effectiveness. The present action simply reflects the new evidence that the so-called "skeletal muscle relaxants" are effective and the increased possibility that the combinations can be shown to be effective.

Accordingly, with respect to Soma Compound Tablets, the revised conclusions concerning the drug are as described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that the combination carisoprodol with phenacetin and caffeine is less-than-effective (probably effective) as described below.

B. *Labeling conditions.* Labeling revised pursuant to this notice should furnish adequate information for safe and effective use of the drug and recommend use of the drug for the following less-than-effective (probably effective) indication: As an adjunct to rest and physical therapy for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of carisoprodol has not been clearly identified, but may be related to its sedative properties. Carisoprodol does not directly relax tense skeletal muscles in man.

C. *Submission of data.* Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) and described in 21 CFR 314.111 (a) (5) and 21 CFR 3.86. Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice applies to all persons who manufacture or distribute a drug product, not the subject of an approved new drug application, which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

Communications forwarded in response to this notice should be identified with the reference number DESI 11792, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Supplements (identify with NDA number): Documents and Records Section (HFD-100), Bureau of Drugs.

Original new drug applications: Documents and Records Section (HFD-100), Bureau of Drugs.

Requests for the Academy's report: Data Preparation Branch (HFD-614), Division of Drug Information Resources, Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Manager (HFD-101), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: March 17, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7386 Filed 3-20-75;8:45 am]

[DESI 6762; Docket No. FDC-D-625; NDA No. 7-696 etc.]

CERTAIN TOPICAL PREPARATIONS FOR OPHTHALMIC OR OTIC USE

Withdrawal of Approval of New Drug Applications

A notice of opportunity for hearing (DESI 6762) was published in the FEDERAL REGISTER of September 11, 1974 (39 FR 32771), pursuant to the evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, in which the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of the new drug applications for certain preparations for use in the eye or ear. The basis of the proposed action was the lack of substantial evidence that the products are effective for their labeled indications. Since no one contested the proposal, approval of the following new drug applications is now being withdrawn.

1. Otodyne otic solution containing zolamine hydrochloride and euprocin hydrochloride; Schering Corporation, Galloping Hill Rd., Kenilworth, NJ 07033 (NDA 7-696).

2. Metreton ophthalmic suspension containing prednisolone acetate and chlorpheniramine gluconate; Schering Corporation (NDA 10-695).

3. Prednefrin 0.12 percent ophthalmic suspension containing prednisolone acetate, phenylephrine hydrochloride and antipyrine; Allergan Pharmaceuticals, Inc., 2525 DuPont Drive, P.O. Box DP, Irvine, CA 92664 (NDA 10-696).

4. Prednefrin-S 0.2 percent ophthalmic solution containing prednisolone and

phenylephrine hydrochloride; Allergan Pharmaceuticals, Inc. (NDA 11-693).

5. Prednefrin Forte 1 percent ophthalmic suspension containing prednisolone acetate, phenylephrine hydrochloride and antipyrine; Allergan Pharmaceuticals, Inc. (NDA 12-107).

The above notice also included Op-Predrin Opthalmic Solution (NDA 11-530) containing prednisolone and phenylephrine hydrochloride, previously marketed by Broemmel Pharmaceuticals, 1235 Sutter Street, San Francisco, CA 94109. As stated in the notice, approval of that NDA had previously been withdrawn on the ground of failure to submit required reports under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). The purpose of including Op-Predrin in the notice of September 11, 1974 was to state the conclusion that this drug lacks substantial evidence of effectiveness for its various labeled indications and to offer all interested persons the opportunity to request a hearing concerning all issues relating to the legal status of all identical, related, or similar drugs.

All drug products which are identical, related, or similar to any of the drugs named above, not the subject of an approved new drug application, are covered by the new drug applications reviewed and are subject to this notice (21 CFR 310.6). Any person who wishes to determine whether a specific product is covered by this notice should write the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

Neither the holders of the applications nor any other person filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and under authority delegated to him (21 CFR 2.121), finds that on the basis of new information before him with respect to the drug products, evaluated together with the evidence available to him when the applications were approved, there is a lack of substantial evidence that the above listed drug products will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, pursuant to the foregoing finding, approval of the new drug applications (or if indicated above, those parts of the applications providing for the drug products listed) and all amendments and supplements thereto, is withdrawn effective March 31, 1975.

Shipment in interstate commerce of the above products for which approval has been or is being withdrawn, or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful.

Dated: March 11, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75-7383 Filed 3-20-75;8:45 am]

[DESI 9397; Docket No. FDC-D-716; NDA 9-408]

MEPHENTERMINE SULFATE FOR ORAL USE

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

The National Academy of Sciences-National Research Council, Drug Efficacy Study Group evaluated the effectiveness of the drug products described below, found the drugs to be less than effective, and submitted its reports to the Commissioner of Food and Drugs. Copies of those reports have previously been made publicly available and are on display at the office of the Food and Drug Administration's Hearing Clerk. After reviewing the Academy's reports and the available data and information, the Commissioner concluded that the drugs were less than effective and published his conclusions in the FEDERAL REGISTER of May 22, 1971 (36 FR 9343) that the drugs are probably and possibly effective and lacking substantial evidence of effectiveness. These products have been used for treating certain types of low blood pressure. No data having been submitted in support of effectiveness, this notice proposes to withdraw approval of the tablet form of the drug. Approval of the elixir form of the drug has previously been withdrawn. Persons wishing to request a hearing must do so by April 21, 1975.

1. Wyamine Sulfate Tablets containing mephentermine sulfate; Wyeth Laboratories, Division American Home Products Corp., Post Office Box 8299, Philadelphia, PA 19101 (NDA 9-408).

2. Wyamine Sulfate Elixir containing mephentermine sulfate; Wyeth Laboratories (NDA 9-397).

Approval of NDA 9-397 for Wyamine Sulfate Elixir was withdrawn in an order published in the FEDERAL REGISTER on March 18, 1972 (37 FR 5711) on the ground of failure to submit required reports under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). At the time that notice was published, no final conclusions concerning effectiveness of mephentermine sulfate elixir had been reached. Those conclusions have now been reached and the purpose of including Wyamine Sulfate Elixir (NDA 9-397) in this notice is to inform all interested persons of such conclusions and offer them the opportunity to request a hearing.

Both of the above drugs have been reclassified as lacking substantial evidence of effectiveness in that no data were submitted in support of effectiveness. On the basis of all of the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), demonstrating the effectiveness of the drugs.

Therefore, notice is given to the holder of new drug application No. 9-408 for Wyamine Sulfate Tablets (mephentermine sulfate) and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application (or if indicated above, those parts of the application providing for the drug product listed above) and all amendments and supplements thereto on the ground that the new information before him with respect to the drug product, evaluated together with the evidence available to him at the time of approval of the application, shows there is a lack of substantial evidence that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holder of the new drug application for Wyamine Sulfate (mephentermine sulfate) Tablets (NDA 9-408) this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product which is identical, related, or similar to either Wyamine Sulfate Tablets or Wyamine Sulfate Elixir, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

In addition to the ground(s) for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products, as defined in § 310.6, e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments Act of 1962; or for any other reason.

In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder

(21 CFR 310, 314), all persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of new drug application No. 9-408 for Wyamine Sulfate (mephentermine sulfate) Tablets should not be withdrawn, and to raise, for administrative determination, all issues relating to the legal status of either of the drug products named above and of all identical, related, or similar drug products.

If any person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before April 21, 1975, a written notice of appearance and request for hearing, and (2) on or before May 20, 1975, the data, information, and analyses, on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 130.14 as published and discussed in detail in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), recodified as 21 CFR 314.200 on March 29, 1974 (39 FR 11680).

The failure of any person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to Wyamine Sulfate (mephentermine sulfate) Tablets and a waiver of any contentions concerning the legal status of either of the drug products named above and of all identical, related, or similar drug products. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application for Wyamine Sulfate (mephentermine sulfate) Tablets, or which requires a hearing with respect to a determination of the legal status of either of the drug products named above and of all identical, related, or similar drug products, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate with the Hearing Clerk, Food and Drug Administration (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, MD 20852.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended; 21 U.S.C. 355), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.-121).

Dated: March 14, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75-7382 Filed 3-20-75;8:45 am]

[DESI 8173; Docket No. FDC-D-710; NDA 10-253]

MONOBENZONE TOPICAL LOTION

Opportunity for Hearing on Proposal to Withdraw Approval of New Drug Application

The National Academy of Sciences-National Research Council, Drug Efficacy Study Group evaluated the effectiveness of the drug products described below, found the drugs to be less than effective, and submitted its reports to the Commissioner of Food and Drugs. Copies of those reports have previously been made publicly available and are on display at the office of the Food and Drug Administration's Hearing Clerk. After reviewing the Academy's reports and the available data and information, the Commissioner concluded that the drugs are less than effective and published his conclusion in the FEDERAL REGISTER of September 18, 1970 (35 FR 14629), that the drugs are possibly effective for their labeled indications. The products are used for treatment of skin disorders. The ointment form of the drug is being allowed to remain on the market pending evaluation of the results of ongoing studies. The lotion form is no longer marketed and this notice proposes to withdraw its approval. Persons who wish to request a hearing must do so by April 21, 1975.

1. NDA 10-253; Benoquin Lotion containing 5 percent monobenzone, and

2. NDA 8-173; Benoquin Ointment containing 20 percent monobenzone; Paul B. Elder Co., 705 East Mulberry Street, P.O. Box 31, Bryan, OH 43506.

A notice was published in the FEDERAL REGISTER of July 11, 1973 (38 FR 18477), stating that, since no alternative depigmenting agents are available, Benoquin Lotion and Ointment may remain on the market pending completion of scientific studies.

The firm, Paul B. Elder Company, informed the Food and Drug Administration on July 5, 1974 that studies were not being conducted on Benoquin Lotion, and on August 1, 1974 further stated that the marketing of that product has been discontinued.

As no person has submitted protocols or expressed an intention to perform additional clinical studies on the lotion form of monobenzone, the exemption (38 FR 18477; July 11, 1973) for continued marketing of that dosage form is hereby revoked. The marketing of Benoquin Ointment is being allowed to continue pending the completion of ongoing clinical studies. This notice of opportunity for hearing pertains only to NDA 10-523, Benoquin Lotion, which, in absence of new information in support of effectiveness, has been reclassified as lacking substantial evidence of effectiveness.

On the basis of all of the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111(a)(5), demonstrating the effectiveness of Benoquin Lotion.

Therefore, notice is given to the holder(s) of the new drug application(s) and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505 (e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) (of if indicated above, those parts of the application(s) providing for the drug product(s) listed above) and all amendments and supplements thereto on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug product(s) will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

In addition to the ground(s) for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating

to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201 (p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR 310.314), the applicant(s) and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the drug application(s) should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

If an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before April 21, 1975, a written notice of appearance and request for hearing, and (2) on or before May 20, 1975, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 130.14 as published and discussed in detail in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), recodified as 21 CFR 314.200 on March 29, 1974 (39 FR 11680).

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of any such product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the fact of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate with the Hearing Clerk, Food and Drug Administration (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, MD 20852.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 52 Stat. 1052-1053, as amended; 21 U.S.C. 355), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.121).

Dated: March 14, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75-7385 Filed 3-20-75;8:45 am]

[DESI 8119; Docket No. FDC-D-690; NDA 8-119]

PARENTERAL DRUG CONTAINING HYDROGENATED ERGOT ALKALOIDS

Withdrawal of Approval of New Drug Application

In a notice of opportunity for hearing (DESI 8119) which was published in the FEDERAL REGISTER of August 6, 1974 (39 FR 28308), the Director of the Bureau of Drugs proposed to issue an order withdrawing approval of the drug product described below. The basis of the proposed action was the lack of substantial evidence that the product is effective for its labeled indications. The product has been used in treatment of hypertension and various vascular disorders. No person contested the proposed action and approval of the new drug application is now being withdrawn.

NDA 8-119; Hydergine Injection containing dihydroergocornine methanesulfonate, dihydroergocristine methanesulfonate, and dihydroergokryptime methanesulfonate; Sandoz Pharmaceuticals Division, Sandoz-Wander, Inc., Route 10, E. Hanover, NJ 07936.

All identical, related, and similar drug products, not the subject of an approved new drug application, are covered by the application reviewed and are subject to this notice 21 CFR 310.6. Any person who wishes to determine whether a specific product is covered by this notice should write the Food and Drug Administration, Division of Drug Labeling Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20852.

Neither the holder of the application nor any other person filed a written appearance of election as provided by said notice. The failure to file such an appearance constitutes an election by such persons not to avail themselves of the opportunity for a hearing.

The Director of the Bureau of Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1053, as amended; 21 U.S.C. 355), and under authority delegated to him (21 CFR 2.121), finds that on the basis of new information before him with respect to the drug product, evaluated together with the evidence available to him when the application was approved, there is a lack of substantial evidence that the drug product will have the effects it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Therefore, pursuant to the foregoing finding, approval of new drug application No. 8-119, and all amendments and supplements applying thereto is withdrawn effective March 31, 1975.

Shipment in interstate commerce of the above-listed product or of any identical, related, or similar product, not the subject of an approved new drug application, will then be unlawful.

Dated: March 14, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75-7381 Filed 3-20-75;8:45 am]

POSSIBLE RISK OF CANCER IN SITU OF THE CERVIX FROM MEDROXYPROGESTERONE ACETATE INJECTABLE AND OTHER SYSTEMIC STEROIDAL CONTRACEPTIVES

Open Hearing

The Food and Drug Administration has pending a supplemental new drug application for Depo-Provera (medroxyprogesterone acetate injectable or MPA) for contraceptive use (NDA 12-541). In anticipation of approval of this supplemental new drug application, a final order was published in the FEDERAL REGISTER of September 12, 1974 (39 FR 32907) providing for patient labeling for MPA and specifying other conditions required for lawful distribution of the drug.

Subsequently, that order was stayed by a notice published in the FEDERAL REGISTER of October 30, 1974 (39 FR 38226). The notice advised that the Commissioner of Food and Drugs would delay the decision on the new drug application until the benefit-risk issues had been further considered. Specifically to be considered is whether or not the drug may be associated with an increased risk of cancer in situ of the cervix. The notice stated that further public consideration of the issues was warranted and that this would occur in an open hearing.

A 1-day hearing on this matter will be held on April 7, 1975, beginning at 8:30 a.m. in Conference Rm. G, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20852. The hearing will be co-chaired by Dr. Theodore King, Chairman of the Obstetrics and Gynecology Advisory Committee, and Professor Jerome Cornfield,

Chairman of the Biometric and Epidemiological Methodology Advisory Committee.

The question of whether systemic steroidal contraceptives (other than MPA) are or are not associated with an increased risk of cervical carcinoma has been the subject of several publications and ongoing studies, and has been discussed previously with the Obstetrics and Gynecology Advisory Committee at its meeting of February 21, 1974. No conclusions could be drawn at that time based upon the available evidence. Therefore, the April 7 hearing will also concern itself with a discussion of any additional studies that may be needed to produce more definitive answers.

At this open hearing, members of both the Obstetrics and Gynecology Advisory Committee and the Biometric and Epidemiological Methodology Advisory Committee will receive and review all of the information presented. The Committees will be asked to answer the following specific questions in their report to the Commissioner:

1. Are the data in the new drug application for MPA adequate for a determination of the incidence of carcinoma in situ of the cervix in women treated with MPA? Specifically:

a. Were the patients adequately screened before entering the study, and what are the implications of the screening procedures on the incidence rate?

b. Was there adequate confirmation of the Pap smears and the histologic diagnoses?

c. Were other risk factors sufficiently assessed?

2. Is it appropriate to compare the data in the new drug application for MPA and the data in the Third National Cancer Institute Survey in regard to the incidence of carcinoma in situ of the cervix? If so, what conclusions would you draw from this comparison?

3. Is it appropriate to compare the data in the new drug application for MPA with control data obtained from the published literature in regard to the incidence of carcinoma in situ of the cervix? If so, what conclusions would you draw from such comparisons?

4. Given all the data and information available to the Advisory Committees, is there evidence of an association between the use of MPA and an increased incidence of carcinoma in situ of the cervix? If so, is there evidence that such association is drug-related?

5. Given all the data and information available to the Advisory Committees, is there evidence of an association between the use of oral contraceptives and an increased incidence of carcinoma in situ of the cervix or cervical dysplasia?

6. If the currently available data raise reasonable doubts as to the answers to questions 4 and 5, what specific additional types of studies are needed to resolve such doubts? Specify objectives and general design for each recommended type of study.

7. Provide any other recommendations you wish to make on the issues under consideration at this hearing.

8. For the Obstetrics and Gynecology Advisory Committee only: Should Depo-Provera be approved at this time or a limited patient population under the conditions stated in the Commissioner's final order (currently stayed) published in the FEDERAL REGISTER of September 12, 1974 (39 FR 32907).

Persons appearing before the Advisory Committees are asked to address the specific issues raised by these questions. Other matters relating to MPA (e.g., data on mammary tumors in dogs, proposed distributional controls on drug, etc.) will not be considered at the hearing.

Any interested person wishing to present data or information on these issues at the hearing must so inform A. T. Gregoire, Ph. D., HFD–130, Rm. 14B–04, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20852, Tel. 301–443–3510 of that intention, and indicate the amount of time requested for his presentation, by close of business on March 28, 1975. The total time for all such presentations will be 2 hours. Dr. Gregoire will then promptly inform each person requesting an opportunity to be heard the time his oral presentation is scheduled to begin and the amount of time allocated for his presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations in view of the time limits. Persons with common interests may be required to make joint presentations. Any interested person may also present written data or information which shall be considered. Three copies of such written presentations shall be furnished to Dr. Gregoire at the address above on or before March 28, 1975.

The presentations and the order in which they will be given at the public hearing consist of the following:

1. The Advisory Committees will hear a presentation by FDA on the charge to the Committees, the history of MPA for its contraceptive indication, and a review of published and unpublished data on cervical changes following systemically administered steroids.

2. Testimony will be given by scientific experts from CDC and the academic community on epidemiological and pathological considerations in the study of cervical cancer in situ. This will be followed by presentations by FDA and the manufacturer of MPA (The Upjohn Co.) of the data in the new drug application bearing on the incidence of cervical cancer in situ. A scientific expert from the National Cancer Institute will discuss the Third NCI Survey, with specific emphasis on cervical cancer in situ.

3. This will be followed by a presentation of data and information by interested parties requesting to be heard.

4. Finally, there will be a public discussion in which the Committees will seek clarification, if necessary, of issues raised by previous speakers.

5. Following this open public hearing, the two Advisory Committees, after considering all information presented, will deliberate in closed session and make final recommendations on these matters to the Commissioner. A notice of the Commissioner's final decision will be published in the FEDERAL REGISTER.

The anticipated time schedule is as follows:

1. 8:30–9:30—FDA presentation.

2. 9:30–12:30—CDC, FDA, Upjohn, and NCI presentations. 12:30–1:30—Lunch.

3. 1:30–3:30—Scheduled presentations by interested persons.

4. 3:30–4:30—Unscheduled presentations by interested persons and clarification of issues raised by previous speakers.

5. 4:30 on—Deliberation in closed session and presentation of recommendations by committees may continue to following day, April 8, if necessary.

All written data or information submitted in response to this notice of open public hearing will be made available for public review in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, during working hours, Monday through Friday.

The Food and Drug Administration requested that Upjohn permit the agency to place all safety data pertinent to this matter on public display, including unpublished trade secret material. Upjohn declined to permit this. Accordingly, only analyses of Upjohn data not previously made public are placed on public display.

The following materials relating to this subject are available for public review in the office of the Hearing Clerk at the address above:

a. FDA and Upjohn analyses on the data in the new drug application concerned with incidence of cervical cancer in situ.

b. Letters to the Secretary dated October 2 and October 9, 1974 from the Chairman of the Subcommittee on Intergovernmental Relations of the Committee on Government Operations, House of Representatives, United States Congress.

c. Memoranda of FDA staff and NCI staff relative to MPA and cervical cancer in situ.

d. FEDERAL REGISTER documents on MPA.

e. The following manuscripts and published reports:

1. Idle, P., Wijnants, P., and Bonte, J., "Cytological Observations of Cervico-vaginal Smears on Hormone Contraception." Dept. of Gynecological Cancer Studies, Oncology Center, Catholic University of Louvain, Belgium.

2. Weld, G., Bartels, P., Annual Report to Ford Foundation on the Study on Effects of Oral Contraceptives. Grant No. 680–0497A–5336, July 1, 1973.

3. Thomas, D. B., "Relationship of Oral Contraceptives to Cervical Carcinogenesis." *Obstet. and Gynecol.* 40:503–518, 1972.

4. Melamed, M. R., Koss, L. G., Flehinger, B. J., Kellaky, R. P., Dubrow, H., "Prevalence Rates of Uterine Cervical Carcinoma in situ for Women Using the Diaphragm or Contraceptive Oral Steroids." *Brit. Med. Jour.* 3:195–200, 1969.

5. Boyce, J. C., Lu, T., Nelson, J. H., Joyce, D., "Cervical Carcinoma and Oral Contraception." *Obstet. and Gynecol.* 40:139–146, 1972.

6. Fidler, H. K., Boyes, D. A., Worth, A. J., "Screening for Malignant Disease by Means of Exfoliative Cytology in Presymptomatic Detection and Early Diagnosis." *A Critical Appraisal.* Williams & Wilkins Company, 1968, pp. 295–333.

7. Cramer, D. W., Cutler, S. J., "Incidence and Histopathology of Malignancies of the Female Genital Organs in the United States." *Amer. Jour. of Obstet. Gynecol.* 118:443–460, 1974.

8. Stern, E., Clark, V. A., Coffelt, C. F., "Contraceptives and Dysplasia: Higher Rate for Pill Choosers." *Science* 169:497–498, 1970.

9. Stern, E., Forsythe, A. B., Youkeles, L., Dixon, W. J., A Cytological Scale for Cervical Carcinogenesis. *Cancer Research* 34:2358–2361, 1974.

10. Stern, E., Shankman, P., Coffelt, C. F., Youkeles, L., Forsythe, A., "Contraceptive Choice and Dysplasia: Changes following the 1970 Senate Hearings." *Contraception* 7:435–441, 1973.

11. Dabancens, A., Prado, R., Larraguibel, R., Zanartu, J., "Intraepithelial Cervical Neoplasia in Women Using Intrauterine Devices and Long-acting Injectable Progestogens as Contraceptives." *Amer. Jour. of Obstet. Gynecol.* 119:1052–1056, 1974.

12. Weid, G. L., Davis, E., Frank, R., Segal, P. B., Meier, P., Rosenthal, 5., "Statistical Evaluation of the Effect of Hormonal Contraceptives on the Cytologic Smears Pattern." *Obstet. and Gynecol.* 27:327–334, 1966.

13. Lundin, F. E., "A Critical Evaluation of Epidemiological Methods in Studying Early Cervical Neoplasia." *Obstet. and Gynecol. Survey* 24:724–734, 1969.

14. Worth, A. J., Boyes, D. A., "A Case Control Study into the Possible Effects of Birth Control Pills on Pre-clinical Carcinoma of the Cervix." *Jour. of Obstet. and Gynaecol. of the British Commonwealth* 79:673–679, 1972.

15. Liu W., Koebel, L., Shipp J., Prisby, H., "Cytologic Changes Following the Use of Oral Contraceptives." *Obstet. and Gynecol.* 30:228–232, 1967.

16. Kline, T. S., Holland, M., Wemple, D., "Atypical Cytology with Contraceptive Hormone Medication." *Am. Jour. Clin. Path.* 53:215–232, 1970.

17. Koss, L. G., "Significance of Dysplasia." *Clin. Obstet. and Gynecol.* 13:873–888, 1970.

18. Martin, C. E., "Marital and Coital Factors in Cervical Cancer." *Amer. Jour. of Public Health* 57:803–814, 1967.

19. Rotkin, I. D., "Sexual Characteristics of a Cervical Cancer Population." *Amer. Jour. of Public Health* 57:815–829, 1967.

20. Nahmias, A. J., Naib, M. Z., Josey, W. E., "Epidemiological Studies Relating Genital Herpatic Infections to Cervical Carcinoma." *Cancer Research* 34:1111–1117, 1974.

21. Vessey, M. P., Thromboembolism, Cancer, and Oral Contraceptives. *Clin. Obstet. and Gynecol,* 17: 65–78, 1974.

22. Powell, L. C., Seymour, R. J., "Effects of Depo-Medroxyprogesterone Acetate as a Contraceptive Agent." *Amer. Jour. of Obstet. and Gynecol.* 110: 36–41, 1971.

23. "Evaluating 21 years of Such Screening." *Medical World News* September 13, 1974, p. 71.

24. Christopherson, W. M., "The Changing Patterns of Cervix Cancer." *Cancer* 21: 283–287, 1971.

25. Christopherson, W. M., et al., "Cervix Cancer Death Rates and Mass Cytologic Screening." *Cancer* 26: 808–811, 1970.

26. Christopherson, W. M., "Cervical Cancer Control in Louisville, Kentucky." *Cancer* 26: 29–38, 1970.

27. Holmquist, N. D., McMahan, C. A., Williams, O. D., "Variability in Classification of Carcinoma In Situ of the Uterine Cervix." *Arch. of Path.* 84: 334–345, 1967.

28. Dougherty, C. M., "Cervical Cytology and Sequential Birth Control Pills." *Obstet. and Gynecol.* 36: 741–744, 1970.

Dated: March 18, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–7530 Filed 3–20–75;8:45 am]

[DESI 11470; Docket No. FDC–D–717; NDA 11–469]

PROTOKYLOL WITH PENTOBARBITAL TABLETS

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application

A notice (DESI 11470) was published in the FEDERAL REGISTER of July 27, 1972 (37 FR 15041), pursuant to the evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, in which the Food and Drug Administration announced its conclusion that the drug product described below is less-than-effective (probably effective for the treatment of bronchospasm associated with acute and chronic bronchial asthma, pulmonary emphysema, bronchitis, and bronchiectasis, and lacking substantial evidence of effectiveness for its other labeled indications), and that additional evidence is required to establish it effectiveness. No data concerning effectiveness having been submitted, the product is now regarded as lacking substantial evidence of effectiveness. This notice announces that conclusion and proposes to withdraw approval of the product. Persons wishing to request a hearing may do so before April 21, 1975.

NDA 11–469; Caytine with Pentobarbital Tablets containing protokylol hydrochloride and pentobarbital; Lakeside Laboratories, Inc., 1707 East North Avenue, Milwaukee, WI 53201.

On the basis of all of the data and information available to him, the Director of the Bureau of Drugs is unaware of any adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111 (a) (5) and 21 CFR 3.86, demonstrating the effectiveness of the combination drug.

Therefore, notice is given to the holder(s) of the new drug application(s) and to all other interested persons that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application(s) (or if indicated above, those parts of the application(s) providing for the drug product(s) listed above) and all amendments and supplements thereto on the ground that new information before him with respect to the drug product(s), evaluated together with the evidence available to him at the time of approval of the application(s), shows there is a lack of substantial evidence that the drug product(s) will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holder(s) of the new drug application(s) specifically named above, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product which is identical, related, or similar to a drug product named above, as defined in 21 CFR 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product he manufactures or distributes. Any person may request an opinion of the applicability of this notice to a specific drug product he manufactures or distributes that may be identical, related, or similar to a drug product named in this notice by writing to the Food and Drug Administration, Bureau of Drugs, Division of Drug Labeling Compliance (HFD–310), 5600 Fishers Lane, Rockville, MD 20852.

In addition to the ground(s) for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6) e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962; or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR 310, 314), the applicant(s) and all other persons subject to this notice pursuant to 21 CFR 310.6 are hereby given an opportunity for a hearing to show why approval of the new drug application(s) should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and of all identical, related, or similar drug products.

If an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 elects to avail himself of the opportunity for a hearing, he shall file (1) on or before April 21, 1975, a written notice of appearance and request for hearing, and (2) on or before May 20, 1975, the data, information, and analyses on which he relies to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance, and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 130.14 as published and discussed in detail in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), recodified as 21 CFR 314.200 on March 29, 1974 (39 FR 11680).

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to avail himself of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of any such drug product. Any such drug product may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but

must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice shall be filed in quintuplicate with the Hearing Clerk, Food and Drug Administration (HFC–20), Room 4–65, 5600 Fishers Lane, Rockville, MD 20852.

All submissions pursuant to this notice, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk during regular business hours, Monday through Friday.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 52 Stat. 1052–1053, as amended; 21 U.S.C. 355), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 2.121).

Dated: March 14, 1975.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc.75–7384 Filed 3–20–75;8:45 am]

RADIOLOGICAL HEALTH ADVISORY COMMITTEES

Request for Nominations for Members

The Food and Drug Administration requests nominations for new members for radiological health advisory committees. Nominations are due by April 30, 1975.

The Secretary of Health, Education, and Welfare and, by delegation, the Commissioner of Food and Drugs, and the Director, Bureau of Radiological Health, are charged with the administration of those portions of the Public Health Service Act (42 U.S.C. 217a, 263b, 263f) that are designed to protect the public health from hazardous radiation emissions.

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), the Medical Radiation Advisory Committee (MRAC), and the Radiation Bio-Effects and Epidemiology Advisory Committee (RBEAC) are charged with advising and consulting with the Commissioner on matters related to radiological health as described below.

The Commissioner requested in a FEDERAL REGISTER publication on July 8, 1974 (39 FR 24940), nominations for the above-mentioned committees to replace members whose terms expired in 1974. Nominations received in response to that publication, but which did not result in committee appointments, will be reconsidered for the vacancies announced herein. The names and affiliations of those appointed, pursuant to the July 8, 1974 request for nominations, follow:

New members on the TEPRSSC are: Dr. Ira Lon Morgan, Columbia Scientific Industries; Dr. Karl Z. Morgan, Georgia Institute of Technology; Mr. Paul Shoop, International Brotherhood of Electrical Workers; Lt. Col. George S. Kush, Office of the Surgeon General, USAF; Mr. B. Jim Porter, Louisiana Division of Radiation Control.

New members appointed to the MRAC are: Dr. James H. Christie, University Hospitals, University of Iowa; Dr. Priscilla W. Laws, Department of Physics and Astronomy, Dickinson College; Mr. Robert J. Roth, New England Baptist Hospital; Dr. Robert E. Roth, Department of Radiation Oncology, University of Alabama at Birmingham; Mrs. Polly C. Story, North Carolina Baptist Hospital and Bowman Gray School of Medicine of Wake Forest University.

All interested persons are invited to nominate qualified candidates for consideration as members of the following committees:

TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

The Technical Electronic Product Radiation Safety Standards Committee, established by the Secretary pursuant to section 358(f)(1)(A) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f), must be consulted before prescribing any performance standards for electronic product radiation safety.

Since its inception in 1969, the TEPRSSC has provided valuable technical and scientific advice to the Bureau of Radiological Health, Food and Drug Administration, on the development of electronic product radiation safety performance standards. Thus far, regulatory performance standards have been issued under 21 CFR Chapter I, Subchapter J, for television sets, cold cathode gas discharge tubes, microwave ovens, diagnostic x-ray systems and their major components, and cabinet x-ray equipment (including x-ray baggage inspection devices for use at airports and similar facilities). The Committee meets approximately twice each year and occasionally reviews documents transmitted by mail.

A second proposed performance standard for laser products was published in the FEDERAL REGISTER of September 4, 1974 (39 FR 32094). Other electronic products for which performance standards may be issued in the future include equipment used for ultrasound therapy, microwave diathermy, ultraviolet irradiation, and electron microscopy.

Pursuant to section 358(f) of the act, members will be appointed by the Commissioner after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety. Each member shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. As required by the act, the Committee is composed of fifteen members selected as follows:

1. Five from governmental agencies including State and Federal governments;
2. Five from the affected industry, after consultation with industry representatives; and
3. Five from the general public, of which at least one shall be representative of organized labor.

Effective December 31, 1975, two members from industry, one from the public sector, and two members from the governmental sector will complete their terms and may be replaced.

Nominations are solicited for engineers or scientists qualified in electronic product radiation safety to fill these vacancies for a 3-year term. Nominations are invited from consumer, industry, government, and professional organizations, and should be sent with accompanying information to:

Mr. Marshall S. Little, Executive Secretary, TEPRSSC,
Food and Drug Administration,
Bureau of Radiological Health (HFX–440),
5600 Fishers Lane,
Rockville, Md. 20852.

MEDICAL RADIATION ADVISORY COMMITTEE

The Medical Radiation Advisory Committee was established under the name Medical X-ray Advisory Committee on October 31, 1963, pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a). It was renamed the Medical Radiation Advisory Committee on June 25, 1970. The Committee advises and consults with the Commissioner on the formulation of policy and development of a coordinated national program relating to application of ionizing radiation to obtain maximum diagnostic information and therapeutic benefit per unit of radiation exposure to the public.

The MRAC meets approximately twice each year and has provided advice to the Bureau of Radiological Health, Food and Drug Administration, on programs related to medical and dental use of x-ray, training of medical radiation users, nuclear medicine, and the development of policy statements on the effective use of medical radiation.

Current Committee emphasis is directed toward qualifications of operators of x-ray equipment and radiological training programs; equipment requirements and standards; examination and procedural efficacy; and the evaluation of computer applications in radiology operations.

The Committee consists of thirteen members, including the chairman. Members are selected and the chairman is appointed by the Commissioner from authorities knowledgeable in the fields of medicine, dentistry, health sciences, engineering, public health, and related technology. Members are invited to serve 4-year terms. Effective July 1, 1975, there will be a total of three vacancies on this Committee. Interested persons are invited to submit names of qualified candidates and accompanying information to:

William S. Cole, M.D., Executive Secretary, MRAC,
Food and Drug Administration,
Bureau of Radiological Health (HFX-4),
5600 Fishers Lane,
Rockville, MD 20852.

RADIATION BIO-EFFECTS AND EPIDEMIOLOGY ADVISORY COMMITTEE

The Radiation Bio-Effects and Epidemiology Advisory Committee was established on October 21, 1971, in accordance with 42 U.S.C. 217a, 263b. The Committee consists of fifteen members, including the chairman, selected by the Commissioner from among authorities knowledgeable in the fields of pathology, radiology, physiology, psychology, genetics, biometrics, epidemiology, toxicology, biophysics, and electronic engineering.

The Committee advises the Commissioner concerning the research bases for electronic product emission standards and radiological health practices. The RBEAC meets approximately twice each year. It has provided the Bureau of Radiological Health, Food and Drug Administration, with advice on the progress of ongoing bio-effects research projects, and recommended priorities for future bio-effects research needs.

Five members will complete their terms on January 31, 1976. Nominations for persons to serve a term of not less than 2 years nor more than 4 years for these vacancies are now solicited. The qualifications are indicated above. Names of qualified candidates and accompanying information should be sent to:

Executive Secretary, RBEAC,
Food and Drug Administration,
Bureau of Radiological Health (HFX-100),
5600 Fishers Lane,
Rockville, MD 20852.

NOMINATIONS AND ACCOMPANYING INFORMATION

To be considered for any of these three Committees, each nomination of a qualified person must be received on or before April 30, 1975, and be accompanied by a curriculum vitae, which provides detailed evidence of nominee qualifications, including current employment, professional affiliations, and where the nominee may be contacted. This information should be sent to the Executive Secretary of the Committee, as set forth above, for which the person is being nominated. Nominations must also state that the person nominated is aware of the nomination, is interested in becoming involved in the effort, and appears to have no conflict of interest.

Dated: March 17, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-7388 Filed 3-20-75;8:45 am]

Office of the Secretary

REVIEW PANEL ON NEW DRUG REGULATION

Meeting

Notice is hereby given, pursuant to Pub. L. 92-463, that the Review Panel on New Drug Regulation, established pursuant to Pub. L. 92-463 by the Secretary, Department of Health, Education, and Welfare, on February 21, 1975, will meet on Tuesday, April 8, 1975, at 8:30 a.m. in room 5051 of the Department of Health, Education, and Welfare's North Building, 330 Independence Avenue, SW., Washington, D.C. The Review Panel will consider matters pertaining to a study of existing policies and procedures for the regulation of new drugs by the Food and Drug Administration in order to advise the Secretary of Health, Education, and Welfare of any deficiencies in the policies and procedures and to make recommendation to the Secretary concerning the elimination of such deficiencies.

The meeting is open to the public.

Further information on the Review Panel may be obtained from Dr. Lionel M. Bernstein, Executive Secretary, Review Panel on New Drug Regulation, Room 4617, HEW North Building, 330 Independence Avenue, SW., Washington, D.C. 20201, telephone (202) 245-7510.

Dated: March 18, 1975.

LIONEL M. BERNSTEIN,
Executive Secretary, Review Panel and New Drug Regulation.

[FR Doc.75-7473 Filed 3-20-75;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Disaster Assistance Administration

[FDAA-458-DR; Docket No. NFD-252]

ALABAMA

Major Disaster and Related Determinations

Pursuant to the authority vested in the Secretary of Housing and Urban Development by the President under Executive Order 11795 of July 11, 1974, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D-74-285; and by virtue of the Act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that on March 14, 1975, the President declared a major disaster as follows:

I have determined that the damage in certain areas of the State of Alabama resulting from severe storms and flooding beginning about January 10, 1975, is of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 93-288. I therefore declare that such a major disaster exists in the State of Alabama.

This declaration of a major disaster supersedes the President's January 18, 1975, declaration of an emergency for the State of Alabama, FDAA-3007-EM.

Notice is hereby given that pursuant to the authority vested in the Secretary of Housing and Urban Development under Executive Order 11795, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D-74-285, I hereby appoint Mr. Thomas P. Credle, HUD Region IV, to act as the Federal Coordinating Officer for this declared major disaster.

I do hereby determine the following areas of the State of Alabama to have been adversely affected by this declared major disaster:

The Counties of:

Barbour	Lowndes
Bullock	Macon
Choctaw	Montgomery
Cleburne	Pike
Coffee	St. Clair
Crenshaw	Shelby
Cullman	Tuscaloosa
Dale	Walker
Dallas	Washington
Geneva	Wilcox
Jefferson	Winston
Lee	

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.)

Dated: March 14, 1975.

THOMAS P. DUNNE,
Administrator, Federal Disaster Assistance Administration.

[FR Doc.75-7442 Filed 3-20-75;8:45 am]

[FDAA-3008-EM; Docket No. NFD-251]

GEORGIA

Emergency Declaration and Related Determinations

Pursuant to the authority vested in the Secretary of Housing and Urban Development by the President under Executive Order 11795 of July 11, 1974, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket No. D-74-285; and by virtue of the Act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that on March 14, 1975, the President declared an emergency as follows:

I have determined that the impact of tornadoes, high winds, and flooding on the State of Georgia, beginning about February 18, 1975, is of sufficient severity and magnitude to warrant a declaration of an emergency under Public Law 93-288. I therefore declare that such an emergency exists in the State of Georgia. You are to determine the specific areas within the State eligible for Federal assistance under this declaration.

Notice is hereby given that pursuant to the authority vested in the Secretary

of Housing and Urban Development under Executive Order 11795, and delegated to me by the Secretary under Department of Housing and Urban Development Delegation of Authority, Docket D–74–285, I hereby appoint Mr. Thomas P. Credle, HUD Region IV, to act as the Federal Coordinating Officer for this declared emergency.

I do hereby determine the following area in the State of Georgia to have been adversely affected by this declared emergency:

The County of: Peach

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.)

Dated: March 14, 1975.

THOMAS P. DUNNE,
Administrator, Federal Disaster Assistance Administration.

[FR Doc.75–7441 Filed 3–20–75;8:45 am]

CIVIL AERONAUTICS BOARD

[Order 75–3–52 Docket No. 26494, Agreement C.A.B. 24979]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Agreement Relating to Passenger-Fare Matters

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 17th day of March, 1975.

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, between various air carriers, foreign air carriers and other air carriers, embodied in the resolutions of the Traffic Conferences of the International Air Transport Association (IATA). The agreement, adopted by mail vote, has been assigned the above-designated C.A.B. agreement number.

Insofar as transportation to/from U.S. points is concerned, Agreement C.A.B. 24979 would increase, effective April 1, 1975, all fares to/from Romania by $2.00 each way to compensate carriers for an increase in the airport service charge recently imposed by the Government of Romania. We will approve the agreement as being reasonable since it reflects a pass-through of an increased passenger service charge in fares to/from Romania previously agreed upon.

The Board, acting pursuant to sections 102, 204(a), 404(b), 412 and 1002 of the Act does not find the following resolutions, incorporated in the agreement indicated, are adverse to the public interest or in violation of the Act:

IATA Resolutions
200 (Mail 235) 003z
JT12 (Mail 862) 003z
JT23 (Mail 354) 003z
JT123 (Mail 748) 003z

Accordingly, it is ordered That, 1. Agreement C.A.B. 24979 be and hereby is approved; and

2. Tariffs implementing the agreement be marked to expire March 31, 1976.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.75–7470 Filed 3–20–75;8:45 am]

[Order 75–3–21, Docket No. 26494, Agreement C.A.B. 24980 R–1 and R–2]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Agreement Relating to Proportional Fare Matters

Issued under delegated authority March 7, 1975.

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, between various air carriers, foreign air carriers and other carriers embodied in the resolutions of the Traffic Conferences of the International Air Transport Association (IATA). The agreement, adopted by mail vote, has been assigned the above-designated C.A.B. agreement number.

The agreement would amend those portions of resolutions governing North/Central Pacific and South Pacific proportional fares which set forth the action to be taken in the event of a general U.S. or Canadian domestic or transborder fare change. The amendments provide for the convening of a proportional fare meeting within 10 days after a fare change is filed with and/or authorized by one or both of the governments concerned. However, when a meeting is called prior to government authorization of any fare change, upon protest by at least two carriers (one in the case of a Canadian change), the meeting may not be held until after government authorization of the fare change.

Pursuant to authority duly delegated by the Board in the Board's Regulations, 14 CFR 385.14, it is not found that the following resolutions, which are incorporated in Agreement C.A.B. 24980 as indicated, are adverse to the public interest or in violation of the Act:

Agreement C.A.B. 24980:	*IATA resolution*
R–1	JT31 (Mail 283) 015a.
R–2	JT31 (Mail 283) 015b.

Accordingly, it is ordered, That:

Agreement C.A.B. 24980 be and hereby is approved.

Persons entitled to petition the Board for review of this order pursuant to the Board's Regulations, 14 CFR 385.50, may file such petitions within ten days after the date of service of this order.

This order shall be effective and become the action of the Civil Aeronautics Board upon expiration of the above period, unless within such period a petition for review thereof is filed or the Board gives notice that it will review this order on its own motion.

This order will be published in the FEDERAL REGISTER.

[SEAL] PHYLLIS T. KAYLOR,
Acting Secretary.

[FR Doc.75–7471 Filed 3–20–75;8:45 am]

[Docket No. 27582; Order 75–3–54]

PAN AMERICAN WORLD AIRWAYS, INC.

Military Excursion Fares Proposed

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 5th day of March, 1975.

By tariff revisions filed January 31, 1975, for effect March 2, 1975, Pan American World Airways, Inc. (Pan American) proposes to establish special round-trip excursion fares from Guam to Hong Kong, Kuala Lumpur and Singapore for use by U.S. military personnel and their dependents stationed on Guam.[1] The fares are subject to a 45-day maximum stay and unlimited stopovers would be permitted.

In its justification, Pan American states that fares are designed to make available vacation travel, not otherwise possible, to U.S. military personnel and their dependents stationed on Guam; that approximately 30 round-trip passengers weekly would use the fare practically all of which can be considered generative rather than diversionary; that the fares would serve to stimulate travel on new routes which are in the developmental stage for Pan American; that the proposed fares would contribute $295,000 to profit; and that the opportunity for travel is simply not available to military personnel because the IATA fares are beyond the range of their discretionary income.

The Board has determined that the proposed fares may be unjust, unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial, or otherwise unlawful, and should be suspended pending investigation.

By Order 74–4–2, dated April 1, 1974, the Board disapproved an agreement reached within the International Air Transport Association (IATA) which would have established similar fares for U.S. military personnel. The Board's disapproval rested on the discrimination inherent in offering special fares for a selected segment of the flying public which are not available to others. The Board has permitted special fares for military personnel stationed abroad and their dependents. However, these fares have been warranted by morale considerations and are limited to travel by the military between their duty stations abroad and homes for the purpose of visiting family and friends—a purpose quite different from vacation travel.[2]

[1] Air Tariffs Corporation, Agent, Tariff C.A.B. No. 44, 12th Revised Page 315.

[2] These special fares are presently available to the military stationed on Guam for travel to the mainland.

Accordingly, pursuant to the Federal Aviation Act of 1958, as amended, and particularly sections 204(a), 403, 801 and 1002(j) thereof,

It is ordered, That: 1. An investigation be instituted to determine whether the fares and provisions in Rule 290, on 8th Revised Page 82–A, and Table 2, on 12th Revised Page 315, to Passenger Fares Tariff No. PF–4, C.A.B. No. 44, issued by Air Tariffs Corporation, Agent, and practices affecting such fares and provisions, are or will be unjust, unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial, or otherwise unlawful, and if found to be unlawful, to take appropriate action to prevent the use of such fares and provisions or rules, regulations, or practices;

2. Pending hearing and decision by the Board, the fares and provisions on the tariff pages specified in paragraph 1 above are suspended and their use deferred to and including March 31, 1976 unless otherwise ordered by the Board, and that no changes be made therein during the period of suspension except by order or special permission of the Board;

3. This order shall be submitted to the President[3] and shall become effective April 1, 1975;

4. The investigation ordered herein be assigned for hearing before an Administrative Law Judge of the Board at a time and place hereafter to be designated; and

5. Copies of this order be served upon Pan American World Airways, Inc., which is hereby made a party to this proceeding.

This order will be published in the FEDERAL REGISTER.

By the Civil Aeronautics Board:

[SEAL] PHYLLIS T. KAYLOR,
Acting Secretary.

[FR Doc.75–7472 Filed 3–20–75;8:45 am]

COMMISSION ON CIVIL RIGHTS.

CALIFORNIA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a factfinding meeting of the California State Advisory Committee (SAC) to this Commission will convene at 9 a.m. on April 11, 1975, in the City of Salinas Council Chambers, City Hall, Salinas, California 93901.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Western Regional Office of the Commission, Room 1015, 312 North Spring Street, Los Angeles, California 90012.

The purpose of this factfinding meeting is an investigation into concerns of secondary education of Mexican Americans in the Salinas Union High School District.

[3] This order was transmitted to the President on March 7, 1975.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.75–7445, Filed 3–20–75;8:45 am]

CALIFORNIA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the California State Advisory Committee (SAC) to this Commission will convene at 7:30 p.m. on April 10, 1975, at the Townhouse, 808 North Main, Peninsula Room, Salinas, California 93901.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Western Regional Office of the Commission, Room 1015, 312 North Spring Street, Los Angeles, California 90012.

The purpose of this meeting is a review of agenda, witnesses and hearing book for one day open meeting.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.75–7446 Filed 3–20–75;8:45 am]

COLORADO STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Colorado State Advisory Committee (SAC) to this Commission will convene at 8 a.m. on April 26, 1975, at the Quality Inn, 1840 Sherman Street, Denver, Colorado 80203.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Mountain States Regional Office of the Commission, Room 216, 1726 Champa Street, Denver, Colorado 80202.

The purpose of this meeting is to review activities concerning a project by the SAC regarding accessibility of minorities and women to the medical and legal professions.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.75–7447 Filed 3–20–75;8:45 am]

DELAWARE STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference of the Delaware State Advisory Committee will convene at 9:30 a.m. on April 12, 1975, at Wilmington High School, Lancaster Avenue and DuPont Road, Wilmington, Delaware.

Persons wishing to attend this conference should contact the Committee Chairman, or the Mid-Atlantic Regional Office of the Commission, Room 510, 2120 L Street NW., Washington, D.C. 20037.

The purpose of this meeting is a conference on equal employment opportunity in the State of Delaware.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.75–7448 Filed 3–20–75;8:45 am]

INDIANA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Indiana State Advisory Committee (SAC) to this Commission scheduled to convene at 10 a.m. on March 22, 1975, at Calumet College, Conference Room, East Chicago, Indiana 46312, will convene at 10 a.m. on March 22, 1975, but will meet at the Holiday Inn, 3830 179th Street, Hammond, Indiana.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32d Floor, Chicago, Illinois 60604.

The purpose of this meeting is the release of Migrant Report-Migrant Assembly Conference Lake County Study Planning.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, Jr.,
Advisory Committee Management Officer.

[FR Doc.75–7449 Filed 3–20–75;8:45 am]

INDIANA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a press conference and planning meeting of the Indiana State Advisory Committee (SAC) to this Commission will convene at 10 a.m. on April 2, 1975,

at the Quality Inn, 1530 N. Meridian, Indianapolis, Indiana.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32d Floor, Chicago, Illinois 60604.

The purpose of this planning and press conference is to release Migrant Report and training session for Migrant Mobilization Conference.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, JR.,
Advisory Committee Management Officer.

[FR Doc.75-7450 Filed 3-20-75;8:45 am]

INDIANA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference of the Indiana State Advisory Committee (SAC) to this Commission will convene at 9:30 a.m. on April 18, 1975, at 2000 W. Jefferson Street, First United Presbyterian Church, Indiana 46901.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32d Floor, Chicago, Illinois 60604.

The purpose of this meeting is discrimination of information in the Indiana Migrant Report formation of a concortium of statewide organization to develop steps for implementation of recommendations contained in the report.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, JR.,
Advisory Committee Management Officer.

[FR Doc.75-7451 Filed 3-20-75;8:45 am]

MICHIGAN STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Michigan State Advisory Committee (SAC) to this Commission will convene at 7:30 p.m. and 10 p.m. on April 10, 11, 1975, at Mott Community College Student Center, 2d Floor, 1401 E. Court Street, Flint, Michigan 48503.

Persons wishing to attend this meeting should contact the Committee Chairman or the Midwestern Regional Office of the Commission, Room 1428, 230 South Dearborn Street, 32d Floor, Chicago, Illinois 60604.

The purpose of this meeting Subcommittee to review results of the first stage of the Committees in Community Development project. Full Committee will discuss potential new members, Approve first interior report on community development project. Continue planning for second hearing.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, JR.,
Advisory Committee Management Officer.

[FR Doc.75-7454 Filed 3-20-75;8:45 am]

NEW JERSEY STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the New Jersey State Advisory Committee (SAC) to this Commission will convene at 7:30 p.m. on April 15, 1975, at the College of Medicine and Dentistry, 100 Bergen Street, Newark, New Jersey.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Northeastern Regional Office of the Commission, Room 1639, 26 Federal Plaza, New York, New York 10007.

The purpose of this meeting is to discuss the prison report.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, JR.,
Advisory Committee Management Officer.

[FR Doc.75-7452 Filed 3-20-75;8:45 am]

PENNSYLVANIA STATE ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the rules and regulations of the United States Commission on Civil Rights, that a planning meeting of the Pennsylvania State Advisory Committee (SAC) to this Commission will convene at 10 a.m. on April 9, 1975, in the Federal Building, 600 Arch Street, Room 6310, Philadelphia, Pa.

Persons wishing to attend this meeting should contact the Committee Chairman, or the Mid-Atlantic Regional Office of the Commission, Room 510, 2120 L Street NW., Washington, D.C. 20425.

The purpose of this meeting is to discuss civil rights activities in the State of Pennsylvania.

This meeting will be conducted pursuant to the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 17, 1975.

ISAIAH T. CRESWELL, JR.,
Advisory Committee Management Officer.

[FR Doc.75-7453 Filed 3-20-75;8:45 am]

CIVIL SERVICE COMMISSION

FEDERAL EMPLOYEES PAY COUNCIL

Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, Pub. L. 92-463, notice is hereby given that the Federal Employees Pay Council will meet at 2 p.m. on Wednesday, April 23, 1975. This meeting will be held in room 5323 of the U.S. Civil Service Commission building, 1900 E Street NW., and will consist of continued discussions on the fiscal year 1976 comparability adjustment for the statutory pay systems of the Federal Government.

The Chairman of the U.S. Civil Service Commission is responsible for the making of determinations under section 10(d) of the Federal Advisory Committee Act as to whether or not meetings of the Federal Employees Pay Council shall be open to the public. He has determined that this meeting will consist of exchanges of opinions and information which, if written, would fall within exemptions (2) or (5) of 5 U.S.C. 552(b). Therefore, this meeting will not be open to the public.

For the President's Agent:

RICHARD H. HALL,
Advisory Committee Management Officer for the President's Agent.

[FR Doc.75-7440 Filed 3-20-75;8:45 am]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

CERTAIN COTTON TEXTILE PRODUCTS PRODUCED OR MANUFACTURED IN THAILAND

Entry or Withdrawal From Warehouse for Consumption

MARCH 18, 1975.

On March 28, 1974 there was published in the FEDERAL REGISTER (39 FR 11458) a letter dated March 25, 1974 from the Chairman, Committee for the Implementation of Textile Agreements, to the Commissioner of Customs, establishing levels of restraint applicable to certain specified categories of cotton textiles and cotton textile products produced or manufactured in Thailand and exported to the United States during the twelve-month period beginning on April 1, 1974. As set forth in that letter, the levels of restraint are subject to adjustment pursuant to paragraph 9 of the Bilateral Cotton Textile Agreement of March 16, 1972, between the Governments of the United States and Thailand, which provides for the limited carryover of shortfalls in certain categories to the next agreement year.

Accordingly, pursuant to the provision of the bilateral agreement referred to above, there is published below a letter of March 18, 1975, from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs amending the level of restraint applicable to cotton textile products in Category 60, produced or manufactured in Thailand and exported to the United States during the twelve-month period which began on April 1, 1974.

ALAN POLANSKY,
Acting Chairman, Committee for the Implementation of Textile Agreements, and Acting Deputy Assistant Secretary for Resources and Trade Assistance, Department of Commerce.

COMMISSIONER OF CUSTOMS,
Department of the Treasury,
Washington, D.C. 20229.

DEAR MR. COMMISSIONER: On March 25, 1974, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry during the twelve-month period beginning on April 1, 1974 of cotton textiles and cotton textile products in certain specified categories produced or manufactured in Thailand in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

Pursuant to paragraph 9 of the Bilateral Cotton Textile Agreement of March 16, 1972, between the Governments of the United States and Thailand, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, you are directed to increase, effective on March 21, 1975, the level of restraint established for cotton textile products in Category 60 to 45,985 dozen[2] for the twelve-month period which began on April 1, 1974.

The actions taken with respect to the Government of Thailand and with respect to imports of cotton textiles and cotton textile products from Thailand have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ALAN POLANSKY,
Acting Chairman, Committee for the Implementation of Textile Agreements, and Acting Deputy Assistant Secretary for Resources and Trade Assistance, Department of Commerce.

[FR Doc.75-7414 Filed 3-20-75;8:45 am]

[1] The term "adjustment" refers to those provisions of the Bilateral Cotton Textile Agreement of March 16, 1972, between the Governments of the United States and Thailand, which provide, in part, that within the aggregate and applicable group limits, limits on certain categories may be exceeded by not more than five percent; for the limited carryover of shortfalls in certain categories to the next agreement year; and for administrative arrangements.

[2] This level has not been adjusted to reflect any entries made on or after April 1, 1974.

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1975

Proposed Additions

Notice is hereby given pursuant to section 2(a)(2) of Pub. L. 92-28; 85 Stat. 79, of the proposed additions of the following services to Procurement List 1975, November 12, 1974 (39 FR 39964).

INDUSTRIAL CLASS 7349

Janitorial/Custodial, Atomic Energy Commission, Richland, Washington, for following buildings:
- Hanford Works:
  - 700 Area Buildings:
    - Building 701-A
    - Building 703
    - Building 712
    - Building 747
    - Building 747-A
  - 1100 Area Buildings:
    - Building 1166
    - Building 1167
    - Building 1167-A
    - Building 1170
    - Building 1171

Janitorial/Custodial, Bonneville Power Administration, Pasco, Washington, for following locations:
- Pasco Operations and Maintenance Headquarters, Buildings 69-C and 102, and Franklin Substation

Janitorial/Custodial, District Office, Bureau of Land Management, Roseburg, Oregon.

Comments and views regarding these proposed additions may be filed with the Committee not later than April 21, 1975. Communications should be addressed to the Executive Director, Committee for Purchase from the Blind and Other Severely Handicapped, 2009 Fourteenth Street North, Suite 610, Arlington, Virginia 22201.

By the Committee.

C. W. FLETCHER,
Executive Director.

[FR Doc.75-7427 Filed 3-20-75;8:45 am]

CONSUMER PRODUCT SAFETY COMMISSION

CHILDREN'S SLEEPWEAR

Sizes 7 Through 14 (FF 5-74); Policy Statement

In this notice the Consumer Product Safety Commission issues a two-part policy statement regarding the applicability of the Standard for the Flammability of Children's Sleepwear, Sizes 7 through 14 (FF 5-74), as amended. The Commission issued the Standard on May 1, 1974 (39 FR 15210), under the Flammable Fabrics Act (15 U.S.C. 1191 et seq.), and elsewhere in the FEDERAL REGISTER today has amended the Standard to require affirmative labeling.

The Standard becomes effective on May 1, 1975 and applies to garments of children's sleepwear in sizes 7 through 14 and to fabric or related material intended or promoted for use in such children's sleepwear. It requires that these items of children's sleepwear in sizes 7 through 14 manufactured on or after May 1, 1975 comply with the Standard.

Background. In the FEDERAL REGISTER of May 1, 1974 (39 FR 15228) the Commission published a notice of possible need for amendment of the Standard. Two of the four issues listed in that notice were:

1. The possible need to define the term "manufacture" as used in the Standard to clarify which items of children's sleepwear in the production/distribution chain on the effective date of the Standard must comply with the Standard, and

2. The possible need to clarify for the purpose of the Standard which items are to be considered "in inventory or with the trade" on the effective date of the Standard and therefore exempt from the Standard.

In the FEDERAL REGISTER of January 20, 1975 (40 FR 3276) the Commission withdrew the notice of possible need for amendment of the Standard as to these two items. Although the Commission believes it is necessary to clarify the definitions of these two terms, the Commission determined that it was not necessary to amend the Standard for this purpose because the clarification would be an interpretive rule, general statement of policy or rule of agency procedure or practice and therefore notice of proposed rulemaking is not required under the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A).

Therefore, for administrative expediency and to better provide notice to the public of the Commission policy, the Commission published in the FEDERAL REGISTER of January 20, 1975 (40 FR 3282) a two-part policy statement regarding the applicability of the Standard. The Commission invited public comment on the policy statement.

In essence the policy statement provides:

1. For the purpose of the Standard the Commission considers the manufacturing process to end at the time the item is completely assembled, all functional materials have been affixed, and labeling of a permanent nature has been permanently affixed. Thus, items of children's sleepwear which are "manufactured" on or after May 1, 1975, as defined in the policy statement, must comply with the Standard.

2. All items of children's sleepwear which are "in inventory or with the trade" on May 1, 1975 are exempt from the Standard, as provided in section 4(b) of the Flammable Fabrics Act. For domestically-made goods to gain the exemption, the manufacturing process must have ended prior to May 1, 1975. For foreign-made goods to gain the exemption, the manufacturing process must have ended and the goods must have been entered into the United States before May 1, 1975.

Comments. Four comments regarding the policy statement were received. One comment supported the policy statement. The three other comments raised separate issues.

1. One comment stated that the terms "manufactured" and "in inventory or

with the trade" should be defined in the Standard itself to make their meanings more precise and lasting than may be the case in a policy statement. The comment pointed out that the two terms describe the dividing line between regulated and nonregulated goods under the Standard.

The Commission believes it is important to clarify the definitions of the terms "manufactured" and "in inventory or with the trade" so the public and particularly those subject to the standard understand the Commission's policy on the applicability of the Standard. Therefore, the Commission published a two-part policy statement on January 20, 1975 to clarify the terms. This procedure allowed more rapid notice to the public of the Commission's policy than would have an amendment to the Standard. Although it was not legally required to do so, the Commission invited comment on the policy statement.

Therefore, although it might have been preferable to include the policy within the Standard for ease of reference, the Commission chose to provide more expeditious notice of its policy by publishing a separate policy statement. It should be noted that the time during which the policy will be of greatest concern to those subject to the Standard is during the periods immediately before and after the Standard goes into effect, since at these times the issues of when items were "manufactured" and "in inventory or with the trade" are of most concern to persons subject to the standard.

2. One comment stated that it is more appropriate for the policy statement to focus upon when the process of manufacturing begins than when it ends, because once the fabric is cut, the materials have been committed to garment manufacture. Therefore, the comment suggested that the Standard should apply to all items of children's sleepwear for which the manufacturing process begins after the Standard's effective date and the term "manufacture" should be defined as "the cutting of the fabric."

The Commission is not persuaded that a garment of sleepwear subject to the Standard should be considered to have been "manufactured" on or after May 1, 1975 if the fabric has been cut prior to that date. The result of this interpretation would be that noncomplying garments could continue to be sewn and permanent labels could be attached long after May 1, 1975, the effective date of the Standard.

The Commission believes that the generally understood definition of the term manufacture includes the entire process of producing a final object or assembling materials into a final form. Therefore, the Commission believes that a garment should not be considered to have been "manufactured" when the fabric for the garment has merely been cut. The Commission believes that persons subject to the Standard have had sufficient time to comply with the Standard during the one year period between the issuance of the Standard on May 1, 1974 and its effective date of May 1, 1975, and that therefore this policy statement will not impose undue hardship on those subject to the Standard.

It should also be noted that the Standard applies to both children's sleepwear garments in sizes 7 through 14 and to fabric or related material intended or promoted for use in such sleepwear. The definition the commenter suggests would be applicable only to garments and not to fabric intended for use in such garments.

3. An association of retailers questions whether the retailer or the manufacturer has the responsibility to attach nonpermanent affirmative labels to items of children's sleepwear manufactured during the three years after the effective date of the Standard.

The comment suggests that the policy statement clarify that the manufacturer must attach to the item or to the package enclosing the item the nonpermanent affirmative label required by the standard and proposed regulations issued under the Standard (40 FR 3279, January 20, 1975). The comment states that requiring the retailer to affirmatively label items of children's sleepwear would represent a considerable expense for the retailer and that it would not unduly burden manufacturers to attach such a label.

In amending the Standard to require affirmative labeling of complying items of children's sleepwear for a period of three years after the effective date of the Standard, the Commission has not identified whether manufacturers, distributors, or retailers have the responsibility of affixing the required labels. However, the Standard requires that the label statements must be readily visible to ultimate consumers at the point of sale.

The Commission believes it is the responsibility of the person who sells items of sleepwear to consumers to assure that the required labeling is present. However, the person who sells to consumers is free to make arrangements in the ordinary course of business with his/her supplier as to affixing the required labeling. Therefore, the Commission declines to amend the Policy Statement to place the burden for affixing labeling solely on the manufacturer.

The Commission has considered the comments received in response to the January 20, 1975 invitation for comments on the policy statement regarding the applicability of the Standard for the Flammability of Children's Sleepwear; Sizes 7 through 14 (FF 5–74) (39 FR 15228, May 1, 1974) as amended elsewhere in the FEDERAL REGISTER today. The Commission has determined that there is no need to revise its two-part Policy Statement of January 20, 1975 (40 FR 3282). Therefore, the Commission restates its two-part policy regarding the Standard for the Flammability of Children's Sleepwear; Sizes 7 through 14 (FF 5–74), as amended. The Commission will enforce the Standard in accordance with this policy.

Policy. 1. It is the policy of the Commission that all items of children's sleepwear in sizes 7 through 14 (including garments and fabric or related material intended or promoted for use in such children's sleepwear) are subject to the Standard FF 5–74 unless the manufacturing process has ended before May 1, 1975. The manufacturing process is deemed to end, for the purposes of the Standard, at the time the item is completely assembled, all functional materials have been affixed, and labeling of a permanent nature has been stamped, sewn, or otherwise permanently affixed to the item. Affixing of temporary price or promotional information or the packaging of items of sleepwear (including garments and fabrics or related material intended or promoted for use in such sleepwear) does not affect the date on which the manufacturing process is deemed to end.

2. All items of children's sleepwear in sizes 7 through 14 (including garments and fabric or related material intended or promoted for use in such children's sleepwear) which are in inventory or with the trade on the effective date of Standard FF 5–74 are exempt from the requirements of the Standard. For domestically-made items of children's sleepwear in sizes 7 through 14 to be considered "in inventory or with the trade" on the effective date of the Standard, the manufacturing process must have ended prior to May 1, 1975. For foreign-made items of children's sleepwear in sizes 7 through 14 to be considered "in inventory or with the trade" on the effective date of the Standard, the manufacturing process must have ended and the goods must have been entered into the United States before May 1, 1975.

Dated: March 18, 1975.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc.75-7456 Filed 3-20-75;8:45 am]

COUNCIL ON ENVIRONMENTAL QUALITY

ENVIRONMENTAL IMPACT STATEMENT

Availability

Environmental impact statements received by the Council on Environmental Quality from March 10 through March 14, 1975. The date of receipt for each statement is noted in the statement summary. Under Council Guidelines the minimum period for public review and comment on draft environmental impact statements is forty-five (45) days from this FEDERAL REGISTER notice of availability. (May 5, 1975) The thirty (30) day period for each final statement begins on the day the statement is made available for review from the originating agency. Back copies will also be available at cost,

from the Environmental Law Institute, 1346 Connecticut Avenue, Washington, D.C. 20036.

DEPARTMENT OF AGRICULTURE

Contact: David Ward, Acting Coordinator, Environmental Quality Activities, Office of the Secretary, U.S. Department of Agriculture, Room 331-E, Administration Building, Washington, D.C. 20250, 202-447-3853.

FOREST SERVICE

Draft

Herbicide Use on National Forests of Alaska, March 11: The action proposed involves vegetation management with the use of herbicides around forest airfields and on road, railroad, and powerline rights-of-way in Tongass and Chugach National Forests, Alaska. The herbicides proposed for use include 2,4-D, picloram, amitrole, sodium metaborate, sodium chlorate, and bromacil. The program may adversely affect non-target species. (ELR Order No. 50337.)

Eightmile-Blue Creek Units, Six Rivers National Forest (2), Humboldt County, Del Norte, Calif., March 10: The statement is a draft supplement to a draft is filed with CEQ November 14, 1974. The statement expands the socio-economic impacts from the completion of the Gasquet-Orleans Road and the current contract for the 6.6 mile segment of the road. (108 pages). (ELR Order No. 50332.)

Idaho City Unit, Boise National Forest, Boise County, Elmore, Idaho, March 10: The statement refers to the land use plan for the 366,190-acre Idaho City Planning Unit of Boise National Forest. The Unit is divided into five management areas and further into management units for protection, development, and use. Minor adverse effects from some development activities will be temporary stream sedimentation and air pollution. (ELR Order No. 50331.)

Buck Creek and North Fork Catawba River Units, Pisga, Avery and McDowell Counties, Burke, N.C., March 10: The statement concerns the 10-year management of the North Fork Catawba River Unit and the Buck Creek Unit, a total of 59,674 acres of Pisgah National Forest. Adverse impacts can result from timber harvesting, road construction and concentrated recreational use. (ELR Order No. 50335.)

Final

Cohutta Mountains, Chattahoochee National Forest, Georgia and Tennessee, March 10: The statement refers to a proposed management plan for the 49,500 acre Cohutta Mountains Unit of the Chattachoochee National Forest. Under the plan, 34,500 acres would be designated for wildland management, and the remaining 10,900 acres would be managed for a variety of resource outputs. Commercial timber harvest will average 500,000 board feet per year; requiring seven miles of new, low standard roads (74 pages). Comments made by: DOT, USDA, EPA, DOI, and State and local agencies and concerned citizens. (ELR Order No. 50328.)

Lake Fork Management Unit, Wallowa-Whitman National Forest, Baker County, Wallowa, Oreg., March 10: The statement refers to the Lake Fork Management Unit located in the Wallowa-Whitman National Forest. The proposed plan is the selection of long range resource allocation plan and management activity direction. The project area consists of 17,400 acres. Adverse impacts are soil and water quality degradation where development activities are allowed, and increased noise and air pollution due to construction and forest visitors. Comments made by: USDA, COE, DOI, and State agencies and concerned citizens. (ELR Order No. 50329.)

DEPARTMENT OF DEFENSE

ARMY CORPS

Contact: Mr. Francis X. Kelly, Director, Office of Public Affairs, Attn: DAEN-PAP, Office of the Chief of Engineers, U.S. Army Corps of Engineers, 1000 Independence Avenue SW., Washington, D.C. 20314. 202-693-6861.

Draft

Squalcum Small Boat Basin, March 10: Proposed is the enlarging of Squalicum Small Boat Basin an additional 46 acres to provide moorage space for about 725 recreational boats. The project involves the removal of 600 feet of existing breakwater, the construction of 1,500 feet of a new breakwater and the dredging of 1,000,000 cubic yards of material. Adverse impacts include the disturbance of migrating salmon and the dredging of wetlands (Seattle District). (ELR Order No. 50336.)

Menominee Harbor and River, Maintenance Dredging, Michigan and Wisconsin, March 14: Proposed is the maintenance dredging to be performed every five years to maintain authorized depths of the harbor. In conjunction with the dredging, a diked disposal will be constructed. Adverse impacts include disruption of the benthic community, reintroduction of toxic flood plain impact, destruction of wildlife habitat, and health and safety hazards (Chicago District). (ELR Order No. 50347.)

Final

McClellan-Kerr Arkansas Navigation System, Arkansas, March 11: The statement refers to the continued operation and maintenance of the McClellan-Kerr Arkansas River Navigation System. Adverse impact of system operation includes the effects of hydroelectric power production methods on fish and other aquatic life, and those of temporary turbidity from dredging (Little Rock District). Comments made by: USDA, EPA, DOI, and State agencies. (ELR Order No. 50341.)

Indian River Inlet, Project Maintenance, March 12.

Draft

Coos Bay (supplement), Coos County, Oreg.: Notice of availability of this draft supplement was previously published by the Council in the FEDERAL REGISTER issue of March 7, 1975. Due to incomplete distribution of the supplement for review, that notice is hereby withdrawn. The notice printed below is to be considered the official notice of availability for purposes of determining the 45-day period for review and comment.

Proposed is the construction of a channel across the outer bar of Coos Bay 45 feet deep and 300 feet wide, and a 15-mile long inner channel. The project also includes the enlarging of existing turning basins. Construction will inovlve blasting, dredging, and disposal of an estimated 8,550,000 cubic yards of material at sea, in-Bay, and on land. Construction disruption and disturbance of 125 acres of ocean and estuarine bottom area and 437 acres of land disposal area, would result. When the project is completed, the area will require about 1 to 2 months additional dredging time each dredging interval (Portland District). (ELR Order No. 50267.)

DEPARTMENT OF COMMERCE

Contact: Dr. Sidney R. Galler, Deputy Assistant Secretary for Environmental Affairs, Department of Commerce, Washington, D.C. 20230, 202-967-4335.

Draft

Coastal Zone Management Program, Washington, March 14: The statement concerns the Coastal Zone Management Program application of the State of Washington. Approval and implementation of the program will restrict or prohibit land and water uses in certain parts of the Washington coast, while promoting and encouraging development and use activities in other parts. This may affect property values, property tax revenues, and resource extraction and exploration. (ELR Order No. 50348.)

Sussex County, Delaware: The project involves continuing operation and maintenance activities in the navigable portions of the Indian River Inlet and Bay. Included in the project are channel dredging, repair of jetties, and spoil disposal on existing sites. Dredging will produce temporary local turbidity, which may release trapped pollutants into the water and disturb marine biota. Established vegetation will be destroyed at the disposal sites (Philadelphia District). Comments made by: DOC, USDA, EPA, HUD, and State agencies. (ELR Order No. 50342.)

DEPARTMENT OF HUD

Contact: Mr. Richard H. Broun, Acting Director, Office of Environmental Quality, Room 7206, 451 7th Street SW., Washington, D.C. 20410. 202-755-6295. Section 104(h).

Draft

San Jose Community Development, Santa Clara County, Calif., March 13: The statement concerns the Housing and Community Development plan for the City of San Jose. Half of the $18,577,000 block grant will be spent to continue urban renewal projects already underway. The remainder will be spent on rehabilitation of older neighborhoods, facilities for child care and the handicapped, and low-income housing scattered throughout the city. Demolition of some existing structures and displacement of families will result (233 pages). (ELR Order No. 50344.)

DEPARTMENT OF INTERIOR

Contact: Mr. Bruce Blanchard, Director, Environmental Project Review, Room 7260, Department of the Interior, Washington, D.C. 20240. 202-343-3891.

BONNEVILLE POWER ADMINISTRATION

Draft

Ashe-Pebble Springs 500-kV Line (supplement), Washington and Oregon, March 10: The statement, a supplement to the Proposed Program for Fiscal Year 1976 final eis, concerns the construction of an 80-mile long, 500-kV single circuit transmission line from Ashe Substation in the northeastern portion of the AEC Hanford Reservation to a proposed Pebble Springs Substation near Arlington, Oregon. The project will require acquisition of from 49 to 58 miles of new right-of-way, and in some areas, especially at the Columbia River where extremely tall towers may be required, degradation of the visual environment will result. (ELR Order No. 50330.)

Final

BPA Proposed Fiscal Year 1976 Program, March 14: The statement refers to BPA's proposed program for FY 1976, including new facility additions and modifications. The states of Washington, Oregon, Idaho, Montana, and Wyoming are involved. Among program impacts are: the conversion of 2,200 acres of forest land to use as transmission line right-of-way; the effects of herbicide use (for vegetation control on rights-of-way); visual impact from transmission line construction; and effects on air and water quality. Comments made by: DOI, USDA, HUD, EPA, AEC, FPC, AHP, COE, and State and local agencies. (ELR Order No. 50349.)

GENERAL SERVICES ADMINISTRATION

Contact: Mr. Andrew E. Kauders, Executive Director of Environmental Affairs, General Services Administration, 18th and F Streets, N.W., Washington, D.C. 20405, (202) 343-4161.

Final

Federal Office Building and Court House, Helena, Lewis and Clark County, Mont., March 11. The statement refers to the proposed construction of a Federal Office Building and Court House in Helena, Montana. Three hundred and twenty-five off-street parking spaces will be provided to accommodate employee, visitor and official vehicles. The structure will house approximately 450 employees and have a net usable area of 90,000 sq. ft. There will be short-termed adverse impacts normally associated with construction (71 pages). Comments made by: AHP, DOI, USDA, COE, AEC, HUD, EPA, State, and local agencies. (ELR order No. 50338.)

Federal Building and Courthouse, Columbia, Richland County, S.C. Proposed is the construction of a new Federal Building and U.S. Courthouse with parking and vehicle maintenance facilities. The project will encompass 464,250 square feet, and will include parking for 595 cars. The building will replace four government-owned buildings and 19 leased locations. There will be adverse impact from construction disruption (105 pages). Comments made by: COE, DOC, AHP, EPA, DOI, DOT, USDA, FPC, HEW, one State agency. (ELR order No. 50339.)

DEPARTMENT OF LABOR

Draft

Inorganic Arsenic, Proposed Regulation. The statement concerns the Occupational Safety and Health Administration's proposed regulation of inorganic arsenic. The regulation would specify maximum levels of arsenic to which employees could be exposed. The proposed regulation would increase worker safety but at the same time, decrease worker efficiency and result in higher prices of products produced with inorganic arsenic (82 pages). (ELR order No. 50350.)

NUCLEAR REGULATORY COMMISSION

Contract: Mr. A. Giambusso, Director of Division of Reactor Licensing, P-722, NRC, Washington, D.C. 20545. (301) 973-7373.

Final

Washington Public Power System, Units 1 & 4, Benton County, Wash. Proposed is the issuance of construction permits to the Washington Public Power Supply System for the construction of WPPSS Nuclear Projects No. 1 and 4 on ERDA's Hanford Reservation. Each station will produce up to 3600 MWt and 1218 MWe. A predicted maximum level of 3760 MWt (1267 MWe) is anticipated at a future date. Cooling towers will be constructed, and water will be obtained from and discharged to the Columbia River. Comments made by: USDA, AHP, HUD, DOT, EPA, DOI. (ELR order No. 50346.)

DEPARTMENT OF TRANSPORTATION

Contact: Mr. Martin Convisser, Director, Office of Environmental Affairs, 400 7th Street, S.W., Washington, D.C. 20590. (202) 426-4357.

FEDERAL HIGHWAY ADMINISTRATION

Draft

U.S. 50, Salida to Coaldale, Chaffee and Fremont Counties, Colo. Proposed is the construction of a 2-lane, 19-mile segment of U.S. 50 between Salida and Coaldale in Central Colorado. Approximately 170 acres of BLM and grazing land would be committed to the project. Adverse impacts include at least two minor encroachments in the Arkansas River and disruption, noise, and air pollution of construction (225 pages). (ELR order No. 50333.)

U.S. 6 Bypass, Council Bluffs, Pottawattamie County, Iowa. The statement concerns a proposal to construct a 1.2-mile long bypass of U.S. 6. The roadway would have two lanes in each direction separated by a 16-foot median. The project would displace up to 93 families and 53 businesses (107 pages). (ELR order No. 50334.)

I-94, Hennepin County, Minn. Proposed is the construction of a 3.7 mile, 8-lane section of I-94 from U.S. 12/I-394 northerly to 40th Ave. North in Hennepin County, Minn. The project will require the acquisition of 34 acres of land in addition to the 163 acres already acquired, and will displace an additional 75 residential units and 22 businesses. FHWA design noise levels cannot feasibly be met for all land use categories; therefore exceptions will be requested (90 pages). (ELR order No. 50340.)

Final

Loop 436, U.S. 59, Panola County, Tex. The project involves the construction of Loop 436, which will extend for 6.1 miles from U.S. 59 north of Carthage to U.S. 59 south of Carthage. Adverse impacts are the acquisition of land for right-of-way, the displacement of six families, and negative impacts normally associated with construction (70 pages). Comments made by: DOT, HLW, USDA, 2COE, 2DOI, 2 State agencies. (ELR order No. 50345.)

U.S. COAST GUARD

Kodiak Sewage Disposal System, Alaska. A sewage disposal system is proposed for U.S.CG Base Kodiak. The system will consist of collection and treatment facilities in accordance with the Federal Water Pollution Control Act, as amended. Sewage is presently collected and discharged, without treatment, directly into tidal waters of St. Paul Harbor. Comments made by: DOI, USDA, USN, HEW, USCG, EPA, State agencies. (ELR order No. 50343.)

GARY L. WIDMAN,
General Counsel.

[FR Doc.75-7405 Filed 3-20-75;8:45 am]

ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

HERCULES, INC.

Intent to Grant Exclusive Patent License

Notice is hereby given of an intent to grant to Hercules, Inc. of Wilmington, Delaware, an exclusive license to manufacture, use, and sell in the United States the invention described in U.S. Patent No. 3,414,570, entitled "N_2, N_4, N_6 Tripicrylmelamine", issued December 3, 1968 to the United States of America as represented by the U.S. Atomic Energy Commission, now the U.S. Energy Research and Development Administration. A copy of the subject patent can be obtained from the U.S. Patent and Trademark Office, Washington, D.C. 20231. The proposed license will have a duration of five years, will be royalty bearing, and will contain other terms and conditions to be negotiated by the parties in accordance with Energy Research and Development Administration patent licensing regulations, Title 10 CFR Part 781. ERDA will grant the license unless within sixty days of this notice the Assistant General Counsel for Patents, Energy Research and Development Administration, Washington, D.C. 20545, receives in writing any of the following together with supporting documents:

(i) A statement from any person setting forth reasons why it would not be in the best interest of the United States to grant the proposed license; or

(ii) An application for a non-exclusive license to manufacture, use, or sell the invention in the United States in accordance with Title 10 CFR 781, in which applicant states that he has already brought the invention to practical application or is likely to bring the invention to practical application expeditiously.

The Assistant General Counsel for Patents will review all written responses to this notice and will provide opportunity for a hearing before granting the exclusive license.

Dated at Germantown, Maryland this 17th day of March, 1975.

JAMES E. DENNY,
Assistant General Counsel for Patents.

[FR Doc.75-7495 Filed 3-20-75;8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 348-5]

DISCHARGE OF POLLUTANTS

Administrative Order

In accordance with section 101(e) of the Federal Water Pollution Control Act Amendments of 1972 (33 U.S.C. 1251(e)) which encourages public participation in the enforcement of any plan established by the Administrator, notice is hereby given that an agreement has been reached between Jack E. Ravan, Regional Administrator, Region IV, and Louisiana Land and Exploration Company, concerning certain property in Mobile, Alabama. The agreement requires that Louisiana Land and Exploration Company:

1. Provide culverts through the road or causeway constructed between the crude fractionation unit and Chickasaw Creek for the purpose of insuring adequate circulation of waters in accordance with the results of a hydrological survey and in consultation with EPA.

2. Place dredge spoil resulting from duly permitted dredging of Chickasaw Creek in the spoil disposal site agreed upon with EPA, to wit: the 46 acres, more or less, consisting of ridges ranging to elevations of 17 feet above sea level datum of 1929, and including an isolated pocket of swamp containing no more than 16 acres of wetland vegetation, situated in the northwest quarter of Section 14, Township 3 South, Range 1 West.

3. Insure that excess fresh water leaves the spoil disposal site in sheet flow through a natural outlet as shown on the survey transmitted to EPA by letter dated February 26, 1975, from Walk, Haydel & Associates.

4. Contact EPA immediately for a determination of alternate disposal methods if salt water is detected in the effluent from the disposal site, as in accordance with the monitoring program outlines in the Corps of Engineers' permit and EPA's letter of March 6, 1975, to the Corps of Engineers. Such methods may include construction of a dike at the outlet and pumping the return water via pipeline to Chickasaw Creek, if salinity is deemed excessive and potentially harmful to vegetation.

5. Meet applicable State water quality standards if return water is discharged directly into Chickasaw Creek.

6. Insure that total suspended solids in the effluent discharged through the outlet depression does not exceed 100 mg/l at any time. Readings in excess of this limit will require immediate implementation of remedial or preventive measures to achieve compliance.

7. Obtain approval from EPA for future discharge of dredged or fill material in any wetland area within the disposal site that is not affected by the dredged spoil disposal.

8. May discharge fill material to create a road or causeway from U.S. Highway No. 43 to the fractionation facility if adequate bridges and/or culverts are provided to insure proper circulation of water in the adjacent swamp.

The United States Environmental Protection Agency, Region IV, will receive, before close of business on March 31, 1975, written comments relating to the agreement. Comments should be addressed to Director, Enforcement Division, Environmental Protection Agency, 1421 Peachtree Street, NE., Atlanta, Georgia 30309, and refer to AO Number 74-42(w).

The order may be examined at the office of the United States Environmental Protection Agency, Region IV, at the above-referenced address: U.S. Army, Corps of Engineers, Mobile District, Post Office Box 2288, 109 St. Joseph Street, Mobile, Alabama 36628; U.S. Fish & Wildlife Service, Post Office Box 4277, St. Andrews Station, 1008 Beck Avenue, Panama City, Florida 32401.

A copy of the Order may be obtained in person or by mail from the Environmental Protection Agency, Region IV, office.

Dated: March 13, 1975.

JACK E. RAVAN,
Regional Administrator, Region IV.

[FR Doc.75-7342 Filed 3-20-75;8:45 am]

[FRL 348-3]

BASF WYANDOTTE CORPORATION

Renewal of Temporary Tolerance

BASF Wyandotte Corp., 100 Cherry Hill Road, Parsippany, N.J. 07054, was granted a temporary tolerance for residues of the herbicide fluchloralin [*N*-(2-chloroethyl) - α,α,α - trifluoro - 2,6 - dinitro-*N*-propyl-*p*-toluidine] in or on the raw agricultural commodity cottonseed at 0.05 part per million in connection with Pesticide Petition No. 3G1395 (Notice was published in FEDERAL REGISTER of February 26, 1974 (39 FR 7483)). This tolerance expired February 20, 1975.

The company has requested a 1-year renewal of the temporary tolerance for residues of the herbicide in or on cottonseed at 0.05 part per million to obtain additional experimental data.

It is concluded that such renewal of the temporary tolerance will protect the public health. A condition under which this temporary tolerance is renewed is that the herbicide will be used in accordance with the temporary permit which is being issued concurrently and which provides for distribution under the BASF Wyandotte Corp. name.

This temporary tolerance expires March 17, 1976. Residues remaining in or on the above raw agricultural commodity after expiration of this tolerance will not be considered actionable if the pesticide is legally applied during the term, and in accordance with provisions of the temporary permit/tolerance.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 516; (21 U.S.C. 346a(j))), the authority transferred to the Administrator of the Environmental Protection Agency (35 FR 15623), and the authority delegated by the Administrator to the Deputy Administrator for Pesticide Programs (39 FR 18805).

Dated: March 17, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-7338 Filed 3-20-75;8:45 am]

[FRL 348-1]

ELANCO PRODUCTS CO.

Establishment of Temporary Tolerances

Elanco Products Co., Div. of Eli Lilly & Co., P.O. Box 1750, Indianapolis, IN 46206, submitted a petition (PP 5G1563) requesting establishment of temporary tolerances for negligible residues of the herbicide oryzalin (3,5-dinitro-*N*⁴,*N*⁴-dipropylsulfanilamide) in or on the raw agricultural commodities almond hulls, citrus fruits, figs, nuts, pistachios, pome fruits, small fruit, and stone fruit at 0.05 part per million.

It has been determined that the temporary tolerances of 0.05 part per million for negligible residues of the herbicide in or on the above raw agricultural commodities will protect the public health. They are therefore established as requested on condition that the herbicide be used in accordance with the temporary permit being issued concurrently and which provides for distribution under the Elanco Products Co. name.

These temporary tolerances expire March 17, 1978. Residues remaining in or on the above raw agricultural commodities after expiration of these tolerances will not be considered actionable if the pesticide is legally applied during the term, and in accordance with provisions of the temporary permit/tolerances.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 516; (21 U.S.C. 346a(j))), the authority transferred to the Administrator of the Environmental Protection Agency (35 FR 15623), and the authority delegated by the Administrator to the Deputy Assistant Administrator for Pesticide Programs (39 FR 18805).

Dated: March 17, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-7339 Filed 3-20-75;8:45 am]

[FRL 348-2]

MONSANTO CO.

Establishment of Temporary Tolerance

Monsanto Co., 800 N. Lindbergh Boulevard, St. Louis, MO 63166, submitted a petition (PP 5G1561) requesting establishment of a temporary tolerance for combined residues of the herbicide glyphosate (*N*-(phosphonomethyl) glycine) and its metabolite aminomethylphosphonic acid in or on grapes at 0.2 part per million.

It has been determined that this temporary tolerance will protect the public health. It is therefore established on condition that the herbicide be used in accordance with the temporary permit being issued concurrently and which provides for distribution under the Monsanto Co. name.

This temporary tolerance expires March 17, 1976. Residues remaining in or on the above raw agricultural commodity after expiration of this temporary tolerance will not be considered actionable if the pesticide is legally applied during the term, and in accordance with provisions of the temporary permit/temporary tolerance.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 516; (21 U.S.C. 346a(j))), the authority transferred to the Administrator of the Environmental Protection Agency (35 FR 15623), and the authority delegated by the Administrator to the Deputy Assistant Administrator for Pesticide Programs (39 FR 18805).

Dated: March 17, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-7340 Filed 3-20-75;8:45 am]

[FRL 347-8]

PREVENTION OF SIGNIFICANT AIR QUALITY DETERIORATION

Availability of Technical Support Document

On December 5, 1974, (39 FR 42510) the Administrator of the Environmental

Protection Agency (EPA) promulgated final regulations for prevention of significant air quality deterioration in each state. The preamble to that action indicated that a detailed explanation of the technical and policy considerations which form the basis for the regulations was under preparation. This document, entitled "Technical Support Document—EPA Regulations for Preventing the Significant Deterioration of Air Quality,"[1] is now available for public inspection at EPA's Regional Offices and EPA's Freedom of Information Center, 401 M Street SW., Washington, D.C. 20460, and will be available shortly for general distribution through the National Technical Information Service, 5258 Port Royal Road, Springfield, Virginia 22151. Several of the studies and reports referenced in this document are quite voluminous and are not available for general distribution; however, they are available for public inspection at the Freedom of Information Center at the above address.

Dated: March 17, 1975.

ROGER STRELOW,
Assistant Administrator for Air and Waste Management.

[FR Doc.75-7343 Filed 3-20-75;8:45 am]

[FRL 348-4]

SHELL CHEMICAL CO.

Renewal of Temporary Tolerance

Shell Chemical Co., Suite 200, 1025 Connecticut Avenue NW., Washington, D.C. 20036, was granted temporary tolerances for residues of the herbicide 2-[[4-chloro-6-(ethylamino)-s-triazin-2-yl]-amino]-2-methylpropionitrile in or on the raw agricultural commodities cottonseed and soybeans at 0.05 part per million on November 5, 1973, in connection with Pesticide Petition No. 3G1377 (notice was published in the FEDERAL REGISTER of November 12 and December 7, 1973 (38 FR 31203 and 38 FR 33797)). These temporary tolerances expired November 6, 1974.

The company has requested a one-year renewal of the temporary tolerance for residues of the herbicide in or on soybeans at 0.05 part per million to obtain additional experimental data.

It is concluded that such renewal of the temporary tolerance will protect the public health. A condition under which this temporary tolerance is renewed is that the herbicide will be used in accordance with the temporary permit which is being issued concurrently and which provides for distribution under the Shell Chemical Co. name.

This temporary tolerance expires March 17, 1976. Residues remaining in or on the above raw agricultural commodity after expiration of this tolerance will not be considered actionable if the pesticide is legally applied during the term, and in accordance with provisions of the temporary permit/tolerance.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 516; (21 U.S.C. 346a(j))), the authority transferred to the Administrator of the Environmental Protection Agency (35 FR 15623), and the authority delegated by the Administrator to the Deputy Assistant Administrator for Pesticide Programs (39 FR 18805).

Dated: March 17, 1975.

EDWIN L. JOHNSON,
Acting Deputy Assistant Administrator for Pesticide Programs.

[FR Doc.75-7341 Filed 3-20-75;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 20196, File Nos. BPH-8711 and 20197; File No. BPH-8725]

A. C. ELLIOTT, JR.; MELVIN PULLEY

Memorandum Opinion and Order Enlarging Issues

1. This proceeding involves the mutually exclusive applications of A. C. Elliott, Jr. (Elliott), Quitman, Mississippi and Melvin Pulley (Pulley), Quitman, Mississippi, for a new FM broadcast station at Quitman, Mississippi. The Review Board now has before it a petition to enlarge issues, filed January 6, 1975, by Elliott,[1] requesting the addition of the following issues:

a. To determine the facts and circumstances surrounding the apparent alteration of the December 14, 1974 affidavit of Ernest Moore and its submission to the Commission by Melvin Pulley;

b. To determine, in light of the evidence adduced under the foregoing issue, the effect upon Melvin Pulley's requisite and/or comparative qualifications to be a Commission licensee.

2. Petitioner contends that good cause exists to warrant consideration of his late filed motion, because the document upon which this motion is based was submitted as part of Pulley's December 20, 1974, supplement to an opposition to a petition to enlarge issues, filed October 23, 1974, by Elliott.[2] As an attachment to his December 20, 1974, supplement, Pulley included, inter alia, an affidavit of Ernest Moore, a community leader interviewee, purportedly sworn to and acknowledged before Barbara G. Mayo, a notary public, on December 14, 1974. The affidavit reads as follows:

I do remember talking to Melvin Pulley about community needs and problems. During Nov. Dec. 1973.[3]

Elliott asserts that this affidavit, the first sentence of which is typewritten, while the second sentence is handwritten, had been altered by Pulley without the knowledge of the affiant and then submitted by Pulley to the Commission. In support of this allegation, Elliott submits an affidavit dated December 28, 1974, in which Moore[4] states: (1) That his December 14, 1974, affidavit had been altered without his knowledge by someone writing in the words "During Nov. Dec. 1973;" (2) that upon being asked to sign a statement acknowledging an interview, Pulley had not asked him about any dates; and (3) that he does not remember the exact date of his interview. Also submitted is an affidavit dated December 30, 1974, in which Elliott relates his conversation with Moore concerning the circumstances surrounding the preparation of the latter's December 14, 1974, affidavit; Elliott contends that on or about December 13, 1974, Moore signed a statement to the effect that he remembered talking to Melvin Pulley about community needs, that Pulley returned to Moore's home the following day accompanied by a notary public who, while remaining in Pulley's automobile, asked Moore if he had signed a statement for Pulley, and that Moore replied in the affirmative without being shown the statement or having his attention drawn to the dates.

3. In his opposition, Pulley maintains that the instant petition is a deliberate and willful attempt on the part of Elliott to deceive the Commission. Elliott's contention that Pulley had Moore's December 14, 1974 statement notarized after Moore had signed it and returned the following day with the notary, is false, Pulley avers. Rather according to Pulley, he asked Moore to sign the original typewritten statement and Moore did so; subsequently, he (Pulley) added the handwritten dates in the presence of the notary, Mrs. Barbara G. Mayo. Pulley then took Mrs. Mayo to Moore, at which time, she assured herself that Moore had signed the December 14, 1974 statement and that he acknowledged the handwritten dates; and then, Mrs. Mayo notarized Moore's statement and recited the above-mentioned procedure in her jurat. In support of this position, Pulley submits an affidavit, in which he states: (1) That on December 14, he and Barbara G. Mayo went to the home of Ernest Moore; (2) that Moore was introduced to Mrs. Mayo and was told that she was a notary public; (3) that Moore was asked to read the statement "I do remember talking to Melvin Pulley about community needs

[1] Filed as part of the original document.

[1] The Board also has before it the following related pleadings: (a) opposition, filed January 20, 1975, by Pulley; (b) comments, filed January 21, 1975, by the Broadcast Bureau; and (c) reply, filed January 31, 1975, by Elliott.

[2] Elliott's motion was acted on by Review Board Memorandum Opinion and Order, FCC 75R-48, ____ FCC 2d ____, released February 10, 1975. See specifically paragraph 6 thereof.

[3] With his petition to enlarge issues, filed October 23, 1974, Elliott had submitted an affidavit dated June 4, 1974, and notarized on September 17, 1974, in which Ernest Moore stated that he had not been interviewed by Pulley.

[4] Moore's December 28, 1974, affidavit was notarized on December 30, 1974.

and problems;"[5] (4) that Mrs. Mayo instructed him [Pulley] to make certain that Moore acknowledged the handwritten dates; (5) that Moore stated that he had signed the statement; and (6) that Moore acknowledged the written in dates of November, December 1973. To substantiate his own affidavit, Pulley submits Mrs. Mayo's affidavit, in which she states, *inter alia*, that on December 14, 1974, Moore was asked if he recognized a typewritten statement with a handwritten date; that Moore was then handed the statement; and that Moore stated "that that was the date," that it was his signature, and that he remembered signing it.

4. In reply, Elliott submits an affidavit dated January 24, 1975, in which Moore states that the words "during Nov. Dec. 1973" in his December 14, 1974 affidavit were not pointed out to him at any time by either Pulley or the notary public. However, even assuming that Pulley's explanation of the procedure which he followed to obtain Moore's affidavit is accepted, Elliott reasons, the fact remains that this questionable procedure was concealed from the Commission when Pulley submitted Moore's affidavit to it. Elliott contends that Pulley led the Commission to believe that Moore had signed the December 14, 1974, statement as it was submitted to the Commission. Thus, maintains Elliott, a serious question arises as to Pulley's candor, and the requested issues should be specified.[6]

5. The Review Board will add the requested issues. First, petitioner has shown good cause for the delay in filing, as required by section 1.229(b) of the Commission's rules. The instant petition, which is based upon Moore's December 14, 1974 affidavit, was filed on January 6, 1975, just two and one-half weeks after Moore's affidavit was submitted to the Commission. With regard to the merits of the instant petition, there is a serious conflict in the various affidavits submitted by the parties. Specifically, there is a direct conflict between Ernest Moore's assertion that the addition of the handwritten words, "during Nov. Dec. 1973," to his December 14, 1974 affidavit had not been brought to his attention at any time by either Melvin Pulley or the notary public and the statements of Melvin Pulley and Barbara G. Mayo, who is the notary public in question, to the effect that Pulley directed Moore's attention to the handwritten dates. In the Board's view, the conflict in the affidavits necessitates the addition of the requested issues. See *Rosemor Broadcasting Company, Inc.*, 46 FCC 2d 1132, 30 RR 2d 360 (1974); and *Christian Voice of Central Ohio*, 26 FCC 2d 76, 20 RR 2d 389 (1970). However, not only is there a serious question as to whether Pulley submitted a substantively false affidavit (the Moore affidavit) to the Commission,[7] but there is also a question as to whether Pulley knowingly submitted a false jurat, executed by Mrs. Mayo, to the Commission.[8] Since the Board is unable to resolve these issues on the basis of the pleadings, an evidentiary inquiry into all the facts surrounding the procurement and submission of the affidavit in question is appropriate. See *Rosemor Broadcasting Company, Inc., supra.*

6. Accordingly, *It is ordered*, That the petition to enlarge issues, filed January 6, 1975, by A. C. Elliott, Jr., *is granted;* and that the issues in this proceeding *are enlarged* as follows:

(a) To determine whether Melvin Pulley has made misrepresentations or abused Commission processes or been lacking in candor with respect to a document submitted to the Commission purporting to be Ernest Moore's December 14, 1974 affidavit.

(b) To determine, in the light of the evidence adduced pursuant to the above issue, whether Melvin Pulley possesses the basic or comparative qualifications to be a Commission licensee; and

7. *It is further ordered*, That the burden of proceeding with the introduction of evidence under the issues added herein *shall be* on A. C. Elliott, Jr. and the burden of proof under these issues *shall be* on Melvin Pulley.

Adopted: March 13, 1975.

Released: March 18, 1975.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7410 Filed 3-20-75;8:45 am]

[5] In his opposition pleading, Pulley contends that his attached affidavit affirmatively shows that Moore read the typewritten statement with the handwritten dates. However, in that affidavit, Pulley merely states that Moore was asked to read the statement. There is no indication whether or not Moore actually read it.

[6] The Board does not agree with Elliott's contention in this regard. If Moore's affidavit was properly acknowledged by him, then the Commission would have no interest in the exact procedure used to procure that affidavit.

[7] "It is * * * fundamental to the regulatory process that the Commission be able to rely on the representations of those whom it licenses and those who come before it seeking licenses. Therefore, the Commission must demand candor from those who come before it and must refuse to tolerate deliberate misrepresentations." *Nick J. Chaconas*, 28 FCC 2d 231, 233, 21 RR 2d 576, 579 (1971); reconsideration denied, 35 FCC 2d 698, 24 RR 2d 811 (1971); affirmed 486 F. 2d 1314 (D.C. Cir. 1973). See also *FCC* v. *WOKO, Inc.*, 329 U.S. 223 (1946).

[8] The submission of a false jurat to the Commission is a serious matter and has, in the past, been the subject of severe sanction by the Board. See *3 J's Broadcasting Co.*, 41 FCC 2d 664, 27 RR 2d 1396 (1973), review denied, FCC 74-86, released January 30, 1974. See also *WIOO, Inc.*, 37 FCC 2d 740, 25 RR 2d 567 (1972).

[Docket No. 20376; FCC 75-253]

AMERICAN TELEPHONE AND TELEGRAPH CO.

Charges for Interstate Telephone Service; Memorandum Opinion and Order Instituting Investigation and Hearing

1. The Commission has before it for consideration proposed tariff revisions filed by the American Telephone and Telegraph Company (AT&T) on January 3, 1975, calling for generally increased rates for the Bell System's interstate services, to be effective March 4, 1975. The proposed revisions are to: AT&T's Tariffs FCC No. 263, Long Distance Message Telecommunications Service (MTS); No. 259, Wide Area Telecommunications Service (WATS); and No. 260, Private Line Service. In its letter transmitting the revised tariff schedules and in information furnished in support of the proposed rate changes, AT&T states that its rate adjustments have been designed to produce a 7.2 percent net increase in Bell's interstate revenues on a future test year basis (or about $717 million annually before taxes), a 13.5–14.5 percent return on equity, and an overall rate of return of 10½ to 11 percent on Bell's interstate investment.

2. We have received numerous formal and informal objections to such filing[1] seeking its rejection or designation for formal investigation with an accounting order and suspension of the effective date of the revised tariff schedules for the maximum period permitted under present law.

[1] Formal pleadings were timely filed by the following parties: City of Chicago ("Chicago"), Commonwealth of Pennsylvania ("Pennsylvania"), The Council on Wage and Price Stability (the "Council"), the Executive Agencies of the United States, (the "Executive Agencies"), The National Small Business Association ("NSBA"), American Broadcasting Companies, Inc., CBS Inc., and National Broadcasting Company, Inc. (the "Network Companies"), The Intermountain Network, Inc. ("IMN"), Mutual Broadcasting System, Inc. ("Mutual"), The American Newspaper Publishers Association ("ANPA"), Associated Press ("AP"), Commodity News Services, Inc. ("CNS"), United Press International, Inc. ("UPI"), The Ad Hoc Telecommunications Committee (the "Ad Hoc Committee"), Aeronautical Radio, Inc. ("ARINC"), Aerospace Industries Association of America, Inc. ("AIA"), Air Transport Association of America ("ATA"), National Data Corporation ("National Data"), Data Transmission Company ("Datran"), and our Common Carrier Bureau's Trial Staff in Docket No. 19129 (the "Trial Staff"). Also before us are timely filed objections by the People of the State of California and the Public Utilities Commission of the State of California ("California"). In addition, numerous informal objections have been received and letters and telegrams expressing interest in the proposed rate increases and any hearings to be held with respect thereto, or commenting on the merits of the proposed rates. AT&T timely filed a reply on February 5, 1975. Appendix A, a list of the pleadings filed, is filed as part of the original document.

3. The tariff revisions would result in generally increased MTS rates for service within the United States, except Hawaii and Alaska, and between the United States, except Hawaii and Alaska, and Canada and Mexico.[2] They would result in generally increased rate levels for WATS and Private Line services.

4. Revisions in MTS tariff schedules of charges and conditions of service within the United States are designed to provide for a 7.2 percent increase in revenues and include the following changes: (1) A one-minute initial period for all customer dialed station calls in all time periods; (2) a 35 percent discount for all customer dialed station calls in the evening rate period; and (3) a 60 percent discount for all customer dialed station calls in the night and weekend rate periods. Proportionately larger increases in long-distance rates have been placed on those services where the costs are relatively greater, namely, on person-to-person calls, operator handled station calls, and calls of short mileages. Revisions in the U.S.-Canada proposed schedule include: (1) Introduction of a dial station-to-station rate for the Day and Evening rate periods in addition to the present Dial Station-to-Station Night rate period; (2) establishment of a one-minute initial rate period for all time periods with a 10 cent minimum charge per message; (3) discounts of 35 percent for the Evening and 60 percent for the Night rate periods, applicable to Dial Station-to-Station initial periods and additional minutes for all classes of service; (4) a uniform 24-hour rate for an initial 3-minute period for all Operator Station-to-Station and Person-to-Person messages; (5) common additional minute rates for all classes of services; (6) reduction of the number of mileage rate steps from 27 to 23; (7) elimination of the fifteen cent surcharge for collect calls; (8) a night discount rate period for additional minutes for Operator Station-to-Station and Person-to-Person messages and extension of the Night reduced rate period from 6 a.m. to 8 a.m.; and (9) general increases and decreases in the different classes of service. Revisions in the U.S.-Mexico proposed schedule include: (1) A Simple Station Rate Class for all hours of the day and all days of the week. Simple Station Service would apply to station messages dialed by the customer or station messages that could be dialed by the customer if facilities were available; (2) a uniform 24-hour rate for the initial 3-minute period for all Person-to-Person messages; (3) a common additional minute rate for all call classes beginning at 245 miles for Day calls and 86 miles for Evening calls; (4) reduction of the number of mileage rate steps from 27 to 21; (5) elimination of the surcharge for collect calls; (6) modification of the Evening rate period from 8 p.m. to 11 p.m., and extension of the Night rate period to 8 a.m., and (7) general increases and decreases in the different classes of service.

5. Revisions in the WATS schedules would provide for: (1) Increased rates for measured time service for distances up to 900 miles and decreased monthly rates for measured time service for distances beyond 900 miles; (2) increased monthly rates for Full Business Day Service for distances up to 1,600 miles, and decreased monthly rates for Full Business Day Service beyond 1,600 miles; and (3) with the exception of installation, move and conversion charges for WATS and extension stations, all other rates and charges in Tariff F.C.C. No. 259 (e.g., monthly rates and installation charges for connecting arrangements) would be increased 7.8 percent and rounded in the same manner as the equipment rates for Private Line Service.

6. Bell alleges that its proposed revisions in Private Line Services will increase all domestic rate elements in Tariff F.C.C. No. 260 by 7.8 percent, except the rates for television service (Series 7000 services) and any items that were filed to become effective after September 1, 1974. After application of the 7.8 percent increase, each rate element, with the exception of rates for interexchange channel mileage, would be rounded to the nearest five cents for items up to $100 and to the nearest dollar for items of $100 or more. Rates for Telpak (Series 5000) and wide band high speed data and facsimile (Series 8000) base capacity would be rounded to the nearest five cents while all other interexchange channel mileage rates would be rounded to the nearest cent.

7. AT&T explained its reasons for seeking the proposed increased rates for its interstate services in a letter dated January 3, 1975 to Chairman Wiley.[3] It therein stated:

> economic and financial circumstances now require an interstate earning level of 10½ to 11 percent on investment, in order to sustain the financial integrity of the Bell System and to permit the attraction of necessary debt and equity capital under prevailing conditions in the money markets.

AT&T estimates that the charges for about 30 percent of all MTS calls will be lower; and that by altering their calling habits, customers may take advantage of further savings in their long-distance calls. According to AT&T, its pricing innovations will also promote more efficient use of the telephone network, facilities improvements in productivity, and produce substantial cost savings.

8. AT&T stated that the proposed increases in WATS and Private Line rates were filed to achieve about the same proportionate increase in the revenue levels for those services as that which would be derived from MTS. The WATS rate changes are designed to maintain approximately the same rate relationships that now exist between WATS and MTS. According to AT&T's January 3 letter:

> In view of the pendency of several Commission proceedings relating to the rate structure of the private line services, we are not now filing structural revisions within those services. Rather for purposes of this overall rate increase filing, we are generally applying the same percentage increase to the various rate elements in the private line services * * *
>
> The filed rate changes are designed to produce increased revenues from Bell's interstate services of about $717 million per year and, together with associated cost savings, to improve net earnings after taxes by about $433 million per year at the 1975 level of business.
>
> These rate changes are of critical and immediate importance because of the extraordinary financial and economic conditions currently affecting Bell's cost of operations and cost of capital.

AT&T's filing is comprised of 267 tariff pages and 240 pages of statements by Company officials and outside consultants and more than 8,000 pages of related data and work papers in support of various aspects of the tariff revisions.

9. The Commission received petitions containing requests that we suspend and investigate the AT&T tariff revisions from California, Chicago, Pennsylvania, the Executive Agencies, the Council, the Network Companies, NSBA, Datran, National Data, Mutual, and the Trial Staff. The Network Companies and IMN confine their requests for suspension to private line service rate revisions. The Separated Trial Staff requests that we suspend only the MTS revisions, arguing that this action would reduce the present subsidization of other services by MTS rate payers. Other petitions seeking rejection, cancellation, or withdrawal of the AT&T tariff revisions or, as alternative relief, suspension and investigation of these revisions were received from CNS, ANPA, ARINC, AIA, ATA, AP and UPI. ARINC has confined its request for rejection or suspension to the Series 5000 private line services and teletypewriter equipment; ATA has confined its request to Series 5000 services. The Ad Hoc Committee has requested that we reject the AT&T tariff revisions for the private line services. ANPA has also filed a separate petition requesting rejection. Among these petitioners urging rejection of AT&T's tariff revisions, AP, AIA, CNS, ANPA, UPI and the Ad Hoc Committee have argued that we have the authority to reject these revisions without a hearing since AT&T's rates were implicitly prescribed by the Commission in Docket No. 19129,[4] and thus, under section

[2] All the revisions are published to become effective on March 4, 1975 except certain rates from the United States to Mexico and Canada which were published to become effective on March 29, 1975.

[3] AT&T's January 3, 1975 letter is Appendix B, filed as part of the original document.

[4] Decision and Order in Phase I of the Message Toll Telephone Rate Case, Docket No. 19129, 38 FCC 2d 213 (1972), reconsideration denied, 42 FCC 2d 293 (1973), appealed *sub nom Ralph Nadar* v *FCC* Nos. 73-1045, 73-2051 (D.C. Cir.). See also 38 FCC 2d 984 (1973).

205 of the Act.[5] AT&T cannot file higher rates without first obtaining the Commission's approval. AIA, ATA, and ARINC have argued that we can reject the tariff revisions without a hearing because AT&T's data supporting its revisions do not comply with § 61.38 of the Commission's rules.[6] In addition, ATA asserts that we can summarily reject the private line service rate increases since prior such increases are still under consideration in Docket No. 18128, and ARINC asserts that summary rejection can be predicated on AT&T's failure to consider the competitive nature of Telpak service. Many of these same petitioners have argued that we should exercise this power to summarily reject AT&T's tariff revisions in order not to unduly disrupt proceedings in other dockets.[7]

10. Various petitioners urging suspension have asserted that AT&T has failed to justify adequately its proposed tariff revisions. The Council and Mutual argue that AT&T's increased rates can only be based in small part upon increased operating costs. The Council further argues that neither AT&T's increased cost of debt nor its needs for favorable equity financing justifies the magnitude of AT&T's proposed rate increases. Mutual, Pennsylvania and AIA also believe that the rate increases cannot be predicated on a need for a higher equity return or higher debt costs. Mutual adds that AT&T's capital requirements are likely to be reduced in 1975 through tax and economic relief as well as reduced customer demand. The Separated Trial Staff asserts that AT&T's expectations as to 1975 spending levels, on which its proposed rates are based, are in error since these expectations overlook present inefficiencies in the Bell System's operating and capital acquisition programs, as revealed in the Docket No. 19129 inquiry; a $600 million cutback in 1975 construction; and recent labor force reductions together with a freeze on new hiring. The Separated Trial Staff urges the Commission to require that AT&T submit updated cost data reflecting all possible economies so that by the end of the suspension period lower rates can be substituted for those now proposed. The Executive Agencies believe that an investigation is necessary because AT&T's proposals far exceed rates declared to be reasonable in Docket No. 19129; because AT&T bases its revised tariffs on a hypothetical debt ratio; and because AT&T has used questionable methods to arrive at an equity component. The Executive Agencies, the Council, and the Separated Trial Staff also believe that AT&T has failed to justify its revised rate structure in MTS and the Network Companies question lack of such structural revisions in the private line services. IMN and the Network Companies state that AT&T has made no showing that additional capital needs for all its services justify increased rates in the Series 6000 audio services. National Data incorporates the Council's objections in its petition.

11. The economic impact of AT&T's tariff revisions have been cited by petitioners as justifying at least a suspension and investigation. The Council requests that if we find AT&T's rate structure modification to be justified after an investigation, we should take steps, such as phasing rate revisions, to ameliorate any inflationary impact. Concern for small and intermediate sized businesses is voiced by the Council, NSBA, and National Data. NSBA asks that we require special information from AT&T summarizing the anticipated impact of the proposed rates on large and small business users. National Data further petitions the Commission to seek from AT&T a voluntary deferral of the effective date of the tariffs beyond the three month suspension period. UPI, AP, ANPA, CNS, and IMN have noted the operating costs of newspapers and news services are highly sensitive to increased charges for communications services. For this reason, they argue AT&T's tariff revisions should at least be suspended, and the adverse impact on regional news collection and dissemination investigated. Mutual and the Network Companies have argued that the rate increases for Series 6000 private line services will adversely impact radio networking and therefore should be investigated. Pennsylvania and California object to AT&T's tariff revisions because of their effect on rate payers for intrastate service. Pennsylvania notes that AT&T's interstate rate increases would lead to increased intrastate rates by virtue of the parity which Pennsylvania maintains between intrastate long-distance charges and the interstate levels. California requests that, if its petition to suspend and investigate is granted, the Commission designate as an issue modifications to the Separations Manual procedures[8] and further order AT&T to submit the revenue requirements effects on each state as a consequence of the proposed rate increases. Alternatively, if its petition is denied, California requests a Commission order specifying that no shift in revenue requirements will be made as a result of the rate increases until possible separation manual changes have been considered. Other petitioners concerned with the economic effects of AT&T's tariff revisions include the Separated Trial Staff, ARINC, AIA, and the Executive Agencies.

12. Several petitioners have argued that AT&T's tariff revisions are unlawfully discriminatory under section 202 (a).[9] California argues that the revised MTS rate structure discriminates against rate payers in certain states vis-a-vis rate payers in other states. National Data argues that the tariff revisions unlawfully discriminate against WATS users whose access lines are concentrated in the lower numbered service areas. Since DDS, a competitive service, is not included in AT&T's tariff revisions, Datran argues that there is unlawful discrimination against customers of AT&T's monopoly services.

13. Separation of various issues raised by AT&T's tariff revisions is requested by several petitioners. The Council has argued that we establish at least two proceedings, one for rate level issues and another for rate structure issues. The Separated Trial Staff asks the Commission to assign all rate structure questions presented by AT&T's proposal to the Phase II inquiry in Docket No. 19129 on the grounds that similar rate structure issues have been raised and considered in that proceeding. Many petitioners, including the Executive Agencies, have urged the Commission to order AT&T to keep accurate accounts of all monies received by reason of the tariff revisions in the event that these revisions are found unjustified after the period of suspension has passed and the revisions have gone into effect. Mutual has requested that we require AT&T to include quality of service specifications in its tariff schedule and to provide a schedule of refunds to customers should it fail to meet these specifications.

14. AT&T opposed all petitions seeking to delay the effective date of the tariff. In AT&T's view, a suspension will irrevocably deny it just and reasonable rates which are urgently needed, while an accounting order will fully protect the interests of AT&T's customers. With respect to the petitions urging rejection, AT&T argues that there is no valid basis for such action. The Commission cannot invoke section 205, AT&T asserts, because in our Phase I Order in Docket 19129 there was no "full hearing" on the rate issues or explicit prescription of rates; and no jurisdictional finding that the 1972 rates were "just and reasonable" as mandated by section 205. AT&T argues further that the issuance of an accounting order in the 1972 decision was inconsistent with an implied prescription of rates. Finally, although rates of return were set as just and reasonable in the 1972 decision, AT&T argues that section 205 does not authorize us to prescribe rates of return which cannot later be changed without Commission order. AT&T asserts that its data complied with § 61.38 of our rules. It argues that a rejection would be effectively a prescription of rates and therefore invalid without the hearings and findings required by section 205. In response to the Council's petition for suspension, AT&T argues that the Council significantly underestimated AT&T's increased labor and equity costs. It also takes issue with the Council's methods of estimating AT&T's necessary revenue increases. AT&T further notes that the Council has not supported

[5] 47 U.S.C. 205.
[6] 47 CFR 61.38.
[7] The Message Toll Telephone Rate Case (Docket No. 19129); the Telpak/Private Line Case (Docket No. 18128); the WATS case (Docket No. 19989); and The High Density-Low Density Rate Structure Case (Docket No. 19919).
[8] 47 CFR Part 67.
[9] 47 U.S.C. 202(a).

its stated concern that small and intermediate business users will face severe hardship under the revised tariffs. The suggestion to phase the rate increases is, in AT&T's view, contrary to national objectives in that the revised MTS structure will actually curb inflation by allowing customers to make substantial cost savings. With respect to the Trial Staff's petition, AT&T asserts that the Trial Staff has made only one-sided contentions as to inefficiencies in operation and plant investment and failed to recognize AT&T's need to attract substantial amounts of new capital in future years. AT&T objects to the Trial Staff's request for suspending only MTS rate increases and questions the Trial Staff's methods in arriving at its conclusion that MTS ratepayers subsidize other services. AT&T also denies Datran's assertion that the revised tariffs unlawfully discriminate against customers of AT&T's monopoly services and National Data's assertion that WATS increases over short distances are unjustified. Finally, AT&T disagrees with California's computation of the anticipated separations effect of the revised tariff and, in addition, argues that the separations effect issue should be addressed in a proceeding directed to the formulation of jurisdictional separations procedures.

Discussion. 15. On November 22, 1972, the Commission adopted and released its Decision and Order in Phase I of Docket No. 19129 (38 FCC 2d 213) prescribing 8.5% as the rate of return required by AT&T "to enable it to attract capital at reasonable cost and to maintain the credit of Bell; and to assure continued, adequate and safe interstate and foreign communications service to the public and to provide for necessary expansion to meet future requirements" 38 FCC 2d 213, 245. Although AT&T was allowed to file rate revisions designed to increase its interstate return only to the level of 8.5 percent, the Commission established a range above this level, i.e., 8.5 to 9.0 percent as an incentive for efficiency, to permit AT&T through improved efficiency or productivity gains to increase its earnings under such rates within a reasonable range above 8.5 percent without regulatory action on our part.

16. This action by the Commission was taken after a full evidentiary hearing, during which extensive evidence and exhibits were presented by Bell and other parties. Based upon this extensive record, the Commission determined the prevailing cost of debt[10] and equity[11] for Bell, and established the appropriate rate of return required to cover those costs. This action was a properly determined prescription of Bell's rate of return.[12] The effect of this action was to bar Bell from filing any rate revisions designed to increase its overall rate of return above the 8.5 percent level without obtaining the Commission's approval to increase this level by demonstrating that the level was no longer adequate.[13]

17. The Commission's action did not relate to the question of specific rate structure. This issue is being investigated in Docket 18128 and Phase II of Docket 19129. Thus, while Bell is legally free to alter its rate structure, the Commission's prescription prevents it from doing so in such a manner as to increase its overall earnings level above 8.5 percent.[14] In seeking a modification of the order, a heavy burden clearly rests with Bell to demonstrate the basis for and extent of any modifications it proposes. Absent a finding by the Commission, that the prescribed rate of return should be modified, based upon known changes in Bell's capital costs and structure, the filing of a tariff designed to produce a rate of return in excess of 8.5 percent is prima facie unlawful.

18. In its present filing, AT&T seeks to increase its overall rate of return from 8.5 percent to 10.5–11 percent. It alleges such action is mandated by economic changes which have taken place since our Phase I order. These changes, according to Bell, have raised its cost of embedded debt from 6.0 percent to 6.9 percent and its cost of equity from 10.5 percent to 13.5 percent–14.5 percent.

19. We are, of course, cognizant of the general changes and trends in the national economy. We also note that Bell's rate of return showed a decline to 7.89 percent in the last quarter of 1974, even though it was 8.53 percent overall for the year. Such a decline, if continued, would adversely impact Bell's ability to serve the public. We are also concerned that the recent downward trend in Bell's interest coverage be arrested, to avoid any possibility that its bond ratings might be downrated with attendant impact on the availability and cost of debt financing. We wish to stress that our obligation to protect the consumer requires us not only to assure ourselves that excessive rates are not being charged but also that the carrier is financially capable of providing the consumer the needed service. This requires a rate of return sufficient to allow investors to have confidence in the financial integrity of the carrier so that it can maintain its credit and attract needed capital. *F.P.C.* v. *Hope Natural Gas Co.*, 320 U.S. 591, 603 (1944); *F.P.C.* v. *Memphis Light, Gas & Water Div.*, 411 U.S. 458, 465–6 (1973).

20. While we must reject AT&T's tariff filing as being in violation of our prior prescription order, we will consider those elements of the filing which seek to increase the rate of return as a request for modification of our prescription, and will address them accordingly. After carefully scrutinizing Bell's filing and all comments received, we believe that some modification of Bell's prescribed rate of return is in order. Bell's embedded cost of debt is a matter of historical record and the result of simple mathematical computation. No petitioner has objected to Bell's evidence that it has risen from 6.0 percent to 6.9 percent and is unlikely to decrease within the immediate future. Further, it is a matter of official notice that the proportion of debt in Bell's capital structure is 49 percent. However, while recent trends in the economy would indicate that the cost of equity may no longer be 10.5 percent, Bell has failed to show clearly whether and to what extent the cost of equity now exceeds 10.5 percent. This question must be tested in the crucible of an evidentiary hearing, and we are in this decision instituting such a hearing to be conducted on an expedited basis.[15]

21. In view of the above we have determined that our prescription, to the extent indicated above, should be modified. We thus conclude that the just, fair and reasonable rate of return for Bell, under present conditions is 8.74 percent computed as follows: [16]

[In percent]

Item	Proportion of capital	Cost rate	Proportion of total cost
Debt	49	6.9	3.33
Total equity	51	10.5	5.36
Total Cost			[1] 8.74

[1] See basis of previous prescription 33 FCC 2d 213, 241. We shall still permit Bell to reach a 9 percent rate of return through increased efficiency and productivity.

22. Achievement by Bell of the 8.74 percent rate of return on its interstate operations that we have found herein to be appropriate, will require rate adjustments which will produce approximately $365 million in additional gross revenues before Federal income taxes over and above the comparable annualized fourth quarter 1974 revenues. We hereby authorize Bell to file such a tariff on not less than one day's notice. See 47 USC 203.

23. We now turn to the specific requests for relief in the petitions before us. Since we are rejecting herein the subject AT&T tariff filing, and instituting an investigation into the appropriate Bell rate of return we must deny those parts of the petitions listed in Paragraph 9 above which request suspension of the tariff filing and an investigation to be ordered

[10] The embedded cost of debt was determined to be 6 percent. AT&T 38 FCC 2d 213, 229.

[11] The cost of equity was determined to be 10.5 percent. AT&T 38 FCC 2d 213, 238.

[12] See 42 FCC 2d 293, 300 (1973) where we characterized our Phase I Order as a prescription.

[13] As noted above, the rate of return could be increased through increased efficiency and productivity, a maximum level of 9.0 percent was authorized, but this is not the situation presented by Bell's present tariff filing.

[14] This distinction between prescribing a rate and an earning level explains why the Commission could issue an accounting order on Bell's rates. While the earning level was prescribed, the rates were carrier-made and thus subject to an accounting order. *Arizona Grocery Co.* v. *Atchinson, Topeka & Santa Fe Ry.* 284 U.S. 370, 390 (1932).

[15] This hearing, which will be limited to the appropriate levels for Bell's cost of equity and overall rate of return, should be completed within 9 months.

[16] Under the unique economic circumstances now existent we are prepared for purposes of this filing to accept the last quarter of 1974 as a valid test period.

on such filing.[17] For the same reasons, we grant the petitions insofar as they seek rejection of the tariffs as unlawfully increasing a prescribed rate of return. We therefore need not reach the question concerning the effect of the tariff filing on other pending proceedings, as requested by several petitioners.

24. We agree with the separated staff of our Common Carrier Bureau in Docket No. 19129 that the primary interest of the ratepaying public, the Commission, and the Bell System would best be served by concluding Phase II of the hearing in that proceeding as soon as possible. Thus, we consider it inappropriate to include any rate structure or other issue raised in this new tariff in the Phase II proceeding, as well as our inquiries into Private Line Services (Docket No. 18128) and WATS (Docket No. 19989).

25. Finally, we believe it inappropriate to include the question of separations, as requested by California, in the narrow hearing ordered herein. We note that separations questions are presently deferred pending developments in Docket No. 20003 and should properly be before a federal-state joint board, such as that existing in the on-going Docket No. 18866 investigation. No purpose is served by having the same question examined in two forums.

26. *Accordingly, it is ordered,* That the tariff revisions filed by AT&T with its Transmittal No. 12241 are rejected;

27. *It is further ordered,* That pursuant to the provisions of Sections 4(i), and 4(j), 201, 205 and 403 of the Communications Act of 1934, as amended, an investigation and hearing is instituted into the authorized rate of return of AT&T from interstate services.

28. *It is further ordered,* That, pending the outcome of this hearing or further action by the Commission on the basis of known changes in Bell's capital structure or cost of capital, the prescribed rate of return for Bell's interstate operations shall be 8.74 percent.

29. *It is further ordered,* That, for the purpose of this hearing, the parties shall address themselves only to the current cost of capital of AT&T, with particular reference to the cost of equity and to the proper overall rate of return required.

30. *It is further ordered,* That the hearings in this investigation shall be expedited and held at a time and place to be specified by subsequent order and that the Administrative Law Judge appointed to preside at the hearing shall issue an Initial Decision at the close of the record;

31. *It is further ordered,* That the American Telephone and Telegraph Company is made a party respondent in this proceeding, and that all other interested persons wishing to participate may do so by filing a notice of intent to participate within 10 days of the release of this Order;

32. *It is further ordered,* That a separated trial staff will participate in this proceeding pursuant to § 1.1209(d) of the Commission's rules;

33. *It is further ordered,* That, for the purposes of tariffs filed pursuant to this Order, the provisions of §§ 61.38 and 61.58 of the Commission's rules, 47 CFR 61.38, 61.58 are waived, as provided herein;

34. *It is further ordered,* That the following procedures will apply in this proceeding:

(a) The record for decision will consist of staff. Interrogatories and information record by respondent, interested persons and the Common Carrier Bureau trial staff Interrogatories and information requests and responses thereto shall be part of the record. Such submittals together with supporting documentation and workpapers will be available for public inspection as they are received.

(b) All matters submitted for the record, including answers to interrogatories and responses to information requests, must be identified as to sponsoring party, numbered consecutively and identified with the name of a person by whom or under whose supervision the submittal was prepared.

(c) The source of all data must be clearly and specifically noted. Supporting documents which are not readily available and working papers must be presented with the submittals to which they apply. Statistical studies will be submitted and supported in the form prescribed in § 1.363 of the Commission's rules.

(d) Original and five copies of all matters submitted for the record as well as of supporting documentation and workpapers must be filed with the Commission. Part I of our rules governs as to the number of copies for other submissions, such as briefs, pleadings and proposed findings. Matters submitted for the record shall be served on all interested persons filing a notice of intent to participate ("participants") and upon the presiding Administrative Law Judge.

(e) Interrogatories and requests for information must be filed with the Commission and served on the participants to this proceeding. Objections to interrogatories and information requests should be resolved, if possible, by immediate informal conferences between the persons involved and the Trial Staff. If such persons are unable to resolve their differences, the Administrative Law Judge should be notified, and on notification should convene an immediate oral conference of the persons involved. After oral presentations by such persons and the Trial Staff the Judge shall forthwith issue a ruling. Appeals from such rulings shall be governed by 47 CFR 1.301 except that the Judge shall set an expedited procedure.

(f) After the return of interrogatories as provided herein, oral evidentiary-type proceedings shall be conducted as may be necessary to elicit on the record such relevant, material and competent information as required for resolution of the issues herein.

35. *It is further ordered,* That the following schedule will be adhered to:

(a) Within 10 days of the release of this Order AT&T shall identify and file those portions of its material filed in support of the subject tariff revisions which relate to the cost of equity and rate of return issues.

(b) Any participant may file interrogatories and requests for information within 20 days after the filing of the above material by AT&T. Answers to such interrogatories and requests shall be filed within 20 days of the filing thereof.

(c) Within 7 days of the filing of answers to interrogatories and information requests, all parties shall identify the witnesses they intend to call in oral proceedings. Such proceedings shall commence 7 days thereafter.

(d) Proposed findings of fact and conclusions of law shall be filed within 30 days of the completion of the oral proceedings, and replies shall be filed within 15 days thereafter.

(e) We intend to issue a decision in this matter within nine months of the release of this Order.

36. *It is further ordered,* That the petitions filed herein are granted to the extent indicated above and otherwise are denied.

Adopted: March 4, 1975.

Released: March 6, 1975.

FEDERAL COMMUNICATIONS COMMISSION,[18]

[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7176 Filed 3-20-75;8:45 am]

[17] We note that, under § 1.44(a) of our rules, petitions to suspend and reject may not be combined into a single pleading, since rejection requests should be addressed to the Chief, Common Carrier Bureau, while suspension motions were properly addressed to us. However, we shall waive § 1.44(a) on our own motion and consider the pleadings properly before us.

[18] Commissioner Quello concurring in result; Statements of Commissioners Lee, Hooks and Reid filed as part of original document. Commissioners Lee and Hooks concurring in part and dissenting in part; Commissioner Reid concurring.

RADIO TECHNICAL COMMISSION FOR AERONAUTICS

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Radio Technical Commission for Aeronautics Special Committee 127, Emergency Locator Transmitters. It is to be held on April 9, 1975 in Conference Room 6332, Nassif Building, 400 Seventh Street, SW., Washington, D.C., commencing at 9 a.m.

AGENDA

1. Opening Comments by Chairman.
2. Administrative announcements.
3. Review and Approval of Minutes of the meeting of January 29, 1975.
4. Reports of Task Groups:
   a. Inertial Switches.
   b. Battery Standards.
   c. Antenna Standards.
   d. Cockpit Control and Alerting.
5. New Business.
6. Task Assignments.
7. Date and place of next meeting.

The meeting is open to the public on a space available basis. Any member of the public may file a written statement with the Commission either before or after the meeting. Any member of the public wishing to make an oral statement must consult with the Commission prior to the meeting.

Those desiring more specific information may contact the RTCA Secretariat, Suite 655, 1717 H Street, NW., Washington, D.C. 20006, or phone, Area Code (202) 296-0484.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] VINCENT J. MULLINS,
Secretary.

[FR Doc.75-7411 Filed 3-20-75;8:45 am]

FEDERAL HOME LOAN BANK BOARD

[H. C. #187]

BROADVIEW FINANCIAL CORP.

Receipt of Application for Permission To Acquire Control of St. Clair Savings Association

MARCH 18, 1975.

Notice is hereby given that the Federal Savings and Loan Insurance Corporation has received an application from Broadview Financial Corporation, Cleveland, Ohio, a unitary savings and loan holding company, for approval of acquisition of control of the St. Clair Savings Association, Cleveland, Ohio, an insured institution, under the provisions of section 408(e) of the National Housing Act, as amended (12 U.S.C. 1730a. (e)), and section 584.4 of the regulations for Savings and Loan Holding Companies, said acquisition to be effected through the purchase of all of the stock of Capital Bancorporation for cash from the applicant. Comments on the proposed acquisition should be submitted to the Director, Holding Companies Section, Office of Examinations and Supervision, Federal Home Loan Bank Board, Washington, D.C. 20552, on or before April 21, 1975.

[SEAL] GRENVILLE L. MILLARD, JR.,
Assistant Secretary,
Federal Home Loan Bank Board.

[FR Doc.75-7426 Filed 3-20-75;8:45 am]

FEDERAL POWER COMMISSION

[Docket No. CP74-320]

COLORADO INTERSTATE GAS CO., A DIVISION OF COLORADO INTERSTATE CORP.

Order Providing for Hearing Granting Interventions, and Issuing Temporary Certificate

MARCH 14, 1975.

On June 14, 1974, Colorado Interstate Gas Company, a division of Colorado Interstate Corporation (CIG) filed an application pursuant to section 7(c) of the National Gas Act for a certificate of public convenience and necessity authorizing the acquisition of the Latigo Field in Arapahoe County, Colorado, and the construction and operation of facilities to develop the field for use as an underground gas storage reservoir, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

CIG proposes to acquire the working interest[1] of producers presently operating the Latigo Field in Arapahoe County, including 17 existing wells, a small gasoline plant and mineral and storage rights at a total estimated cost of $6,964,666. The field will be developed over a period from 1975 through 1979 as follows:

1975. Convert seven existing wells to storage use; drill two new gas storage, two potable water and two saltwater disposal wells; convert two wells to observation wells; install approximately 6 miles of 16-inch lateral pipeline, and construct a 3,300 horsepower compressor station and miscellaneous support facilities at estimated cost of $4,897,612.

1976. Construct a central dehydration facility and a hydrocarbon liquids extraction plant; drill four new gas storage wells; convert two wells to observation wells and install necessary gathering and miscellaneous support facilities at an estimated cost of $3,895,049.

1977. Drill six new gas storage wells; convert four wells to observation wells and install the necessary gathering and miscellaneous support facilities at a total estimated cost of $1,563,822.

1978. Drill six new gas storage wells; convert two wells to observation wells; install a 1,100 horsepower compressor station addition and install the necessary gathering and miscellaneous support facilities at an estimated cost of $2,434,030.

1979. Construct a 1,100 horsepower compressor station addition at an estimated cost of $993,633.

Upon completion of the project the Latigo Field will consist of 25 storage injection-withdrawal wells, ten observation wells, two saltwater disposal wells, two freshwater wells, a 5,500 horsepower injection compressor facility, a central dehydration and hydrocarbon extraction facility, 6 miles of 16-inch lateral pipeline, approximately 8.6 miles of 6- to 18-inch gathering line, approximately 5 miles of 2-inch line and .63 mile of 6-inch saltwater gathering and disposal line, 14 field line gas heater-separators, measurement facilities and a small septic tank facility at a total estimated cost of $20,753,812.

Approximately 9,700,000 Mcf was expected to be in the reservoir as of October 1, 1974, the anticipated acquisition date. Of this amount 8,023,000 Mcf represents recoverable base storage acquired in place at a cost of $1,953,535 or 24.35 cents per Mcf. The remaining 1,700,000 Mcf at a cost of $413,916 (24.35 cents/Mcf) is treated as non-recoverable base storage gas and is included in gas plant and depreciated.

Prior to filing of this instant application, CIG purchased gas from producers in the Latigo Field. This gas, after processing, was delivered into CIG's 20-inch mainline where it was commingled with CIG's interstate gas supply flowing into Colorado and eventually delivered in the Denver area. No applications were made for the sale of this gas by the producers. Nevertheless, this transaction is clearly within interstate commerce as set forth by the La Veca doctrine in *California* vs. *La Veca Gathering Company*, 379 U.S. 366 (1965). Therefore, any termination of service will require the producers to file applications for abandonment of their service. Our granting of such abandonments is necessarily a condition precedent to the effectiveness of any temporary certificate granted to CIG. Nothing herein should be construed as a waiver by the Commission of its authority to institute a proceeding against CIG and all the producers involved to show cause why they should not be held in violation of the Natural Gas Act.

CIG proposed to commence withdrawals from the field during the 1974-75 heating season, whereas, injections will begin during the spring of 1975.[2]

Upon completion of the project (1978-79 heating season), CIG proposes an ultimate total storage volume of 22,378,000 Mcf of which 12,000,000 Mcf will be the annual working storage. Peak day withdrawals are estimated to be 140,000 Mcf per day.

Because CIG proposed to utilize an existing gas and oil field which is currently subject to operations similar to those proposed, we find any approval of this project would not constitute a major Federal action significantly affecting the quality of the human environment. In addition, the proposed pipelines will not cross any highways, railroads or continuously flowing streams, and the installation of the compressor unit will not cause any significant increase in local noise levels.

In Docket No. RP74-77 it was estimated that CIG's production of new reserves will exceed its estimated deficiency by 22,370,000 Mcf in 1975, 32,422,000 Mcf in 1976, 19,588,000 Mcf in 1977, and 630,000 Mcf in 1978. If new supplies do not develop as anticipated, CIG will allocate any deficiency in accordance with the terms of its curtailment plan on file in Docket No. RP72-122.

No new or additional customers will be served as a result of this project. CIG has stabilized total transmission system peak day deliveries at the 1973-74

[1] The owners of the working interest are Amoco Production Company, Anschutz Corporation, Champlin Petroleum Company, McCulloch Oil Corporation, Gas Development Enterprises, Sundance Oil Company, Inc., Texaco Inc., Mr. Thomas G. Dorough and Western Drilling.

[2] Proposed peak day withdrawals are 3,000 Mcf during the 1974-75 heating season, 21,000 Mcf during the 1975-76 heating season, 74,000 Mcf during the 1976-77 heating season, 115,000 Mcf during the 1977-78 heating season and 140,000 Mcf during the 1978-79 heating season.

level of 1,361,098 Mcf.[3] Development of the proposed storage will eliminate the projected peak day deficiencies through the 1976–77 heating season and will contribute to the reduction of deficiencies through the 1978–79 heating season. Annual deficiencies are expected to increase from 11,828,000 Mcf in the 1974–75 Fiscal Year[4] 114,243,000 Mcf in the 1978–79 Fiscal Year. These facilities would supply inventory that will be required to offset, in part, these prospective shortfalls. If acquisition is not allowed now, the facilities will not be in service in time to accumulate an inventory from the system off peak gas to supply projected shortfalls in the 1975–76 winter season. For this reason, the Commission is of the opinion that an emergency exists on CIG's system, within the purview of section 7 of the Natural Gas Act, which warrants the issuance of a temporary cretificate for acquisition of the field, construction of the facilities scheduled for construction in 1975, and injection of gas into storage. However, the issuance of this certificate is not to be construed as a predisposition on the merits of the permanent application nor should it prejudice in any manner the ultimate disposition of the permanent application.

The incremental cost of service for the first full season of operation (1979–1980) at ultimate development is estimated to be $3,914,454, including return at 9.75 percent and reflecting the deductions of revenues received from the sale of hydrocarbon liquids.[5] Based on a total transmission system demand cost service of $1.73 per Mcf (as filed in Docket No. RP74–77) CIG estimated 1979–1980 incremental revenues to be $2,990,400 or $924,054 less than the incremental cost of service. Because of the high cost of this storage service, because all costs will not be recovered, and because of the uncertainty of supply it shall be an issue of a formal hearing to determine whether the proposed rolled-in pricing method is the proper method to recover the cost of service. In this regard, CIG shall submit evidence and sponsoring witnesses showing requirements of customers according to the end-use plan on file; including any projected changes in market requirements for the years through 1984. Included in the evidence shall be a showing of the manner by which CIG contemplates that it will use the storage inventory to meet the needs of its high priority customers in sufficient detail to indicate the end-use by classes of service, and by individual customers. CIG shall show whether a market exists for the storage service if it were provided on a separate rate schedule under which all costs associated with the project would be recovered. CIG shall show why it is in the public interest for the proposed storage service not to fully recover its costs. CIG shall demonstrate for this record its proposed source of supply showing projected amounts and projected duration. In the evidence, it shall be shown that termination of the sales by the producers in Latigo Field will harm no segment of the CIG market.

After due notice by publication in the FEDERAL REGISTER on July 16, 1974 (39 FR 26064), a joint petition to intervene was filed by Public Service Company of Colorado, Western Slope Gas Company and Cheyenne Light, Fuel and Power Company. These petitioners state that they fully support the application of CIG. The City and County of Denver also filed a petiton to intervene. The Public Utilities Commission of the State of Colorado filed its notice out of time.

The Commission finds. (1) Good cause exists to set for hearing and dispositon the matters involved in the proceedings in Docket No. CP74–320.

(2) Good cause exists to grant the interventions previously cited since the participation of those intervenors may be in the public interest.

(3) Participation of the late intervenor will not delay the instant proceeding and, therefore, good cause exists for permitting the filing of the late petition to intervene.

(4) An emergency exists on CIG's system to an extent sufficient to justify the issuance of a temporary certificate of public convenience and necessity pursuant to section 7(c) of the Natural Gas Act.

The Commission orders. (A) Pursuant to the authority of the Natural Gas Act particularly sections 7 and 15 thereof, the Commission's rules of practice and procedure and the regulations under the Natural Gas Act [18 CFR, Chapter 1], a public hearing shall be held commencing May 6, 1975, in a hearing room of the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426 concerning the propriety of issuing a permanent certificate of public convenience and necessity for the project proposed herein.

(B) On or before April 8, 1975, CIG and all supporting intervenors shall file and serve its testimony and exhibits comprising its case-in-chief upon all parties including Commission Staff.

(C) An Administrative Law Judge, to be designated by the Chief Administrative Law Judge for that purpose—see Delegation of Authority, 18 CFR 3.5(d)—shall preside at the hearings in this proceeding and shall prescribe relevant procedural matters not herein provided.

(D) Pursuant to section 7(c) of the Natural Gas Act and based upon the Commission's findings that an emergency exists on CIG's system by virtue of projected shortages in the winter 1975–76 season. A temporary certificate is hereby issued as hereinafter conditioned for the acquisition and construction of facilities and for the injection of gas and is to be so issued without prejudice to such ultimate disposition of the application for certificate as the record compiled herein may require.

(E) The temporary authorization herein above granted is conditioned as follows:

(1) The maximum inventory of natural gas stored in the "J" sand in the Dakota Formation in the Latigo Field shall not exceed 22.4 million Mcf at 14.73 psia and 60° F. and the reservoir pressure shall not exceed 2,600 psia without prior authorization of the Commission.

(2) Applicant shall submit semiannual reports (to coincide with the termination of the injection and withdrawal cycles) containing the following information on proposed operations:

(a) The volumes of natural gas injected and volumes withdrawn during each month of the cycle.

(b) The volume of natural gas in the storage reservoir at the end of the cycle.

(c) The maximum daily injection and withdrawal rates experienced during the cycle.

(d) The shut-in bottom-hold or wellhead pressure of each well in the storage field and the average of such pressures.

(e) The average working pressure on maximum days (referred to in Item 3) taken at a central measuring point where the total volume injected or withdrawn is measured.

(f) A tabulation of wells drilled, cleaned or recompleted, with subsea elevations of formations and casing settings. Copies of any core analyses, gamma ray, neutron or other electric log surveys and back-pressure tests conducted during the period.

(g) Reports shall continue to be filed semi-annually until the average shut-in reservoir pressure has reached or has closely approximated the maximum storage pressure permitted in the Commission's order, and thereafter until two additional injection and withdrawal cycles have been completed. Upon completion of those two cycles, the filing of reports shall be discontinued unless otherwise ordered by the Commission.

(3) Any producer selling to CIG out of the Latigo Field shall file without prejudice for abandonment under Section 7 (b) of the Natural Gas Act and a final decision on any such application shall be a condition precedent to the effectiveness of the temporary certificate herein granted.

(4) CIG shall file executed contracts for the acquisition of working interests from the producers in the Latigo Field reflecting costs comparable with those estimated herein when effective by virtue of compliance with all of the conditions herein and in particular the conditions precedent set forth in Paragraph E(3) above.

(F) The temporary authorization will be subject to Applicant's compliance with all applicable Commission regulations under the Natural Gas Act and particularly the general terms and conditions set forth in paragraphs (a), (c)(3), (c)

[3] Although 1973–74 peak day deliveries were 1,377,098 Mcf, CIG will reduce its delivery obligation to Kansas-Nebraska Natural Gas Company by 16,000 Mcf per day pursuant to a new service agreement effective October 1, 1974, approved in Docket No. CP74–209.

[4] CIG's Fiscal Year begins October 1.

[5] Storage gas inventory is estimated to be $3,573,162 including the $1,953,535 cost of recoverable base storage acquired in place.

(4), (e), (f), and (g) of section 157.20 of such regulations. However, all necessary Federal, state and local authorizations shall be obtained by Applicant with respect to all facilities constructed pursuant to the instant authorization so long as such local authorizations or actions are not inconsistent with the Commerce Clause of the Constitution of the United States and our jurisdiction. Copies of such authorizations shall be submitted to the Commission and shall include, but shall not be limited to, building permits and statements of compliance with applicable Government and industry safety codes governing the design, installation, inspection, testing, construction, operation replacement, and maintenance of facilities. Copies of all authorizations shall be submitted to the Commission upon receipt.

By the Commission.

Issued: March 14, 1975.

[SEAL] MARY B. KIDD, *Acting Secretary.*

[FR Doc.75-7376 Filed 3-20-75;8:45 am]

[Docket No. RP75-47-2]

COLUMBIA GAS TRANSMISSION CORPORATION

Natural Gas Pipelines; Petition for Relief

MARCH 18, 1975.

On December 20, 1974, as supplemented January 22, 1975, Teledyne Ohiocast, Springfield, Ohio, filed with the Commission a petition for extraordinary relief exempting it from the curtailment procedures of Columbia Gas Transmission Corporation in the annual volume of 130,480 Mcf of natural gas for the two-year period commencing October 15, 1974. Protests or petitions for intervention due March 26, 1975.

Take notice that on December 20, 1974, as supplemented January 22, 1975, Teledyne Ohiocast (Petitioner), Springfield, Ohio, filed a petition, pursuant to section 1.7(b) of the Commission's rules of practice and procedure and Commission Order No. 467-C, seeking relief from the currently effective curtailment procedures of Columbia Gas Transmission Corporation. The petition requests an exempt allocation of natural gas in the annual volume of 130,480 Mcf for the period of October 15, 1974 through October 14, 1976. On March 7, 1975, the Ohio Public Utilities Commission filed a notice of intervention to confer standing on Petitioner.

In support of its petition for extraordinary relief, Petitioner states that it produces high alloy castings for the petro-chemical industry, the steel industry, the automotive industry, industrial furnace builders, and paper equipment manufacturers. Such products are alleged to be in critically short supply Petitioner claims to have no other source of natural gas and no existing alternate fuel capabilities.

It appears reasonable and consistent with the public interest in this proceeding to prescribe a period shorter than 15 days for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) on or before March 26, 1975. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene in accordance with the Commission's rules. This filing which was made with the Commission is available for public inspection.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-7502 Filed 3-20-75;10:57 am]

[Docket No. CP75-260]

CONSOLIDATED GAS SUPPLY CORP.

Application

MARCH 14, 1975.

Take notice that on March 4, 1975, Consolidated Gas Supply Corporation (Applicant), 445 West Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP75-260 an application pursuant to section 7 (b) and (c) of the Natural Gas Act and section 157.7(g) of the Regulations thereunder (18 CFR 157.7 (g)), for a certificate of public convenience and necessity authorizing the construction and for permission and approval of the abandonment, for the 12-month period commencing July 1, 1975, and operation of field gas compression and related metering and appurtenant facilities, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in the construction and abandonment of facilities which will not result in changing Applicant's system salable capacity or service from that authorized prior to the filing of the instant application.

Applicant states that the total cost of the proposed construction and abandonment will not exceed $3,000,000, nor will the cost of any single project exceed $500,000. Applicant states that the proposed facilities will be financed from funds on hand and funds to be obtained from Applicant's parent corporation, Consolidated Natural Gas Company.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 7, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB, *Secretary.*

[FR Doc.75-7364 Filed 3-20-75;8:45 am]

[Docket No. CP75-241]

CREOLE GAS PIPELINE CORP.

Application

MARCH 14, 1975.

Take notice that on February 21, 1975, Creole Pipeline Corporation (Applicant) 225 Baronne Street, New Orleans, Louisiana 70112, filed in Docket No. CP75-241 an application pursuant to section 1(c) of the Natural Gas Act and Part 152 of the regulations thereunder for exemption from the provisions of the Natural Gas Act, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

In support of this application and in accordance with section 152.3(c) of the Commission's regulations (18 CFR 152.3(c)), Applicant states the following regarding its existing service for which Applicant seeks exemption:

Applicant owns and operates two natural gas pipelines located exclusively within St. Bernard Parish, Louisiana. One is an eight-inch line which extends from the boundary of the Ysclosky processing plant of Shell Oil Company (Shell) in St. Bernard Parish to Chalmette, St. Bernard Parish. Applicant renders transportation service through this line for Tenneco Oil Company (Tenneco) and Amstar Corporation. The gas transported for each is received from the Ysclosky plant and is transported to Tenneco's Chalmette refinery and Amstar's Chalmette plant. In each case all of the gas transported is consumed within the State of Louisiana. The other natural gas pipe-

line owned and operated by Applicant is a 16- and 12-inch line which extends from the boundary of the Yscloskey plant to a point on the boundary between St. Bernard Parish and Orleans Parish at Bayou Bienvenu, Louisiana. This line is utilized for the transportation of natural gas received from OKC Corporation (OKC) at the Yscloskey plant for ultimate delivery to the OKC's cement plant in Orleans Parish. From the point on the boundary line referred to above, the natural gas transported by Creole for OKC is transported to the OKC plant through a pipeline owned by New Orleans Public Service Company, Inc. (NOPSI). Deliveries of natural gas to Air Products and Chemicals, Inc.'s (Air Products), plant in Orleans Parish are made through the 16- and 12-inch line in the same fashion. This gas is nominally sold to Air Products by Applicant. Said gas is nominally purchased by Applicant at the Yscloskey plant from Shell and Tenneco and is delivered to the Air Products' plant through the facilities of Applicant and NOPSI as described above. All of the natural gas delivered through Applicant's 16- and 12-inch line is consumed within the State of Louisiana. Applicant thus has a total of four customers, three transportation customers and one nominal sale customer, none of which are wholesale customers. Applicant states that to the best of its knowledge the natural gas transported through its pipeline facilities is delivered to the Yscloskey plant by Tennessee Gas Transmission Company, a division of Tenneco Inc., in a commingled stream from sources within and without the State of Louisiana.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 1, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7365 Filed 3-20-75;8:45 am]

[Docket No. E-8947]

DELMARVA POWER AND LIGHT CO.

Order Further Extending Procedural Dates

On February 4, 1975, Staff Counsel filed a motion in this proceeding to further extend the procedural dates which were fixed by order issued October 24, 1974, and modified by notice issued January 10, 1975. Staff states that Delmarva Power and Light Company's (Delmarva) initial filing appears to be "unsubstantiated and subject to rejection." They ask the Commission to order Delmarva to supply a current cost projection for period II which should include three months of actual data for October, November, and December of 1974 and for estimated data for January through September, 1975. In the event this motion is denied, Staff would recommend rejection of the proposed changes.

On February 6, 1975, the Municipal Intervenors in this matter filed comments supporting in part, and opposing in part, Staff's motion. It is their contention that the necessary changes by Delmarva amount to "an entirely new case in chief" and that a withdrawal or rejection and new filing is most appropriate. They find a continuation of the present proceeding "unfair and burdensome" since under § 35.19(a) of the Commission's rules and regulations the interest rate on a possible refund would be at 7 percent, whereas a new proceeding would allow a refund including 9 percent interest rate under the revised § 35.19(a).[1] Municipal Intervenors therefore requested that in the event Staff's Motion is granted, § 35.19(a) be waived in order that any refund ordered by the Commission would include interest at 9 percent.

On February 11, 1975, Delmarva filed comments to the Staff's motion. It is the company's contentions that the need for updated information was caused by "changed conditions" and that these additions are both necessary and proper and do not represent a new case.

On February 18, 1975, Accomack-Northampton Electric Cooperative, Chaptank Electric Cooperative, Inc., Delaware Electric Cooperative, Inc., and Delmarva Electric Cooperative, Inc., (Cooperatives) filed a motion in opposition to Staff's Motion for further extension for reasons similar to those of the Municipal Intervenors.

Upon review of the instant pleadings we find it appropriate and in the public interest to grant Staff's requested extension of time to complete discovery and to submit evidence as to the justness and reasonableness of Delmarva's proposed rate changes. We note that the lack of data and information sought to be adduced by Staff does not constitute grounds for rejection of Delmarva's filing. The material requested by the Staff is not required in order for Delmarva to meet the filing requirements of the Commission's regulations. In fact we specifically noted in our order issued October 24, 1974, in this docket that Delmarva's filing, as completed on September 25, 1974, fully complies with the requisite filing requirements of the Commission's regulations. The material sought by the Staff is the type of data needed to test the justness and reasonableness of Delmarva's proposed rate increase, and therefore, to insure a proper evaluation of the proposed changes, we believe that the requested extension should be granted.

As to Municipal Intervenors' request for waiver of § 35.19(a) of the Commission's regulations, we believe that good cause has not been shown to grant the requested waiver. As we said in our order affecting Rate of Interest on Amounts Subject to Refund: "* * * the speculative nature of the fund coupled with the expense of undergoing extensive litigation in regard to the filing would mitigate any probable benefits the company might derive from such a tactic."[2] As we stated in that order, the interest rate on refunds should compensate the customer but not penalize the company for seeking an increase. It is not feasible for us to determine in individual cases whether the rate is adequate. We can only attempt to periodically scrutinize the money market to ascertain if prospective interest rate adjustments to our rules are necessary.

The Commission finds. (1) Good cause exists for granting a further extension of procedural dates in this matter.

(2) Good cause exists to order Delmarva to update their filing as hereinafter provided.

(3) Good cause does not exist to grant Municipal Intervenor's request for waiver of § 35.19(a) of the Commission's regulations.

The Commission orders. (A) Delmarva shall supply by March 24, 1975, their current cost projection for period II which would include three months of actual data (October–December) and for estimated data for nine months (January–September, 1975).

(B) The procedural dates fixed by order issued October 24, 1974, as modified by notice issued January 10, 1975, are hereby modified as follows:

Service of staff's testimony, April 14, 1975.
Service of Intervenor's testimony, April 28, 1975.
Service of Company's rebuttal, May 12, 1975.
Hearing, May 27, 1975.

(C) Municipal Intervenors' request for waiver of § 35.19(a) of the Commission's regulations is hereby denied.

By the Commission.

Issued: March 14, 1975.

[SEAL] KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7366 Filed 3-20-75;8:45 am]

[Docket No. RI75-46 and RI75-76]

EXXON CORP.

Extension of Procedural Dates

MARCH 4, 1975.

On February 26, 1975, Staff Counsel filed a motion to extend the procedural dates fixed by order issued January 8, 1975 in the above-designated matter. The motion states that the parties have been notified and have no objection.

[1] Order No. 513, October 10, 1974.

[2] Id.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Staff's Testimony, March 21, 1975.
Service of Company Rebuttal, March 28, 1975.
Hearing, April 8, 1975 (10 a.m. e.d.t.).

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7623 Filed 3-20-75;10:49 am]

[Docket No. CP75-122]

GRAND GAS CORP.

Order Deferring Action on Application for Permission and Approval To Abandon Sale of Natural Gas

On October 17, 1974, Grand Gas Corp. (Applicant) filed in Docket No. CP75-122 an application, as supplemented January 13, 1975, pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon the sale of natural gas in interstate commerce to Northwest Pipeline Corporation (Northwest) from the Cisco Dome and Book Cliffs Fields, Grand County, Utah. Applicant was authorized to make the subject sale by order issued June 1, 1972 (47 FPC 1440), as amended January 28, 1974 (51 FPC ——).

The Commission in the order of June 1, 1972, found,

(3) The gathering facilities to be constructed and operated by Grand Gas are not within our jurisdiction. Grand Gas' gathering operations are not within our jurisdiction.

and

(8) Applicant in Docket No. CP72-108 will be a gatherer of natural gas and not a natural gas pipeline company within the contemplation of the Regulations under the Natural Gas Act.

The Commission ordered,

(H) That part of the application in Docket No. CP72-108 for authorization to construct and operate gathering facilities is dismissed for want of jurisdiction.

Applicant proposes to abandon the sale of natural gas to Northwest because it proposes to sell its facilities in Grand County to Northwest. In addition to the Cisco Dome and Book Cliffs Fields, Applicant's facilities connect the Cisco Spring, Danish Wash, Agate, Unnamed, and Gravel Pile Fields with the system of Northwest. Upon disposition by Applicant the facilities would become part of Northwest's interstate natural gas pipeline system. In its application Applicant alludes to the aforementioned portions of the order of June 1, 1972, and states that it has been informed that

Northwest Pipeline Corporation is of the opinion that it is not necessary for it to make any filing with the Commission in connection with its acquisition of all the gas gathering facilities and other assets of Applicant as it is of the further opinion that it is fully authorized to so acquire, and thereafter operate, such assets and facilities in connection with its other operations under prior orders of the Commission.

After a preliminary analysis of the application the Commission cannot concur, at this time, in the opinions of Northwest with respect to its acquisition and operation of Applicant's facilities because, notwithstanding the findings in the order of June 1, 1972, the facilities, in fact, and the acquisition and operation thereof by Northwest may be subject to the jurisdiction of the Commission under subsections (c) and (e) of section 7 of the Natural Gas Act. If such should be the case, then any finding that the present or future public convenience or necessity permit the abandonment by Applicant would necessarily have to be coupled with a finding that the acquisition and continued operation of the facilities by Northwest is or will be required by the present or future public convenience and necessity.

The Commission does not have before it any application by Northwest for a certificate of public convenience and necessity authorizing it to acquire and operate the subject facilities. However, it appears that Northwest, as a certificate applicant, may be a necessary party to the instant proceeding in the event that the Commission should find that Applicant's facilities and the acquisition and continued operation thereof are subject to the jurisdiction of the Commission. Mere joinder of Northwest as a party to the instant proceeding would not suffice, since if the Commission should find that the facilities, acquisition, and continued operation are subject to the jurisdiction of the Commission, the Commission could make the required finding under section 7(b) of the Natural Gas Act only if it is able, at the same time, to make the required finding under section 7(e). Therefore, the Commission has no choice but to defer action on the subject application pending receipt of an application by Northwest under subsections (c) and (e) of section 7 of the Natural Gas Act.

The Commission finds. The facilities of Applicant in Grand County, Utah, and the acquisition and operation thereof by Northwest may be subject to the jurisdiction of the Commission under Subsections (c) and (e) of section 7 of the Natural Gas Act.

The Commission orders. (A) Consideration of the application in the instant proceeding is deferred pending receipt of an application filed by Northwest under subsections (c) and (e) of section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing the acquisition and continued operation of the facilities of Applicant.

(B) The Secretary shall serve a copy of this order upon Northwest.

By the Commission.

Issued: March 14, 1975.

[SEAL] MARY B. KIDD,
Acting Secretary.

[FR Doc.75-7367 Filed 3-20-75;8:45 am]

[Docket No. E-8843]

HOLYOKE WATER POWER CO. AND HOLYOKE POWER AND ELECTRIC CO.

Further Extension of Procedural Dates; Correction

FEBRUARY 24, 1975.

In the notice of further extension of procedural dates issued February 18, 1975 and published in the FEDERAL REGISTER on March 4, 1975 40 FR 8994, make changes in paragraph 1, lines 5 and 6, January 14, 1974 to January 14, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7624 Filed 3-20-75;10:49 am]

[Docket Nos. RP73-102; PGA 75-3; AP75-2 and R & D 75-1]

MICHIGAN-WISCONSIN PIPE LINE CO.

Extension of Procedural Dates

MARCH 14, 1975.

On March 11, 1975, Staff Counsel filed a motion to extend the procedural dates fixed by order issued December 27, 1974, in the above-designated matter. The motion states that the parties have been notified and have no objection.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Staff's Testimony, May 6, 1975.
Service of Intervenor's Testimony, May 20, 1975.
Service of Company Rebuttal, June 3, 1975.
Hearing, June 10, 1975.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7368 Filed 3-20-75;8:45 am]

[Docket No. CP75-256]

NATURAL GAS PIPELINE COMPANY OF AMERICA

Application

MARCH 14, 1975.

Take notice that on March 3, 1975, Natural Gas Pipeline of America (Applicant), 122 South Michigan Avenue, Chicago, Illinois 60603, filed in Docket No. CP75-256 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of transmission and storage facilities required to operate its pipeline at authorized levels of delivery capacity during the 1975-76 winter period and to enable Applicant to offer additional storage service to its customers, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

Applicant states that the deliverability of its existing gas supply is insufficient to support operation of its pipeline at authorized levels of capacity. To assure continued full winter deliveries to its existing customers and to enable it to offer

additional storage service to these customers. Applicant proposes to construct and operate facilities to permit expansion of the peak day capacity of its Iowa and Illinois storage fields by 114,000 Mcf. Applicant states that 64,000 Mcf of this increased peak day storage capacity will be reserved to assure operation of its own pipeline facilities at authorized levels of capacity during the 1975–76 winter season, with the remaining 50,000 Mcf available for increased storage service to Applicant's customers.

To effectuate the proposal herein, Applicant proposes that the inventory limitations of its storage fields be expanded as follows:

Storage field:	*Mcf (in thousands)*
Columbus City-Mount Simon Reservoir	28,000
Cairo-Mount Simon (Zone B)	3,500
Cairo-Galesville	8,000
Cairo-Mount Simon Reservoir	39,000
Herscher-Northwest-Mount Simon	18,500
Loudon	65,000

Applicant proposes the following operations to increase peak day capacity of its Iowa and Illinois storage fields by 114,000 Mcf and increase the capacity of its main transmission system between its Iowa storage fields and the terminus of its main transmission system at Joliet, Illinois, to effectuate transportation of the increased daily withdrawals:

(1) Construct approximately 6.0 miles of 20-inch loop pipeline and approximately 0.7 mile of 6-inch and 8-inch gathering pipeline; drill and connect four injection-withdrawal wells; install other miscellaneous facilities; and inject additional cushion gas at Applicant's Columbus City-Mt. Simon Storage Field in Louisa County, Iowa;

(2) Construct approximately 0.3 mile of 6-inch gathering pipeline; drill and connect four injection-withdrawal wells; recomplete three existing Mt. Simon wells to "Zone B" injection-withdrawal wells; install other miscellaneous facilities; and inject additional cushion gas at Applicant's Cairo-Mt. Simon (Zone B) Storage Field in Louisa County, Iowa;

(3) Construct approximately 1.5 miles of 6-inch and 8-inch gathering pipeline; drill and connect nine injection-withdrawal wells; install 4,000 B.H.P. of compression, and other miscellaneous facilities; and inject additional cushion gas at Applicant's Cairo-Mt. Simon Storage Field in Louisa County, Iowa;

(4) Construct approximately 7.2 miles of 6-inch, 8-inch, 16-inch and 20-inch gathering pipeline; drill and connect four injection-withdrawal wells; install 12 wellhead meters and other miscellaneous facilities; and inject cushion gas at Applicant's Cairo Galesville Storage Field in Louisa County, Iowa;

(5) Construct approximately 0.2 mile of 6-inch gathering pipeline; drill and connect two injection-withdrawal wells; install other miscellaneous facilities; and inject additional cushion gas at Applicant's Herscher-Northwest Storage Field in Kankakee County, Illinois;

(6) Construct approximately 0.8 mile of 8-inch gathering pipeline and wellhead facilities; connect three existing wells; install other miscellaneous facilities; and inject additional cushion gas at Applicant's Loudon Storage Field in Fayette County, Illinois; and

(7) Construct approximately 17.3 miles of 36-inch pipeline partially looping Applicant's existing pipeline between its Iowa storage fields and the terminus of its main transmission system at Joliet, Illinois.

The estimated cost of constructing the facilities proposed herein, inclusive of the cost of injecting additional cushion gas, but excluding the cost of cushion gas provided by the customers participating in the new LS–1 storage service, is $18,355,000. Applicant will finance this cost with funds obtained through interim and permanent financing.

Applicant proposes to make the additional storage service available to its existing customers under a new Rate Schedule LS–1. In order to provide flexibility to the customers in their utilization of this storage service a total of 100 days top storage withdrawal would be available over a period beginning December 1 of a year and continuing through March 31 of the next year. The maximum available to each customer would be 100 times his contracted daily withdrawal quantity. To enable Applicant to provide this leased storage service, Applicant proposes to allocate for injection into storage from existing customer entitlements 5,000,000 Mcf of top storage gas each year and 10,000,000 Mcf of cushion gas for the first year of LS–1 service only.

Applicant proposes that service agreements to provide LS–1 service will be for a period of ten years commencing April 1, 1975, but will be cancellable on one year's notice by Applicant if, in Applicant's judgment, storage capacity utilized to provide LS–1 service is necessary to avoid curtailment of flow gas deliveries in the winter period. Upon termination of the LS–1 service, cushion gas will be returned to Applicant's customers.

Applicant proposes that this service would be billed under a monthly demand charge applied uniformly throughout the year. The demand charge would be based on Applicant's average cost of providing 100-day storage, excluding cushion gas cost, in recognition that customers are furnishing the cushion gas for this service, plus a component attributable to the allocated portion of the cost of Applicant's North End pipeline loopings between its market storage fields and the terminus of its system. Based upon estimated costs for the first year of operation Applicant estimates a demand charge of $3.28 per month for each Mcf of buyer's contracted daily withdrawal quantity. In developing its cost of service data Applicant states that it used a 10.34 percent overall rate of return.

Applicant seeks authorization to provide LS–1 storage service to the following customers, in the following quantities:

(Quantities in Mcf per day at 1,000 Btu/ft³)

Customer:	*LS–1*
Associated Natural Gas Co	100
Corning Municipal Utilities	27
Frohna, Mo., city of	11
Illinois Power Co	2,000
Iowa Electric Light & Power Co	1,914
Iowa-Illinois Gas & Electric Co	8,894
Iowa Power & Light Co	655
Iowa Southern Utilities Co	343
Kaskaskia Gas Co	35
Monarch Gas Co	72
Nashville, Ill., city of	54
North Shore Gas Co	4,426
Peoples Gas Light & Coke Co., the	30,929
Peoples Natural Gas Division	117
Perryville, Mo., city of	101
Pinckneyville, Ill., city of	66
Spearville, Kans., city of	13
Sullivan, Ill., city of	94
United Cities Gas Co	150
Total	50,000

Any person desiring to be heard or to make any protest with reference to said application should on or before April 4, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75–7369 Filed 3–20–75;8:45 am]

[Docket No. CP75–106]

NORTHERN NATURAL GAS CO.

Withdrawal and Cancellation of Hearing

MARCH 14, 1975.

On March 7, 1975, Northern Natural Gas Company filed a withdrawal of its application in the above-designated matter which was set for hearing by order issued February 7, 1975. The procedural dates were deferred by notice issued March 4, 1975.

Notice is hereby given that pursuant to section 1.11(d) of the Commission's rules of practice and procedure the withdrawal of the above application shall become effective April 7, 1975. The hearing previously deferred is cancelled.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75–7370 Filed 3–20–75;8:45 am]

[Docket No. E-9220]

NORTHWESTERN PUBLIC SERVICE CO.

Application

MARCH 14, 1975.

Take notice that on March 5, Northwestern Public Service Company (Applicant) filed an application with the Federal Power Commission seeking an order pursuant to Section 204 of the Federal Power Act authorizing it to issue, in separate transactions, not to exceed 30,000 shares of Cumulative Preferred Stock, par value $100 per share, and $15,000,000 principal amount of First Mortgage Bonds. Included in such application is a request for exemption from the competitive bidding requirements of § 34.1a (b) and (c) of the Commission's regulations under the Federal Power Act for each of the transactions to enable the sale of the securities to institutional investors by negotiated private placements.

Applicant is incorporated under the laws of the State of Delaware and is qualified to do business in the States of North Dakota, South Dakota and Nebraska, with its principal business office being in Huron, South Dakota. Applicant is engaged in generating, transmitting, distributing and selling electric energy in the east central portion of South Dakota where it furnishes electric service in 108 communities and in distributing and selling natural gas in three Nebraska communities and in 24 communities in South Dakota.

The Preferred Stock will be issued as a new series of such stock and will rank on a parity with the presently issued and outstanding Preferred Stock. It is proposed that the dividend rate, liquidating preferences, redemption prices and sinking fund provisions, if any, of the new series will be determined by negotiation with the purchasers. The sale of this Preferred Stock is expected to provide Applicant with approximately $3,000,000 of proceeds.

The Bonds are proposed to be issued under and secured by the lien of Applicant's Indenture dated August 1, 1940, as amended and supplemented, and as to be further supplemented by an additional Supplemental Indenture providing for this issue. It is contemplated that the Bonds will be dated as of the date of issue and will bear interest from the first day of the month in which the original issue occurs. The maturity date and the interest rate, as well as the redemption and sinking fund provisions for the Bonds, are proposed to be fixed by negotiation with the purchasers.

A part of the net proceeds from the two financings will be used to refund $6,000,000 principal amount of First Mortgage Bonds, 9¼ percent Series due 1975, which mature September 1, 1975. The remainder of the net proceeds will be used in whole or in part to reduce outstanding short-term bank loan indebtedness, and to the extent not so used, will be applied to payment of costs of Applicant's 1975 construction program.

As of December 31, 1975, Applicant had $14,000,000 of short-term bank loans outstanding which were incurred to finance a portion of Applicant's 1974 construction program. Applicant's expenditures for its 1974 construction program, after conclusion of its last prior long-term financing in July 1974, totaled approximately $10,210,000 of which approximately $7,793,000 was for electric generating facilities (principally the Big Stone Electric Plant Project), $725,000 for electric transmission lines, $338,000 for major electric substations, $912,000 for routine extensions and additions to electric distribution systems, $338,000 for miscellaneous extensions and additions to gas distribution facilities, and $54,000 for miscellaneous, general and transportation facilities.

Applicant's 1975 construction expenditures are estimated to be $14,780,000 of which approximately $1,436,100 is for projects carried over from the prior year, $7,541,000 is for the Big Stone Electric Plant Project, $1,591,500 is for other electric production projects, $576,200 is for major transmission lines, $421,700 is for major electric substations, $739,100 is for routine extensions and additions to electric systems, $952,700 is for miscellaneous projects for the gas distribution systems, $1,231,000 is for permanent work orders, and $290,700 is for miscellaneous, general and transportation facilities. The Big Stone Electric Plant Project involves the construction of a jointly-owned 440 MW generating plant and related transmission facilities near Big Stone City, South Dakota. The plant and the related facilities are scheduled for completion in 1975. Applicant shares in the cost of the plant in proportion to its 32.5 percent ownership interest.

Any person desiring to be heard or to make any protest with reference to said application should on or before April 11, 1975, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's Rules. The application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7371 Filed 3-20-75;8:45 am]

[Docket No. E-8888]

OHIO ELECTRIC CO.

Further Extension of Procedural Dates

MARCH 14, 1975.

On March 6, 1975, Staff Counsel filed a motion to extend the procedural dates fixed by order issued September 16, 1974, as most recently modified by notice issued December 16, 1974, in the above-designated matter. The motion states that the parties have been notified and have no objection.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of staff's and intervenor's testimony, April 11, 1975.
Service of company rebuttal, April 23, 1975.
Hearing, May 6, 1975 (10 a.m. e.d.t.).

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7372 Filed 3-20-75;8:45 am]

[Docket No. RP75-35, et al.]

TENNESSEE GAS PIPELINE COMPANY, A DIVISION OF TENNECO, INC.

Order Granting Motion To Sever and Dismiss Complaint, Redesignating Proceeding, Modifying Previous Order, and Consolidating Proceedings

By order of February 14, 1975, in the instant docket, the Commission consolidated the complaints of Consolidated Edison Company of New York, Inc. (Con Ed), Orange and Rockland Utilities, Inc. (O&R), Knoxville Utilities Board, et al., and Tennessee Public Service Commission (Knoxville), and Pennsylvania Gas and Water Company (Penn Gas), construed Alabama-Tennessee Natural Gas Company's (A-T's) and General Motors Corporation's (GM's) filings as complaints under the Natural Gas Act, consolidated A-T's and GM's filings with the complaints of Con Ed, O&R, Penn Gas, and Knoxville for hearing and decision, and ordered formal hearings to convene on March 25, 1975.

On February 25, 1975, Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee), filed a motion with the Commission, pursuant to section 1.12 of the Commission's rules of practice and procedure, requesting that Knoxville's complaint be severed and either dismissed or consolidated with the investigation in Docket No. RP75-45. Tennessee Gas Pipeline states that "with the conspicuous exception of Knoxville, all complaints filed in the instant proceedings raise questions as to the actual implementation of Tennessee's curtailment plan, while the thrust of Knoxville's complaint is directed toward the gas supply deficiency on the Tennessee Gas Pipeline, which as noted above is the subject of the investigation in Docket No. RP75-45. Additionally Tennessee points out that subsequent to the issuance of our December 24, 1974, order in Docket No. RP75-45, Knoxville filed a motion with the Commission reqeusting that it comthe Commission requesting that its consolidated with the aforementioned investigation because the issues involved in the two proceedings were "identical." On March 6, 1975, Knoxville[1] filed a motion with the Commission requesting its complaint, filed in Docket No. RP75-43, be dismissed without prejudice. In

[1] Motion of Knoxville Utilities Board, et al., and Tennessee Public Service Commission to dismiss without prejudice the complaint filed in Docket No. RP7543. [footnote omitted].

support of its motion Knoxville states that: "the relief sought by the Commission in its investigation in Docket No. RP75-45 is identical to the relief sought by Knoxville in its complaint, and that there is no need for a duplication of hearings relating to the same subject matter." We agree, upon review, of Knoxville's filing we find ourselves in agreement with Tennessee that the complaint is directed toward the cause or causes of the supply deficiency of the Tennessee Gas Pipeline system, and does not go to the implementation of Tennessee's curtailment plan which is the central issue in these consolidated proceedings. Accordingly, we shall grant Tennessee's motion to sever Knoxville's complaint filed in Docket No. RP75-43, from these consolidated proceedings and dismiss same.

Our order of February 14, 1975, in the instant proceeding was designated in Docket Nos. RP74-24, et al., our reference to that docket was solely for the purpose of denying GM's petition to reopen the proceedings in Docket No. RP74-24. Since the instant proceeding was initiated by the filing of Con Ed's complaint in Docket No. RP75-35 on November 19, 1974, and since continued use of the RP74-24, et al., designation may lead to confusion, particularly in the maintenance of separate and distinct records, we shall redesignate the proceeding. Henceforth the instant proceeding will be designated RP75-35, et al.

On February 12, 1975, Berkshire Gas Company (Berkshire), filed in Docket No. RP75-64, a complaint against Tennessee. Berkshire alleges that Tennessee has arbitrarily refused to correct an obvious, good faith error made by Berkshire in its reporting of end use data to be used in the implementation of Tennessee's curtailment plan. Berkshire contends that it erroneously interpreted the inclusion of firm industrial sales up to 300 Mcf per day in Priority 2 and also a 300 Mcf per day limitation on the volumes of process needs that could be included in this category. As a result of this error, Berkshire claims that an annual volume of 545,431 Mcf was listed in Priority 3 rather than Priority 2. Further, Berkshire argues that Tennessee has prime responsibility for compiling accurate end use data to implement its curtailment plan, and thus, by refusing to correct the error, subjects Berkshire to unjust and unreasonable treatment. We believe that Berkshire's complaint involves not only the issue of whether or not Berkshire has been aggrieved by Tennessee's refusal to reclassify the allegedly misplaced volumes but also what responsibility a pipeline has to maintain accurate end use data, and its obligation to correct the end use data upon sufficient proof of error. In our view, Berkshire's complaint goes to the administration of Tennessee's curtailment plan. We shall therefore consolidate Berkshire's complaint, Docket No. RP75-64, with the proceedings in Docket No. RP75-35, et al., and modify our order of February 14, 1975, Docket Nos. RP74-24, et al., to include therein procedures to accommodate the proceedings consolidated by this order.

The Commission finds. (1) Good cause exists to grant Tennessee's motion to sever Knoxville's complaint, filed in Docket No. RP75-43, from the consolidated proceedings in Docket Nos. RP75-35, et al., and dismiss same.

(2) Berkshire Gas Company's complaint, filed in RP75-64, contains questions of law and fact in common with the proceedings in Docket Nos. RP75-35, et al., as such, good cause exists to consolidate those proceedings and to set the consolidated proceedings for formal hearings.

(3) The instant proceedings should henceforth be designated as RP75-35, et al.

The Commission orders. (A) Tennessee Gas Pipeline's motion to sever Knoxville's complaint, from the consolidated proceedings in Docket Nos. RP74-24, et al., is hereby granted.

(B) Berkshire Gas Company's complaint, filed in Docket No. RP75-64, is hereby consolidated for hearing and decision with the proceedings in Docket Nos. RP75-35, et al.

(C) Berkshire shall file and serve its evidence in support of its complaint on all parties including Commission staff at the start of the hearing on March 25, 1975.

(D) The instant proceeding is hereby redesignated as Docket No. RP75-35, et al.

By the Commission.

Issued: March 14, 1975.

[SEAL] MARY B. KIDD,
Acting Secretary.

[FR Doc.75-7373 Filed 3-20-75;8:45 am]

[Docket No. CP75-254]

TRANSCONTINENTAL GAS PIPE LINE CORP. AND TEXAS EASTERN TRANSMISSION CORP.

Application

MARCH 14, 1975.

Take notice that on March 3, 1975, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77001, and Texas Eastern Transmission Corporation (Texas Eastern), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP75-254 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the operation of facilities for the exchange of natural gas, on a Btu basis, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicants propose that from April 16, 1975, through November 15, 1975, Transco will deliver to Texas Eastern at presently authorized points of exchange with Texas Eastern in the Pennsylvania-New Jersey-New York area, up to 60,000 Mcf of gas per day which is equivalent to gas to be injected into storage by Texas Gas Transmission Corporation (Texas Gas) for Transco. Texas Eastern proposes to return such quantities to Transco by concurrently delivering same, or effectuating deliveries of same, to Texas Gas for the account of Transco at the authorized interconnection between the systems of Texas Eastern and Texas Gas at Lebanon, Ohio. Applicants state that the quantity of gas delivered to Texas Gas for the account of Transco will be balanced with the quantity of gas delivered to Texas Eastern by Transco on a Btu basis.

Applicants state that the purpose of their proposed exchange is to assist in effectuating a temporary underground storage arrangement between Transco and Texas Gas.[1]

Any person desiring to be heard or to make any protest with reference to said application should on or before April 7, 1975, file with the Federal Power Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10) and the regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act and the Commission's rules of practice and procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75-7374 Filed 3-20-75;8:45 am]

[Docket No. RP74-20; RP74-83]

UNITED GAS PIPE LINE CO.

Further Extension of Procedural Dates

MARCH 14, 1975.

On March 4, 1975, United Gas Pipe Line Company filed a motion to extend the procedural dates fixed by order issued

[1] Related to said storage arrangement applications were filed by Transco on March 3, 1975, in Docket No. CP75-253 and by Texas Gas on February 27, 1975, in Docket No. CP75-246.

May 16, 1974, as most recently modified by notice issued November 21, 1974, in the above-designated matter. The motion states that the parties have been notified and have no objection.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of staff's testimony on unsettled issues in Rp74–20, April 15, 1975.
Service of intervenor's testimony on unsettled issues in both dockets, April 29, 1975.
Service of company rebuttal, May 13, 1975.
Hearing, May 27, 1975 (10 a.m. E.D.T.).

By direction of the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc.75–7375 Filed 3–20–75;8:45 am]

GENERAL ACCOUNTING OFFICE

REGULATORY REPORTS REVIEW

Notice of Receipt of Report Proposals

The following requests for clearance of reports intended for use in collecting information from the public were received by the Regulatory Reports Review Staff, GAO, on March 13, 1975. See 44 U.S.C. 3512 (c) & (d). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public of such receipt.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed FEA forms are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed form, comments must be received on or before April 8, 1975, and should be addressed to Mr. Monte Canfield, Jr., Director, Office of Special Programs, United States General Accounting Office, 425 I Street, NW., Washington, D.C. 20548.

Further information about the items on this list may be obtained from the Regulatory Reports Review Officer, 202–376–5425.

FEDERAL ENERGY ADMINISTRATION

The Federal Energy Administration requests clearance of the Monthly Cost Allocation Report, FEO–96. This form, in use since February 1974, obtains information on the refiner's domestic and foreign crude petroleum and petroleum product's cost and adjustments to May 15, 1975, selling price for covered products. The number of respondents is approximately 140. The compliance burden is estimated at 16 man-hours per monthly report.

Requests for clearance of FEA P108–M–O, Wholesale Purchaser-Reseller's Certification of Distribution to Purchasers for Uses Under an Allocation Level not Subject to an Allocation Fraction. This form is to be filed by wholesale purchasers resellers to verify that products delivered to them for uses not subject to an allocation fraction were so used. The form will be filed on a monthly or quarterly basis depending on the base period for the product. Respondents are expected to number a maximum of 20,000. Average response time is estimated to be one hour per response.

NORMAN F. HEYL,
Regulatory Reports Review Officer.

[FR Doc.75–7463 Filed 3–20–75;8:45 am]

INTERNATIONAL TRADE COMMISSION

[337–31]

ELECTRONIC PIANOS

Findings and Recommendation

On March 6, 1972, The Wurlitzer Company of Chicago, Illinois, filed a complaint (as supplemented) under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) alleging unfair methods of competition and unfair acts in the importation and sale of (1) Electronic pianos allegedly covered by the claim(s) in U.S. Patents No. 3,038,363; 2,942,512; and 2,949,053; and (2) reeds for electronic pianos allegedly covered by the claim(s) in U.S. Patent No. 3,154,997. Complainant is the owner of these patents.

The Commission conducted a preliminary inquiry with respect to the matters alleged in said complaint pursuant to § 203.3 of the Commission's rules of practice and procedure (19 CFR 203.3) and, on September 22, 1972, pursuant to § 203.4 of the Commission's rules of practice and procedure (19 CFR 203.4), ordered that an investigation (No. 337–31) be instituted with respect to the alleged violations in the importation and sale in the United States of certain electronic pianos. Public hearings were held in connection with this investigation on January 30–31, 1973, March 29, 1973, and August 15, 1974, pursuant to § 203.5 of the Commission's rules of practice and procedure (19 CFR 203.5).

Upon completion of its investigation, the Commission (Commissioners Leonard and Minchew dissenting) finds unfair methods of competition and unfair acts in the unlicensed importation and sale of certain electronic pianos by reason of their being made in accordance with the claim(s) of U.S. Patent No. 3,038,363, the effect or tendency of which is to substantially injure an industry, efficiently and economically operated, in the United States.

The Commission does not find unfair methods of competition or unfair acts in the importation into the United States, or in the sale by the owner, importer, consignee, or agent of either, of (1) Electronic pianos allegedly made in accordance with the claim(s) in U.S. Patent No. 2,942,512; (2) electronic pianos allegedly made in accordance with the claim(s) in U.S. Patent No. 2,949,053; or (3) reeds for electronic pianos allegedly made in accordance with the claim(s) in U.S. Patent No. 3,154,997, the effect or tendency of which is to substantially injure an industry, efficiently and economically operated, in the United States.

The Commission (Commissioners Moore and Ablondi dissenting[1]) recommends that the President not issue an exclusion order to forbid entry into the United States of electronic pianos covered by the claim(s) in U.S. Patent No. 3,038,363.

Under the statute (19 U.S.C. 1337(c)) a rehearing before the Commission may be requested. In accordance with § 201.14 of the Commission's rules of practice and procedure (19 CFR 201.14) a motion for a rehearing may be granted for good cause shown. Any such motion for a rehearing must be in writing and filed with the Secretary of the U.S. International Trade Commission, 8th and E Streets NW., Washington, D.C. 20436, within fourteen (14) days after publication of this notice. The motion must state clearly the grounds which are relied upon for the granting of a rehearing and must be accompanied by nineteen (19) true copies.

By order of the Commission.

Issued: March 17, 1975.

KENNETH R. MASON,
Secretary.

[FR Doc.75–7379 Filed 3–20–75;8:45 am]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (75–22)]

NASA RESEARCH AND TECHNOLOGY ADVISORY COUNCIL, COMMITTEE ON ENERGY TECHNOLOGY AND SPACE PROPULSION

Notice of Meeting

The NASA Research and Technology Advisory Council Committee on Energy Technology and Space Propulsion will meet April 10–11, 1975, at NASA Headquarters, 600 Independence Avenue SW., Washington, D.C. The meeting will be held in Room 625. Members of the public will be admitted on a first-come, first-served basis, up to the seating capacity of the room which is about 40 persons. All visitors must register at the reception desk in Room 625.

The NASA Research and Technology Advisory Council Committee on Energy Technology and Space Propulsion serves in an advisory capacity only. The Chairman is Dr. Beno Sternlicht, and there are 11 members. The following list sets forth the approved agenda and schedule for the April 10–11, 1975, meeting of the Committee on Energy Technology and Space Propulsion. For further information, please contact Mr. R. D. Ginter,

[1] Commissioners Moore and Ablondi recommend that, in accordance with subsection (e) of section 337, the President issue an exclusion order to forbid entry into the United States of electronic pianos covered by the claim(s) in U.S. Patent No. 3,038,363, until expiration of the patent, except where the importation is under license of the owner of U.S. Patent No. 3,038,363.

Area Code 202, 755–8475, or Mr. W. H. Woodward, Area Code 202, 755–3280.

APRIL 10, 1975

Time	Topic
8:30 a.m.	Report of working groups. (Purpose: Each of the four working groups listed below will present findings and recommendations for discussion and approval by the Committee: (1) Space power and propulsion, (2) NASA's terrestrial energy capabilities, (3) potential joint industry/NASA terrestrial energy projects, and (4) NASA surface propulsion technology capabilities.)
1 p.m.	Continuation of working group discussions.

APRIL 11, 1975

8:30 a.m.	Discussion of overall Committee recommendations and work assignments.
1 p.m.	Continuation of above discussion.
3 p.m.	Adjourn.

MARCH 17, 1975.

DUWARD L. CROW,
Assistant Administrator for DOD and Interagency Affairs, National Aeronautics and Space Administration.

[FR Doc.75-7413 Filed 3-20-75;8:45 am]

NUCLEAR REGULATORY COMMISSION

BARNWELL NUCLEAR FUEL PLANT

Establishment of Interim Amount of Financial Protection and Indemnity Fee

On December 19, 1974, the Atomic Energy Commission published in the FEDERAL REGISTER (39 FR 43867) a proposed rule to establish the interim amount of financial protection and interim indemnity fee for the Barnwell Nuclear Fuel Plant (BNFP) presently under construction by Allied-General Nuclear Services (AGNS) in Barnwell, South Carolina. The Atomic Energy Commission issued a construction permit to AGNS for the construction of the Barnwell reprocessing facility in December 1970. Financial protection and indemnity fee amounts are established on an interim basis pending establishment in a later rule making of permanent levels of financial protection and indemnity fees for all reprocessing plants.

On October 11, 1974 the Energy Reorganization Act of 1974[1] was enacted into law. This Act abolished the Atomic Energy Commission and, by section 201 established the Nuclear Regulatory Commission and transferred to that Commission all of the licensing and related regulatory functions of the Atomic Energy Commission. In addition, section 301 of the Energy Reorganization Act provided that any proceedings pending before the AEC at the time of its abolition shall, to the extent that such proceedings relate to functions transferred by the Act, be continued.

Interested persons were invited to submit written comments and suggestions in connection with the proposed amendment by January 20, 1975. No comments were received by either AEC or NRC; therefore the Nuclear Regulatory Commission has adopted the proposed amendment without any changes.

Section 170 of the Atomic Energy Act of 1954, as amended, ("the Act") requires (1) Each license issued under section 104 for medical therapy and research and development reactors to have as a condition of the license a requirement that the licensee have and maintain financial protection of such type and in such amounts as the Commission shall require to cover public liability claims, (2) the licensee to execute and maintain an indemnification agreement with the Commission and (3) the Commission to collect a fee from each licensee with whom an indemnification agreement is executed.

Subsection 170b. of the Act provides that the amount of financial protection required of such licensees shall be equal to the maximum amount of nuclear liability insurance available from private sources except that the Commission may establish a lesser amount on the basis of written criteria, taking into consideration such factors as (1) The cost and terms of private insurance; (2) the type, size, and location of the licensed activity and other factors pertaining to the hazard; and (3) the nature and purpose of the licensed activity.

The annual indemnity fee set by subsection 170f. of the Act is $30 per thousand kilowatts of thermal energy capacity for commercial facilities licensed under section 103. However, for facilities licensed under section 104, and for construction permits issued under section 185, the Commission is authorized to reduce this fee. The Commission is directed to establish written criteria for determination of the fee, taking into consideration such factors as (1) The type, size, and location of the facility involved, and other factors pertaining to the hazard, and (2) the nature and purpose of the facility.

The Commission's regulations in 10 CFR Part 140 prescribe criteria for determining the amounts of financial protection and indemnity fees with specific reference to reactors. No similar criteria have been adopted for other types of facilities, such as reprocessing plants. The Commission has previously established financial protection requirements for two fuel reprocessing facilities, the Nuclear Fuel Services, Inc., Reprocessing plant and the General Electric Company's Midwest Fuel Recovery Plant. Financial protection requirements for both facilities were set by the Commission at $5 million for the preoperational storage of fuel and $20 million for plant operations, with an annual indemnity fee of $500 for storage only of fuel and $4,000 for plant operations.

These financial protection requirements were established on an interim basis since there was not sufficient experience or data available to prescribe financial protection requirements for reprocessing plants as a class. In arriving at the interim amounts, the Commission took into account, in addition to the specific statutory criteria, the following considerations: (a) amount of liability insurance carried by fabricators of cold fuel; (b) liability insurance limits carried by firms engaged in hazardous operations in nonnuclear industries, i.e., chemicals and petroleum; and (c) the maximum amount of nuclear liability insurance available (at that time, $60 million).

The Commission recognizes that there is an ongoing licensing proceeding with respect to the Barnwell Nuclear Fuel Plant pending before an Atomic Safety and Licensing Board. No license will be issued except in accordance with applicable Commission regulations. This rule merely provides the basis for financial protection requirements in the event that a license should be issued.

As a production facility, the Barnwell plant cannot be licensed to receive fuel assemblies unless Allied-General Nuclear Services provides financial protection to protect against public liability arising out of or resulting from a nuclear incident. Pending establishment in a rule making proceeding of financial protection and indemnity fee requirements for reprocessing facilities as a class, notice is hereby given that the Commission has established interim financial protection requirements of $5 million for fuel storage with an annual indemnity fee of $500 at the Barnwell plant. Rule making proceedings on permanent levels of financial protection to be required for all reprocessing plants should be completed by the time the construction of the plant is completed.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, and sections 552 and 553 of title 5 of the United States Code, the interim level of financial protection and the annual indemnity fee, set forth above, are established for the Barnwell facility.

Effective date. The foregoing rule becomes effective on April 20, 1975.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 170, Pub. L. 85-256, 71 Stat. 576 (42 U.S.C. 2210); secs. 201, 301, Pub. L. 93-438, 88 Stat. 1242, 1248)

Dated at Bethesda, Maryland this 14th day of March, 1975.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
Acting Executive Director for Operations.

[FR Doc.75-7349 Filed 3-20-75;8:45 am]

[Docket No. 50-389]

FLORIDA POWER AND LIGHT CO. (ST. LUCIE NUCLEAR POWER PLANT, UNIT 2)

Assignment of Atomic Safety and Licensing Appeal Board

Notice is hereby given that, in accordance with the authority in 10 CFR 2.787

[1] Pub. L. 93-438 (88 Stat. 1233).

(a), the Chairman of the Atomic Safety and Licensing Appeal Panel has assigned the following panel members to serve as the Atomic Safety and Licensing Appeal Board for this proceeding:

Michael C. Farrar, Chairman
Dr. W. Reed Johnson, Member
Richard S. Salzman, Member

Dated: March 14, 1975.

MARGARET E. DU FLO,
Secretary to the Appeal Board.

[FR Doc. 75-7350 Filed 3-20-75;8:45 am]

[Docket No. 50-285]

OMAHA PUBLIC POWER DISTRICT

Proposed Issuance of Amendment to Facility Operating License

The Nuclear Regulatory Commission (the Commission) is considering the issuance of an amendment to Facility Operating License No. DPR-40 issued to Omaha Public Power District (the licensee) for operation of Fort Calhoun Station, Unit 1, a pressurized water reactor located in Washington County, Nebraska, and currently authorized for operation at power levels up to 1420 Mwt.

The amendment would revise provisions in the Technical Specifications in accordance with the licensee's applications for license amendments dated February 3, 1975, March 3, 1975, and March 7, 1975. The amendment would modify operating limits in the Technical Specifications based upon an evaluation of ECCS performance calculated in accordance with an acceptable evaluation model that conforms to the requirements of the Commission's regulations in 10 CFR Part 50, § 50.46. The amendment would modify various limits established in accordance with the Commission's Interim Acceptance Criteria, and would, with respect to Fort Calhoun Station, Unit 1, terminate the further restrictions imposed by the Commission's December 27, 1974, Order For Modification of License, and would impose instead, limitations established in accordance with the Commission's Acceptance Criteria for Emergency Core Cooling Systems for Light Water Nuclear Power Reactors, 10 CFR Part 50, § 50.46.

The applicant also requested modifications of those provisions of the Technical Specifications which relate to installed filter systems and modification of certain operating limits and instrument set points to reflect the results of the licensee's cycle 2 core performance analysis.

Prior to issuance of the proposed license amendment, the Commission will have made the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

By April 21, 1975, the licensee may file a request for a hearing and any person whose interest may be affected by this proceeding may file a request for a hearing in the form of a petition for leave to intervene with respect to the issuance of the amendment to the subject facility operating license. Petitions for leave to intervene must be filed under oath or affirmation in accordance with the provisions of § 2.714 of 10 CFR Part 2 of the Commission's regulations. A petition for leave to intervene must set forth the interest of the petitioner in the proceeding, how that interest may be affected by the results of the proceeding, and the petitioner's contentions with respect to the proposed licensing action. Such petitions must be filed in accordance with the provisions of this FEDERAL REGISTER notice and § 2.714, and must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section, by the above date. A copy of the petition and/or request for a hearing should be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Hope Babcock, Esquire, LeBoef, Lamb, Leiby & MacRae, 1757 N. Street, NW., Washington, D.C. 20036, the attorney for the licensee.

A petition for leave to intervene must be accompanied by a supporting affidavit which identifies the specific aspect or aspects of the proceeding as to which intervention is desired and specifies with particularity the facts on which the petitioner relies as to both his interest and his contentions with regard to each aspect on which intervention is requested. Petitions stating contentions relating only to matters outside the Commission's jurisdiction will be denied.

All petitions will be acted upon by the Commission or licensing board, designated by the Commision or by the Chairman of the Atomic Safety and Licensing Board Panel. Timely petitions will be considered to determine whether a hearing should be noticed or another appropriate order issued regarding the disposition of the petitions.

In the event that a hearing is held and a person is permitted to intervene, he becomes a part to the proceeding and has a right to participate fully in the conduct of the hearing. For example, he may present evidence and examine and cross-examine witnesses.

For further details with respect to this action, see (1) the applications for Amendments dated February 3, 1975, March 3, 1975, and March 7, 1975, and (2) The Commission's Order for Modification of License and the documents referred to in the Order dated December 27, 1974, (published in the FEDERAL REGISTER on January 9, 1975 (40 FR 1772), which are available for public inspection at the Commission's Public Document Room 1717 H Street, NW., Washington, D.C. and at the Blair Public Library, 1665 Lincoln Street, Blair, Nebraska. As they become available, the Commission's related Safety Evaluation and license amendment and any attachments may be inspected at the above locations. A copy of the license amendment and attachments and the Safety Evaluation, when available, may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Maryland this 18th day of March, 1975.

For the Nuclear Regulatory Commission.

GEORGE LEAR,
Chief, Operating Reactors Branch No. 3, Divison of Reactor Licensing.

[FR Doc.75-7571 Filed 3-20-75;8:45 am]

[Docket Nos. STN 50-522, STN 50-523]

PUGET SOUND POWER AND LIGHT CO., ET AL.

Determination of Date for Filing Contentions

In the matter of Puget Sound Power and Light Company, Pacific Power and Light Company, the Washington Water Power Company, Idaho Power Company, and Washington Public Power Supply System (Skagit Nuclear Power Project, Units 1 and 2).

On February 26, 1975, Puget Sound Power and Light Company (Applicant) filed a motion for an order to designate the date on or before which Skagitonians Concerned About Nuclear Plants (SCANP or Intervenor) must file contentions on matters covered by the complete Preliminary Safety Analysis Report (PSAR) filed by Applicant and served upon SCANP on January 23, 1975. Previously SCANP had filed contentions with respect to site suitability.

The Regulatory Staff in its response filed March 13, 1975, to the Applicant's aforesaid motion reported the results of its endeavors to achieve a stipulation with the parties respecting the motion and stated that all parties agreed that SCANP may file its contentions on the PSAR on or before the first prehearing conference scheduled for April 15, 1975. The Staff suggested that the order in this regard be published in the FEDERAL REGISTER in order to give adequate public notice, in addition to the mailing of copies of the order to the parties and to those requesting copies.

The Atomic Safety and Licensing Board finds good cause to accept the stipulation achieved through the endeavors initiated by the Regulatory Staff and also to accept the suggestion for publication in the FEDERAL REGISTER.

Wherefore, it is ordered, pursuant to the Atomic Energy Act, as amended, and the rules of practice of the commission,[1] the motion of Applicant is granted to the extent that the date of April 15, 1975 is designated as the date on or before which Skagitonians Concerned About Nuclear Plants shall file its contentions respecting the Preliminary Safety Analysis Report filed by Applicant and served on January 23, 1975 upon the attorney for SCANP.

---

[1] The Nuclear Regulatory Commission is the nuclear power licensing and regulatory organization successor to the Atomic Energy Commission by virtue of legislation enacted by the Congress, by Pub. L. 93-438.

Issued: March 17, 1975, Bethesda, Maryland.

ATOMIC SAFETY AND LICENSING BOARD,
SAMUEL W. JENSCH,
Chairman.

[FR Doc.75-7351 Filed 3-20-75;8:45 am]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REPORTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on March 18, 1975 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

The symbol (X) identifies proposals which appear to raise no significant issues, and are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503 (202-395-4529), or from the reviewer listed.

NEW FORMS

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration, Cedar Key Sport Fishing Survey Questionnaires, single-time, saltwater fishermen at Cedar Key, Fla., Planchon, P., 395-3898.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary:
- Evaluation Activity Reporting System, OS-12-75, on occasion, organizations, agencies performing evaluations, Human Resources Division, 395-3532.
- Interview Instruments for Assessing State, Capability To Deliver Children's Services, OS-14-75, single-time, State government agencies, Human Resources Division, 395-3532.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Policy Development and Research, Urban Economic Analysis and Planning Survey, single-time, cities and suburban counties over 150,000, Community and Veterans Affairs Division, 395-3532.

DEPARTMENT OF LABOR

Bureau of International Labor Affairs, Petition for Adjustment Assistance, ILAB 20, on occasion, groups of workers, Lowry, R. L., 395-3772.

REVISIONS

ENVIRONMENTAL PROTECTION AGENCY

National Emissions Data System (NEDS) Input Data Forms, EPA 219-220, semiannually, State air pollution control agencies, Natural Resources Division, 395-6827.

DEPARTMENT OF AGRICULTURE

Statistical Reporting Service, Cotton Inquiries, other (see SF-83), cotton producers, Lowry, R. L., 395-3772.

EXTENSIONS

DEPARTMENT OF DEFENSE

Departmental and Other, Application for U.S. Government Bill(s) of Lading/Export Traffic, Release, on occasion, DOD contractors, Lowry, R. L., 395-3772.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education:
- Report on Current Upward Bound Student, OE-1196, on occasion, upward bound project directors, Lowry, R. L., 395-3772.
- Report on Former Upward Bound Student, OE 1197, on occasion, upward bound project directors, Lowry, R. L., 395-3772.

DEPARTMENT OF THE INTERIOR

Bureau of Mines:
- Placer-Mine Production of Gold, Silver and Platinum, 6-1176-A, annually, Evinger, S. K., 395-3648.
- Fuel Consumed for all Purposes at Refineries, 6-1335-A, annually, Evinger, S. K., 395-3648.
- Mica Splittings (Consumption), 6-1259-A, annually, Evinger, S. K., 395-3648.
- Titanium Materials (Consumption), 6-1133-A, annually, Evinger, S. K., 395-3648.
- Production of Ilmenite and Rutile, 6-1135-A, annually, Evinger, S. K., 395-3648.
- Capacity of Petroleum Refineries, 6-1334-A, annually, Evinger, S. K., 395-3648.
- Refinery Report, 6-1300-M, monthly, Evinger, S. K., 395-3648.

PHILLIP D. LARSEN,
Budget and Management Officer.

[FR Doc.75-7522 Filed 3-20-75;8:45 am]

SECURITIES AND EXCHANGE COMMISSION

[70-5646]

CONSOLIDATED NATURAL GAS CO. ET AL.

Proposed Open Account Advances to Subsidiary Companies by Parent Company in Connection with Intrasystem Prepayment of Promissory Notes and Related Transactions

MARCH 14, 1975.

Notice is hereby given that Consolidated Natural Gas Company ("Consolidated") 30 Rockefeller Plaza, New York, New York 10020, a registered holding company, and its subsidiary companies, Consolidated Gas Supply Corporation ("Gas Supply"), The East Ohio Gas Company ("East Ohio"), The Peoples Natural Gas Company ("Peoples"), and West Ohio Gas Company ("West Ohio"), have filed an application-declaration and an amendment thereto with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating sections 6(a), 6(b), 7, 9(a), 10, and 12(b) of the Act and Rule 45 promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the application-declaration, which is summarized below, for a complete statement of the proposed transactions.

It is stated that Consolidated's distribution subsidiaries seasonally accumulate cash over and above current requirements because of their large winter heating business. Other subsidiaries, presently engaged in developing gas supply, have little or no operating cash flow and regularly require capital financing from Consolidated. Therefore, Consolidated may be making short-term borrowings when distribution subsidiaries are making temporary money market investments outside the Consolidated System. It is stated that it would be advantageous to alleviate this situation, and the present filing is designed to establish financing procedures that optimize the internal utilization of excess cash funds accumulated within the System.

It is proposed that the following subsidiaries make temporary prepayments on long-term notes held by Consolidated from excess cash funds, from time to time prior to December 31, 1975, not exceeding at any time the aggregate amounts set forth below:

Gas Supply	$10,000,000
East Ohio Gas	20,000,000
Peoples	5,000,000
West Ohio	3,500,000
Total	38,500,000

Consolidated estimates that the aggregate prepayment of $38,500,000 is the maximum that can be utilized for the temporary financing of other subsidiaries in the System during 1975.

The long-term notes temporarily prepaid by an individual subsidiary will be those bearing the highest interest rate outstanding at the time of each prepayment. Interest on such notes will cease upon prepayment and start again upon reinstatement of the notes.

As funds are thereafter required by such subsidiary for corporate purposes, including construction, it is proposed that advances be made on open account to the subsidiary by Consolidated in an aggregate amount not to exceed the amount of long-term notes previously prepaid, less any current maturities applicable to notes which have matured subsequent to the prepayment dates. The open account advances will bear interest at the same rate or rates as borne by the equivalent principal amounts of the notes previously prepaid by such subsidiary during 1975, but in reverse order to that of the prepayments, i.e., from the lowest rate on the notes previously prepaid to the highest rate. Interest on the open account advances will commence on the date of the advance and

will become due on June 30, 1975, and December 31, 1975, and/or on the date such advances are repaid by the reinstatement of the prepaid notes.

It is proposed that open account advances to a subsidiary be increased or decreased from time to time in accordance with variations in the cash flow of the subsidiary. However, at no time will the advances outstanding be in excess of the notes prepaid. At such time as the open account advances equal the aggregate amount of the prepaid notes, or in any event not later than December 31, 1975, the notes prepaid by a subsidiary will be reinstated in repayment of the related outstanding open account advances made to the subsidiary by Consolidated. However, if the aggregate of the notes prepaid exceeds such advances at the end of 1975, Consolidated proposes to make cash repayment of the difference in order to effect reinstatement of the proposed notes in full. No financing of any subsidiary which may be presently or subsequently authorized by this Commission in connection with the construction or gas storage programs of any such subsidiary will be consummated until such time as advances have been made in amount equal to the amount of notes prepaid.

It is stated that the proposed transactions will be beneficial to the System because they will: (1) Permit subsidiary companies with excess cash to prepay temporarily long-term notes held by Consolidated, with a resulting reduction in their interest expense; (2) make available to Consolidated a temporary cash source for the financing of other companies within the System; and (3) permit Consolidated, which obtains all external financing required by the System, to consequently defer or prepay short-term financing such as inventory loans with banks and commercial paper borrowings for working capital.

The expenses to be incurred in connection with the proposed transactions are estimated not to exceed $4,000. It is stated that the Public Service Commission of West Virginia has jurisdiction over the prepayment and reactivation of the long-term notes and the short-term borrowings proposed by Supply Corporation and that no other State commission and no Federal commission, other than this Commission, has jurisdiction over the proposed transactions. The applicants-declarants request that authority be granted to file certificates under Rule 24 reporting transactions consummated pursuant to this filing on a quarterly basis.

Notice is further given that any interested person may, not later than April 7, 1975, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the filing which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail (air mail if the person being served is located more than 500 miles from the point of mailing) upon the applicants-declarants at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as filed or as it may be amended, may be granted and permitted to become effective as provided in Rule 23 of the general rules and regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive notice of further developments in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-7415 Filed 3-20-75;8:45 am]

[File No. 500-1]

EQUITY FUNDING CORP. OF AMERICA

Suspension of Trading

MARCH 17, 1975.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock, warrants to purchase the stock, 9½ percent debentures due 1990, 5½ percent convertible subordinated debentures due 1991, and all other securities of Equity Funding Corporation of America being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from March 18, 1975 through March 27, 1975.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-7416 Filed 3-20-75;8:45 am]

[File No. 500-1]

INDUSTRIES INTERNATIONAL, INC.

Suspension of Trading

MARCH 17, 1975.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Industries International, Inc. being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from March 18, 1975 through March 27, 1975.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-7417 Filed 3-20-75;8:45 am]

[File No. 500-1]

KMS INDUSTRIES INC.

Suspension of Trading

MARCH 14, 1975.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of KMS Industries Inc. being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from 11 a.m. (e.s.t.) on March 14, 1975, through midnight (e.s.t.) on March 23, 1975.

By the Commission.

[SEAL] SHIRLEY E. HOLLIS, *Assistant Secretary.*

[FR Doc.75-7418 Filed 3-20-75;8:45 am]

[File No. 500-1]

WESTGATE CALIFORNIA CORP.

Suspension of Trading

MARCH 17, 1975.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock (class A and B), the cumulative preferred stock (5 percent and 6 percent), the 6 percent subordinated debentures due 1979 and the 6½ percent convertible subordinated debentures due 1987 being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from March 18, 1975 through March 27, 1975.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-7419 Filed 3-20-75;8:45 am]

[File No. 500-1]

ZENITH DEVELOPMENT CORP.

Suspension of Trading

MARCH 17, 1975.

It appearing to the Securities and Exchange Commission that the summary suspension of trading in the common stock of Zenith Development Corporation

being traded otherwise than on a national securities exchange is required in the public interest and for the protection of investors;

Therefore, pursuant to section 15(c)(5) of the Securities Exchange Act of 1934, trading in such securities otherwise than on a national securities exchange is suspended, for the period from March 18, 1975, through March 27, 1975.

By the Commission.

[SEAL] GEORGE A. FITZSIMMONS, *Secretary.*

[FR Doc.75-7420 Filed 3-20-75;8:45 am]

SMALL BUSINESS ADMINISTRATION

[License No. 09/12-0047]

CAL-WEST CAPITAL CORP.

Notice of License Surrender

Notice is hereby given that Cal-West Capital Corporation, 260 California Street, San Francisco, California 94111, has surrendered its license No. 09/12-0047, issued December 19, 1961.

Cal-West Capital Corporation has complied with all conditions set forth by SBA for surrender of its license. Therefore, under the authority vested by the Small Business Investment Act of 1958, as amended, and pursuant to the regulations promulgated thereunder, the surrender of the license of Cal-West Capital Corporation is hereby accepted and it is no longer licensed to operate as a small business investment company.

Dated: March 11, 1975.

JAMES THOMAS PHELAN, *Deputy Associate Administrator for Investment.*

[FR Doc.75-7394 Filed 3-20-75;8:45 am]

[License No. 02/02-0102]

HANOVER CAPITAL CORP.

Filing of Application for Approval of Conflict of Interest Transaction

Notice is hereby given that Hanover Capital Corporation (Hanover) 223 East 62nd Street, New York, New York 10021, a Federal Licensee under the Small Business Investment Act of 1958, as amended, has filed an application pursuant to § 107.1004(b) of the SBA rules and regulations governing small business investment companies (13 CFR 107.1004 (1974)), for an exemption from the provisions of the conflict of interest regulations.

The exemption, if granted, will permit Hanover to loan funds to Petroleum Recovery Systems, Inc. (PRS), a wholly owned subsidiary of Tenney Engineering, Inc. (Tenney) a publicly-held corporation listed on the American Stock Exchange. PRS and Tenney are both located in Union, New Jersey. The loan is collateralized by the assets of PRS, and is guaranteed by Tenney. In addition, Hanover will receive warrants to purchase Tenney's common stock.

Tenney and PRS are considered to be "Associates" of the Licensee as defined by § 107.3 of the regulations because the chairman of the Board of Directors and a substantial beneficial owner of Tenney is a business partner of the President and sole shareholder of Hanover. This transaction, therefore, will require an exemption pursuant to § 107.1004(b)(1) of the regulations.

Notice is hereby given that any person may, no later than April 7, 1975, submit written comments on the proposed transaction to: Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in New York, New York.

Dated: March 11, 1975.

JAMES THOMAS PHELAN, *Deputy Associate Administrator for Investment.*

[FR Doc.75-7434 Filed 3-20-75;8:45 am]

JACKSON DISTRICT ADVISORY COUNCIL

Notice of Public Meeting

The Small Business Administration Jackson District Advisory Council will meet at 9 a.m., (c.d.t.), Thursday, April 17, 1975, at the Board Room, First National Bank, 301 First National Building, Jackson, Mississippi, to discuss such business as may be presented by members and the staff of the Small Business Administration, and others attending. For further information, call or write Ardis Jones, Small Business Administration, 690 Petroleum Building, 200 E. Pascagoula, Jackson, Mississippi 39201, (601) 969-4363.

Dated: March 12, 1975.

ANTHONY S. STASIO, *Chief Counsel for Advocacy, Small Business Administration.*

[FR Doc.75-7395 Filed 3-20-75;8:45 am]

MARSHALL DISTRICT ADVISORY COUNCIL

Public Meeting

The Small Business Administration Marshall District Advisory Council will meet at 10 a.m., (c.d.t.), Thursday, April 10, 1975, at the Kilgore Community Inn, 801 Highway 259, Kilgore, Texas, to discuss such business as may be presented by members and the staff of the Small Business Administration and others attending. For further information, call or write Emly S. Atkinson, Small Business Administration, 505 East Travis Street, Marshall, Texas 75670, (214) 935-5257.

Dated: March 13, 1975.

ANTHONY S. STASIO, *Chief Counsel for Advocacy, Small Business Administration.*

[FR Doc.75-7435 Filed 3-20-75;8:45 am]

DEPARTMENT OF LABOR

Manpower Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS

Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, (7 U.S.C. 1924 (b), 1932, or 1942 (b)).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The Act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75, published January 29, 1975 (40 FR 4393). In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice to: Deputy Assistant Secretary for Manpower, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C. this 17th day of March, 1975.

BEN BURDETSKY,
Deputy Assistant Secretary for Manpower.

APPLICATIONS RECEIVED DURING THE WEEK ENDING MARCH 14, 1975

Name of applicant	Location of enterprise	Principal product or activity
Millers Super Market	New Haven, W. Va.	Retail super market.
Pyott-Boone Machinery Corp.	Saltville, Va.	Coal mine equipment.
Raeford Turkey Farms, Inc.	Raeford, N.C.	Turkey processing plant.
Axialight Corp.	Mountain Home, N.C.	Manufacturing miniature incandescent lamps.
Emergency One, Inc.	Ocala, Fla.	Manufacturing rescue vehicles.
Skipper Manufacturing, Inc.	Macon, Miss.	Purchase machinery.
Tennlight, Inc.	Greenbrier, Tenn.	Expand shale for lightweight aggregate.
MacLean-Fogg Lock Nut Co. (tenant of city of Tompkinsville, Ky.).	Tompkinsville, Ky.	Manufacturing fasteners.
Carus Corp.	La Salle, Ill.	Expand production of potassium permanganate.
Old Fashioned Milk Co., Inc.	Strum, Wis.	Bottle and sale grade A milk.
King's Pellets, Inc.	Garland, Ark.	Raise grains and forage crops.
Monte L. Christner Co., Inc.	Taylor, Mo.	Agriculture limestone.
Three Crosses Ranch, Inc.	Strawberry Point, Iowa	Provide care and rehabilitative services for teenage boys.

[FR Doc.75-7290 Filed 3-20-75;8:45 am]

INTERSTATE COMMERCE COMMISSION

[Notice No. 726]

ASSIGNMENT OF HEARINGS

MARCH 18, 1975.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC-C-8436, Connecticut Limousine Service, Inc. V. Hyman Levine dba Hy's Livery Service, now assigned April 15, 1975 at Hartford, Connecticut; has been postponed to April 21, 1975 (2 days) at Hartford, Connecticut; in a hearing room to be designated later.

FF-347 Sub 1, Sal, Inc., now assigned April 30, 1975 at Chicago, Illinois, is postponed indefinitely.

MC-F-12243, Wilson Freight Company—Purchase—M. W. Haley Trucking Co. and MC 13123 Sub 74, Wilson Freight Company, now being assigned May 6, 1975 (9 days); in the Netherland Hilton Hotel, Fourth and Race Streets, Cincinnati, Ohio.

MC 97841 Sub 21, General Highway Express, Inc., now being assigned April 7, 1975 (1 week), in Room 235 Federal Office Building, 85 Marconi Blvd., Columbus, Ohio.

MC 139252 Sub 1, Southeastern Warehousing and Distribution Corporation, now being assigned May 12, 1975 (1 week), at Johnson City, Tennessee; in a hearing room to be designated later.

MC 112304 Sub 85, Ace Doran Hauling & Rigging Co., now being assigned April 30, 1975 (1 day) at Chicago, Ill., in Room 1086A, Everett McKinley Dirksen Bldg., 219 South Dearborn St.

MC 107295 Sub 719, Pre-Fab Transit Co., now being assigned May 1, 1975 (2 Days) at Chicago, Ill., in Room 1086A, Everett McKinley Dirksen Bldg., 219 South Dearborn St.

MC 103926 Sub 43, W. T. Mayfield Sons Trucking Co., Inc., application dismissed.

MC 139053 Sub 2, Hiram E. Blue, Jr., Trucking Co., now being assigned May 28, 1975, at Jackson, Miss., in a hearing room to be later designated.

MC-F-12311, Fast Interstate Express, Inc.—Purchase (Portion)—Harper Truck Line, Inc., now being assigned June 6, 1975, at New Orleans, Louisiana, in a hearing room to be later designated.

MC 139932, H & M Drayage Brokerage, Inc., now being assigned June 4, 1975, at New Orleans, Louisiana, in a hearing room to be later designated.

MC 59583 Sub 146, The Mason and Dixon Lines, Incorporated, now being assigned May 28, 1975 (1 day) at Birmingham, Ala.; in a hearing room to be designated later.

MC-F-12322, Tompkins Motor Lines, Inc.—Purchase—Cullman Banana Supply, now being assigned May 29, 1975 (2 days) at Birmingham, Ala.; in a hearing room to be designated later.

MC 74321 Sub 110, B. F. Walker, Inc., now being assigned June 2, 1975 (1 day) at Birmingham, Ala.; in a hearing room to be designated later.

MC 72243 Sub 38, Aetna Freight Lines, Inc., now being assigned June 3, 1975 (2 days) at Birmingham, Ala.; in a hearing room to be designated later.

MC 115162 Sub 294, Poole Truck Line, Inc., MC 121664 Sub 6, G. A. Hornady, Cecil M. Hornady, and B. C. Hornady, dba Hornady Brothers Truck Line, and MC 126305 Sub 6, Boyd Brothers Transportation Co., Inc., now being assigned June 5, 1975 (2 days) at Birmingham, Ala.; in a hearing room to be designated later.

MC 4405 Sub 515, Dealers Transit, Inc., now being assigned May 29, 1975, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 78228 Sub 51, J. Miller Express, Inc., now being assigned May 29, 1975, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 21436 Sub 3, Thomas F. Welsh, dba Reliance Van Company, now being assigned June 3, 1975, at the Office of the Interstate Commerce Commission, Washington, D.C.

MC 123383 Sub 71, Boyle Brothers, Inc., now being assigned June 11, 1975, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 123091 Sub 15, Nick Strimbus, Inc., now being assigned June 19, 1975, at the Offices of the Interstate Commerce Commission, Washington, D.C.

MC 117574 Sub 253, Daily Express, Inc., now being assigned June 19, 1975, at the Offices of the Interstate Commerce Commission, Washington, D.C.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.75-7466 Filed 3-20-75;8:45 am]

FOURTH SECTION APPLICATIONS FOR RELIEF

MARCH 18, 1975.

An application, as summarized below, has been filed requesting relief from the requirements of section 4 of the Interstate Commerce Act to permit common carriers named or described in the application to maintain higher rates and charges at intermediate points than those sought to be established at more distant points.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the general rules of practice (49 CFR 1100.40) and filed on or before April 7, 1975.

FSA No. 42953—*Joint Water-Rail Container Rates—Kawasaki Kisen Kaisha, Ltd.* Filed by Kawasaki Kisen Kaisha, Ltd. (No. 13), for itself and interested rail carriers. Rates on general commodities, between ports in the Federation of Malaysia, The Republic of Singapore and Thailand, and rail stations on the U.S. Atlantic and Gulf Seaboard. Grounds for relief—Water competition.

FSA No. 42954—*Joint Water-Rail Container Rates—Mitsui O.S.K. Lines Ltd.* Filed by Mitsui O.S.K. Lines Ltd. (No. 8), for itself and interested rail carriers. Rates on general commodities, between ports in Hong Kong, Japan, Korea, and Taiwan, and rail stations on the U.S. Atlantic and Gulf Seaboard. Grounds for relief—Water competition.

FSA No. 42955—*Joint Water-Rail Container Rates—The Scindia Steam Navigation Co., Ltd.* Filed by The Scindia Steam Navigation Co., Ltd., (No. 1), for itself and interested rail carriers. Rates on general commodities, from ports in Hong Kong, Japan, Korea, and Taiwan, to rail terminals and water carrier terminals on the U.S. Atlantic and Gulf Seaboard. Grounds for relief—Water competition.

FSA No. 42956—*Joint Water-Rail Container Rates—The Shipping Corporation of India, Ltd.* Filed by The Shipping Corporation of India, Ltd., (No. 1), for itself and interested rail carriers. Rates on general commodities, from ports in Hong Kong, Japan, Korea, and Taiwan, to rail terminals and water carrier terminals on the U.S. Atlantic and Gulf

Seaboard. Grounds for relief—Water competition.

FSA No. 42957—*Joint Water-Rail Container Rates—States Steamship Company.* Filed by States Steamship Company, (No. 2), for itself and interested rail carriers. Rates on general commodities, between ports in Hong Kong, Japan, Korea, and Taiwan, and rail stations on the U.S. Atlantic and Gulf Seaboard. Grounds for relief—Water competition.

By the Commission.

[SEAL] ROBERT L. OSWALD, *Secretary.*

[FR Doc.75-7468 Filed 3-20-75;8:45 am]

[Notice No. 29]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

MARCH 18, 1975.

The following are notices of filing of application, except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application, for temporary authority under section 210a(a) of the Interstate Commerce Act provided for under the new rules of Ex Parte No. MC-67 (49 CFR 1131) published in the FEDERAL REGISTER, issue of April 27, 1965, effective July 1, 1965. These rules provide that protests to the granting of an application must be filed with the field official named in the FEDERAL REGISTER publication, within 15 calendar days after the date of notice of the filing of the application is published in the FEDERAL REGISTER. One copy of such protests must be served on the applicant, or its authorized representative, if any, and the protests must certify that such service has been made. The protests must be specific as to the service which such protestant can and will offer, and must consist of a signed original and six (6) copies.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in field office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

No. MC 46267 (Sub-No. 10TA), filed March 6, 1975. Applicant: SCOTT FREIGHT SERVICE CORP., 4740 Industrial Road, Fort Wayne, Ind. 46825. Applicant's representative: Walter Jones Jr., 601 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities*, except those of unusual value, Classes A and B explosives, livestock, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, between the plant and warehouse facility of Essex International Inc., at or near Topeka, Indiana as an off-route point in connection with applicant's authorized regular route operations, for 180 days. Applicant intends to interline with other motor carriers. Supporting shipper: Essex International Inc., 1601 Wall St., Fort Wayne, Ind. 46802. Send protests to: J. H. Gray, District Supervisor, Interstate Commerce Commission, 345 W. Wayne St., Room 204, Fort Wayne, Ind. 46802.

No. MC 115331 (Sub-No. 338TA), filed March 10, 1975. Applicant: TRUCK TRANSPORT, INCORPORATED, 29 Clayton Hills Lane, St. Louis, Mo. 63131. Applicant's representative: J. R. Ferris (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lead and lead alloys* (except commodities which because of size and weight require use of special transportation equipment), from Glover, Mo., to points in California, Florida, Georgia, Illinois, Indiana, Louisiana, Minnesota, Massachusetts, New Jersey, New York, Pennsylvania, Texas, West Virginia, and Wisconsin, for 180 days. Supporting shipper: American Smelting and Refining Co., 720 Olive Street, St. Louis, Mo. 63101. Send protests to: J. P. Werthmann, District Supervisor, Interstate Commerce Commission, Room 1465, 210 N. 12th Street, St. Louis, Mo. 63101.

No. MC 115496 (Sub-No. 33TA), filed March 7, 1975. Applicant: LUMBER TRANSPORT, INC., P.O. Box 111, Cochran, Ga. 31014. Applicant's representative: Virgil H. Smith, 1587 Phoenix Blvd., Suite 12, Atlanta, Ga. 30349. Authority sought to operates as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Clay*, processed or not processed, in bags or packages, restricted against shipments in bulk on tank vehicles, from the plantsite of Oil-Dri Corp., of America at or near Ochlocknee, Ga., to points in Alabama, Florida, Kentucky, Mississippi, North Carolina, South Carolina, Ohio, Virginia, and Tennessee, for 180 days. Supporting shipper: Oil-Dri Corporation of America, 520 North Michigan Ave., Chicago, Ill. 60611. Send protests to: William L. Scroggs, District Supervisor, 1252 W. Peachtree St. NW., Room 546, Atlanta, Ga. 30309.

No. MC 117975 (Sub-No. 5TA) (Correction), filed February 7, 1975, published in the FEDERAL REGISTER issue of February 28, 1975, and republished as corrected this issue. Applicant: MOTOR EXPRESS, INC., P.O. Box 160, Pearland, Tex. 77581. Applicant's representative: Clayte Binion, 1108 Continental Life Bldg., Fort Worth, Tex. 76102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Bananas*, and (2) bananas when transported in mixed loads with agricultural commodities exempt from economic regulation under section 203(b)(6) of the Act, from Hidalgo, Tex., and points in its Commercial zone to points in Kansas, Georgia, Tennessee, Alabama, Mississippi, Oklahoma, Louisiana, Arkansas, and Texas, for 180 days. Supporting shipper: Glisson and Scales Product Company, 2107 Military Road, Hidalgo, Tex. 78557. Send protests to: John Mensing, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 8610 Federal Bldg., 515 Rusk, Houston, Tex. 77002. The purpose of this republication is to clarify the territorial description.

No. MC 118202 (Sub-No. 46TA), filed March 7, 1975. Applicant: SHULTZ TRANSIT, INC., P.O. Box 503, Winona, Minn. 55987. Applicant's representative: Stanley C. Olsen, Jr., 1000 First National Bank Bldg., Minneapolis, Minn. 55402. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen potatoes and potato products*, from Fairmont, Minn., to points in Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, Denver, Colo., and the District of Columbia, for 180 days. Supporting shipper: Midwest Food Corporation, P.O. Box 100, Clark, S. Dak. 57225. Send protests to: A. N. Spath, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 414 Federal Bldg., & U.S. Court House, 110 S. 4th St., Minneapolis, Minn. 55401.

No. MC 118989 (Sub-No. 121TA), filed March 7, 1975. Applicant: CONTAINER TRANSIT, INC., 5223 South 9th, Milwaukee, Wis. 53221. Applicant's representative: Robert H. Levy, 29 South LaSalle St., Chicago, Ill. 60603. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Containers, container ends, and closures, and materials and supplies used in the manufacture and distribution of containers and container closures* (except commodities in bulk), *and scrap metal*, from the plantsite of American Can Company, located at Whitehouse, Ohio to points in Indiana, Illinois, Michigan, Missouri, Kentucky, and West Virginia, for 180 days. Supporting shipper: American Can Company, 915 Harger Road, Oak Brook, Ill. 60521. Send protests to: John E. Ryden, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 135 West Wells St., Room 807, Milwaukee, Wis. 53203.

No. MC 119226 (Sub-No. 92TA), filed March 4, 1975. Applicant: LIQUID TRANSPORT CORP., 3901 Madison Avenue, Indianapolis, Ind. 46227. Applicant's representative: Robert W. Loser, 1009 Chamber of Commerce Bldg., Indianapolis, Ind. 46204. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Weed killing compounds, liquid*, (in bulk, in tank vehicles), from Lafayette, Ind., to Clinton, Eldorado, El Paso, Pontiac, Pleasant Plains, Ottawa and Springfield, Ill.; and Burlington, Clear Lake, Colfax, Des Moines, Mount Vernon and Davenport, Iowa, for 180 days. Supporting shipper: Eli Lilly and Company,

Elanco Products Division, P.O. Box 618, Indianapolis, Ind. 46204. Send protests to: James W. Habermehl, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 802 Century Bldg., 36 S. Penn. St., Indianapolis, Ind. 46204.

No. MC 129788 (Sub-No. 3TA), filed March 3, 1975. Applicant: NASS TRUCK LINES, INC., P.O. Box "H", Wenona, Ill. 61377. Applicant's representative: E. Stephen Heisley, Suite 805, 666 Eleventh St. NW., Washington, D.C. 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and related advertising materials*, (1) from Detroit, Mich., St. Louis, Mo., and Fort Wayne, Ind., to Bloomington, Ill., and (2) from Detroit, Mich., to Rockford and Rock Island, Ill., for 180 days. Supporting shippers: Baker Liquor Co., Inc., 430 1st St., Rock Island, Ill. 61201. D'Agostin Distributing Co., 4617 Hydraulic Road, Rockford, Ill. Boylan, Inc., 903 E. Croxton Ave., Bloomington, Ill. 61701. Send protests to: Richard K. Shullaw, District Supervisor, Interstate Commerce Commission, Everett McKinley Dirksen Bldg., 219 S. Dearborn St., Room 1086, Chicago, Ill. 60604.

No. MC 138578 (Sub-No. 2TA), filed March 10, 1975. Applicant: L.C.W. TRUCKING, INC., P.O. Box 718, Edinburg, Tex. 78539. Applicant's representative: L. C. Waller (same address as applicant). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Paper and paper products*, from McAllen, Tex., to points in Arkansas, Colorado, Louisiana, Missouri, and New Mexico, for 180 days. Supporting shipper: Valley Corrugated Box, Inc., P.O. Box 38, McAllen, Tex. 78501. Send protests to: Richard H. Dawkins, District Supervisor, Interstate Commerce Commission, 301 Broadway, Room 206, San Antonio, Tex. 78205.

No. MC 140682 TA (Correction), filed February 25, 1975, published in the FEDERAL REGISTER issue of March 7, 1975, and republished as corrected this issue. Applicant: NEW (TRANS) PORT, INC., P.O. Box 118 (Highway 17 S), Riceboro, Ga. 31323. Applicant's representative: Sol H. Proctor, 1107 Blackstone Bldg., Jacksonville, Fla. 33202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, commodities requiring special equipment), between the facilities of Interstate Paper Company at or near Riceboro, Ga., on the one hand, and, on the other, points in Georgia, Florida, and South Carolina, for 180 days. Supporting shipper: Interstate Paper Corporation, Riceboro, Ga. 31323. Send protests to: G. H. Fauss, Jr., District Supervisor, Bureau of Operations, Interstate Commerce Commission, Box 35008, 400 West Bay Street, Jacksonville, Fla. 32202. The purpose of this republication is to add the territorial description which was omitted in the previous publication.

No. MC 140699 (Sub-No. 1TA), filed March 10, 1975. Applicant: JOHN H. CANTRELL, doing business as HOWARD CANTRELL WRECKER SERVICE, 1910 Dickerson Road, Nashville, Tenn. 37207. Applicant's representative: Robert L. Baker, 618 Hamilton Bank Bldg., Nashville, Tenn. 37219. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wrecked, disabled, stolen, repossessed and abandoned vehicles and replacement vehicles* therefore by use of wrecker equipment between those points in Tennessee west of U.S. Highway 27 and east of the western traversal of the Tennessee River on the one hand, and, on the other, all points in the United States (except Alaska and Hawaii), for 180 days. Supporting shippers: Neely Coble, 1130 Polk Ave., Nashville, Tenn. Ryder Truck Lines, 1116 Pilk Ave., Nashville, Tenn. Roadway Express, Inc., 825 Visco Drive, Nashville, Tenn. Pacific Intermountain Express, 81 Trimble St., Nashville, Tenn. T.I.M.E.-DC, Inc., Fesslers Lane, Nashville, Tenn. Send protests to: Joe J. Tate, District Supervisor, Bureau of Operations, Interstate Commerce Commission, A-422 U.S. Court House, 801 Broadway, Nashville, Tenn. 37203.

No. MC 140716 TA, filed March 5, 1975. Applicant: GREAT NORTHERN TRANSPORTATION COMPANY, 901 Antietam, Detrpit, Mich. 48226. Applicant's representative: S. Harrison Kahn, Suite 733 Investment Bldg., Washington, D.C. 20005. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Malt beverages and related advertising material*, from Detroit, Mich., to (1) Aurora, Berwyn, Bloomington, Champaign, Chicago, Lansing, Danville, Elgin, Geneva, Joliet, and Rockford, Ill.; (2) Anderson, Fort Wayne, Gary, Hammond, Indianapolis, Lafayette, La Porte, Muncie, Noblesville, Richmond, South Bend, and Terre Haute, Ind.; (3) Frankfort, Lexington, and Louisville, Ky.; (4) Athens, Cambridge, Chillicothe, Cincinnati, Columbus, Coshocton, Covington, Dayton, East Liverpool, Findlay, Lancaster, Lucasville, Marietta, Springfield, Toledo, Zanesville, Mingo Junction, Madison, St. Henry, and Youngstown, Ohio; (5) Barkeyville, Harrisburg, Lancaster, Nicholson, Pittsburgh, Scranton, Youngstown, and Oil City, Pa.; (6) Albany, Buffalo, Corning, Elmira, Guilderland, Rochester, Syracuse, and Utica, N.Y.; (7) Chattanooga, Cookville, Humboldt, Knoxville, Memphis, and Nashville, Tenn.; (8) Charleston, Clarksburg, Fairmont, Follansbee, Elkins, Huntington, New Martinsville, Weston, Parkersburg, and Wheeling, W. Va.; (9) Beloit and Milwaukee, Wis.; (10) Cumberland, Md.; (11) Richmond and Bristol, Va.; *equipment, material, and supplies used in and useful for the production and distribution of malt beverages*, from Chicago, Colton, and Streator, Ill., Richmond, Indiana, Findlay, Whitehouse and Zanesville, Ohio, and Charleroi and Lancaster, Pa., Williamsburg, Va., to Detroit, Mich. Restriction: The above-described transportation service is to be performed under a continuing contract or contracts with the Stroh Brewery Company, Detroit, Mich., for 180 days. Supporting shipper: The Stroh Brewery Company, 909 East Elizabeth St., Detroit, Mich. 48226. Send protests to: Melvin F. Kirsch, District Supervisor, Interstate Commerce Commission, 1110 Broderick Tower, 10 Witherell Ave., Detroit, Mich. 48226.

No. MC 140720 (Sub-No. 1TA), filed March 10, 1975. Applicant: FORD PARCEL SERVICE, INC., 2644 Michigan, St. Louis, Mo. 63118. Applicant's representative: B. W. La Tourette, Jr., 11 S. Meramec, Suite 1400, St. Louis, Mo. 63105. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Retail and catalog merchandise, household appliances, new household furniture and household furnishings, musical instruments, plumbing and heating equipment, building and remodeling equipment, accessories and supplies and other retail and catalog deliveries*, between points in the City of St. Louis, Mo., St. Louis County, Mo., St. Clair, Madison and Monroe Counties, Ill., for 180 days. Supporting shipper: Sears, Roebuck and Co., 7447 Skokie Blvd., Skokie Ill. Send protests to: J. P. Werthmann, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Room 1465, 210 N. 12th St., St. Louis, Mo. 63101.

No. MC 140721 TA, filed March 11, 1975. Applicant: C. A. PERRY & SON, INC., Route 1, Hobbsville, N.C. 27946. Applicant's representative: Chester A. Zyblut, 1522 K Street NW., Washington, D.C. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (a) *Liquid fertilizer and fertilizer materials*, (in bulk, in tank vehicles) and (b) *Fertilizer and fertilizer materials, dry*, in bulk, and in bags, from Chesapeake, Suffolk and Hopewell, Va., to points in North Carolina, located on and east of U.S. Highway 220 and 1, for 180 days. Supporting shippers: Central Fertilizer Co., Inc., Shawboro, N.C. 27973. Tidewater Chemical Corporation, Route 2, St. Brides Station, Chesapeake, Va. 23322. Swift Chemical Co., Box 7537, Chesapeake, Va. 23324. Send protests to: Archie W. Andrews, District Supervisor, Bureau of Operations, Interstate Commerce Commission, P.O. Box 26896, Raleigh, N.C. 27611.

APPLICATIONS OF PASSENGERS

No. MC 140555 (Sub-No. 1 TA), filed March 11, 1975. Applicant: J G EXEC, 1651 S. Du Pont Highway, c/o Bailey & Son, Inc., Dover, Del. 19901. Applicant's representative: Donald R. Williams, 414 S. State Street, Dover, Del. 19901. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and*

their luggage in the same limousine vehicle, between Philadelphia, International Airport and Various points in Kent County, Del. Restriction: No more than 12 passengers at the same time and in the same limousine vehicle, for 180 days. Supporting shippers: Wyoming Block Co., Inc., Southern Blvd., Wyoming, Del. 19934. Quality Inn & Hub Restaurant, Route 13, Dover, Del. 19901. Allen Travel Agency, Inc., 139 S. State St., Dover, Del. 19901. Send protests to: William L. Hughes, District Supervisor, Interstate Commerce Commission, 814-B Federal Bldg., Baltimore, Md. 21201.

No. MC 105154 (Sub-No. 8TA), filed March 4, 1975. Applicant: ROBERT G. WRIGHT, doing business as STAR VALLEY-JACKSON STAGES, 1945 Eagle Drive, Idaho Falls, Idaho 83401. Applicant's representative: Robert G. Wright (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Passengers and their baggage* in the same vehicle and special and charter operations, between Idaho Falls, Rigby, Rexburg, Sugar City, Teton City, Tetonia and Driggs, Idaho and Grand Targhee Sko Area, for 180 days. Supporting shipper: Grand Targhee Sko Resort, East of City, Rexburg, Idaho 83440. Send protests to: C. W. Campbell, District Supervisor, Interstate Commerce Commission, 550 West Fort St., Box 07, Boise, Idaho 83724.

By the Commission.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.75-7469 Filed 3-20-75;8:45 am]

[Notice No. 251]

MOTOR CARRIER TRANSFER PROCEEDINGS

MARCH 21, 1975.

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 CFR Part 1132:

No. MC-FC-75740. By application filed March 12, 1975, JAMES DOYLE, doing business as DOYLE'S FUEL SERVICE, Box 582, Kenai, AK 99611, seeks temporary authority to lease the operating rights of TACHICK FREIGHT LINE, INC., Box 488, Soldonta, AK, under section 210a(b). The transfer to JAMES DOYLE, doing business as DOYLE'S FUEL SERVICE, of the operating rights of TACHICK FREIGHT LINE, INC., is presently pending.

By the Commission.

[SEAL] ROBERT L. OSWALD,
Secretary.

[FR Doc.75-7467 Filed 3-20-75;8:45 am]

[Rule 19; Ex Parte No. 241; Exemption No. 90, Amdt. No. 2]

RAILROAD CAR SERVICE

Expiration of Exemption

Upon further consideration of Exemption No. 90 issued November 27, 1974.

It is ordered, That, under authority vested in me by Car Service Rule 19, Exemption No. 90 to the Mandatory Car Service Rules ordered in Ex Parte No. 241 be, and it is hereby, amended to expire June 15, 1975.

This amendment shall become effective March 15, 1975.

Issued at Washington, D.C., March 12, 1975.

INTERSTATE COMMERCE COMMISSION,
[SEAL] R. D. PFAHLER,

[FR Doc.75-7465 Filed 3-20-75;8:45 am]

federal register

FRIDAY, MARCH 21, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 56

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

OVER-THE-COUNTER DRUGS

Proposed Establishment of Monographs for OTC Laxative, Antidiarrheal, Emetic and Antiemetic Products

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 334, 335, 336, 337]

OVER-THE-COUNTER DRUGS

Proposal To Establish Monographs for OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Products

Pursuant to Part 330 (21 CFR Part 330), the Commissioner of Food and Drugs received on February 10, 1975, the report of the Advisory Review Panel on over-the-counter (OTC) laxative, antidiarrheal, emetic and antiemetic drug products. In accordance with § 330.10 (a)(6), the Commissioner is issuing (1) a proposed regulation containing the monographs recommended by the Panel establishing conditions under which OTC laxative, antidiarrheal, emetic and antiemetic drugs are generally recognized as safe and effective and not misbranded, (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding, (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above, and (4) the conclusions and recommendations of the Panel to the Commissioner. The summary minutes of the Panel meetings are on public display in the Office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852.

The purpose of issuing the unaltered conclusions and recommendations of the Panel is to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The Commissioner has not yet evaluated the report, but has concluded that it should first be issued as a formal proposal in order to obtain full public comment before any decision is made on the recommendations of the Panel. The report of this Panel represents their best scientific judgment. It has been prepared independently of the Food and Drug Administration and does not necessarily reflect the Agency's position on any particular matter contained therein. After a careful review of this document and all comments submitted in response to it, the Commissioner will prepare a tentative final regulation to establish monographs for OTC laxative, antidiarrheal, emetic and antiemetic products.

In accordance with § 330.10(a)(2), all data and information concerning OTC laxative, antidiarrheal, emetic, and antiemetic drug products submitted for consideration by the Advisory Review Panel have been handled as confidential by the Panel and the Food and Drug Administration. All such data and information shall be put on public display at the office of the Hearing Clerk, Food and Drug Administration, on or before April 21, 1975, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality shall be submitted to the Food and Drug Administration, Bureau of Drugs, Division of OTC Drug Products Evaluation (HFD-109), 5600 Fishers Lane, Rockville, MD 20852.

Based upon the conclusions and recommendations of the Panel, the Commissioner proposes, upon publication of the final regulation:

1. That the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient to classify such conditions either as generally recognized as safe and effective and not misbranded or as not being generally recognized as safe and effective or would result in misbranding (Category III) be permitted to remain in use for 2 years after the date of publication of the final monograph in the FEDERAL REGISTER, if the manufacturer or distributor of any such drug utilizing such conditions in the interim conducts tests and studies adequate and appropriate to satisfy the questions raised with respect to the particular condition by the Panel.

The conclusions and recommendations contained in the report of the Advisory Review Panel on OTC laxative, antidiarrheal, emetic and antiemetic drug products to the Commissioner are as follows:

In the FEDERAL REGISTER of January 5, 1972 (37 FR 85), the Commissioner of Food and Drugs announced a proposed review of the safety, effectiveness and labeling of all OTC drugs by independent advisory review panels. On May 8, 1972, the Commissioner signed the final regulations providing for the OTC drug review under § 330.10 (formerly § 130.301) published in the FEDERAL REGISTER of May 11, 1972 (37 FR 9464), which were made effective immediately. Pursuant to these regulations the Commissioner issued a request for data and information on all laxative, antidiarrheal, emetic, and antiemetic active ingredients in drug products, in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614).

The Commissioner appointed the following panel to review the data and information submitted, and to prepare a report on the safety, effectiveness, and labeling of OTC laxative, antidiarrheal, emetic, and antiemetic drug products pursuant to § 330.10(a)(1):

Nicholas C. Hightower, Jr., M.D., Ph. D., Chairman
Carol R. Angle, M.D.
James C. Cain, M.D.
Ivan E. Danhof, M.D., Ph. D.
James W. Freston, M.D., Ph. D.
Albert L. Picchioni, Ph. D.
Sheila West, Pharm. D.

The Panel was first convened on April 30, 1973, in an organizational meeting. Working meetings were held on June 15-16, August 3-4, September 21-22, November 16-17, 1973; January 25-26, April 5-6, May 31-June 1, July 19-20, September 26-28, October 11, and November 11, 1974, and January 24-25, 1975. All Panel members attended all meetings.

Four non-voting liaison representatives served on the Panel. Mrs. Dennis Hanson, nominated by an ad hoc group of consumer organizations, served until she resigned from the Panel in September 1973, and was replaced by Mr. Kevin V. Brennan, also nominated by the consumer organizations. William E. O'Malley, M.D., Ph. D., nominated by the Proprietary Association, served until he resigned from the Panel in April 1974 and was replaced by Hugh Miller, M.D., also nominated by the Proprietary Association.

Pierre J. Deslauriers, an employee of the Food and Drug Administration, served as Executive Secretary to the Panel. John T. McElroy, J.D., an employee of the Food and Drug Administration, served as Panel Administrator. Lee Quon, R. Ph., served as Drug Information Analyst until August 1973, followed by Thomas H. Gingrich, R. Ph.

In addition to the Panel members and liaison representatives, the Panel utilized the advice of the following consultants:

K. Ashgar, Ph. D.
William Bachrach, Ph. D., M.D.
James Christensen, M.D.
C. A. Dujovne, M.D.
Asher Graybiel, M.D.
Walter Hansen
A. F. Hofmann, M.D.
C. T. G. King, Ph. D.
J. Lamar, Ph. D.
Henry Laurens, M.D.
Albert I. Mendeloff, M.D.
L. F. Schoenfield, Ph. D., M.D.
Samuel Shapiro, M.D.
J. L. Thistle, M.D.
Richard L. Wikoff, Ph. D.
James G. Wilson, Ph. D.

The following individuals were given an opportunity to appear before the Panel to express their views either at their own or the Panel's request:

Clealand Baker
Paul Bass, Ph. D.
Ivan T. Beck, M.D.
E. W. Cantrell, Ph. D.
Charles S. David, M.D.
Bruce Doerr, D.V.M.
Herbert L. Dupont, M.D.
Michael Hospador, Ph. D.
C. H. Kratochvil, M.D., Ph. D.
Ben Marr Lanman, M.D.
Harry Leyland, Ph. D.
Stanley Lorber, M.D.
H. J. Lutz
Robert M. Rees, M.D.
David Schlichting, Ph. D.
O. Boyd Shaffer, Ph. D.

No person who so requested was denied an opportunity to appear before the Panel.

Because the charge to the Panel required the review of four classes of OTC drugs (i.e. laxative, antidiarrheal, emetic and antiemetic drugs), the Panel has prepared its conclusions and recommendations in four separate sections. Each section covers the submission of data and information, a listing of claimed active ingredients, and the classification of the ingredients by the Panel for each class of OTC drugs.

The Panel has thoroughly reviewed the literature, and the various data submissions, has listened to additional testimony from interested parties and has considered all pertinent data and information submitted through September 28, 1974, in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings with respect to these classes of drugs are set out in three categories:

I. Conditions under which laxative products are generally recognized as safe and effective and are not misbranded.

II. Conditions under which laxative products are not generally recognized as safe and effective or are misbranded.

III. Conditions for which the available data are insufficient to permit final classification at this time.

The Panel recommends the following for each category of drugs:

1. That the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient to classify such conditions either as generally recognized as safe and effective and not misbranded or as not being generally recognized as safe and effective or would result in misbranding (Category III) be permitted to remain in use for 2 years after the date of publication of the final monograph in the FEDERAL REGISTER, if the manufacturer or distributor of any such drug utilizing such conditions in the interim conducts tests and studies adequate and appropriate to satisfy the questions raised with respect to the particular condition by the Panel.

I. LAXATIVES

Pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) requesting the submission of data and information of OTC laxative drugs, the following firms made submissions relating to marketed products:

A. DATA AND INFORMATION SUBMISSIONS

Firm	Marketed Products
Abbott Laboratories, North Chicago, Ill. 60064	Maltsupex, Maltsupex Filmtab.
Beecham, Inc. Clifton, N.J. 07012	Syllamalt Effervescent, Syllamalt Powder, Eno.
Boehringer Ingelheim Ltd., Elmsford, N.Y. 10523.	Dulcoax Suppositories, Dulcolax Tablets.
Briston-Myers Co., New York, N.Y. 10022	Bran Tablets, Sal Hepatica.
Burton, Parson & Co., Inc., Washington, D.C. 20027.	Konsyl, L. A. Formula, Psyllium Hydrophilic Mucilloid with Dextrose.
Carter Wallace, Inc., Cranbury, N.J. 08512	Carter's Little Pills.
Chattem Drug & Chemical Co., Chattanooga, Tenn. 37409.	Black-Draught Granulated, Black-Draught Powder, Black-Draught Senna-Lax Tablet, Syrup of Black-Draught.
Combe Inc., White Plains, N.Y. 10604	Espotabs.
Cooper Laboratories, Inc., Cedar Knoll, N.J. 07927.	Kondremul Plain, Kondremul with Cascara, Kondremul with Phenophthalein, Neo-Kondremul.
Denver Chemical Manufacturing Co., Stamford, Conn. 06904.	Rectalad Enema.
Dorsey Laboratories, Lincoln, Nebr. 68501	Vacuetts Suppositories.
Ex-Lax, Inc., Brooklyn, N.Y. 11217	Ex-Lax Chocolated, Ex-Lax Instant Mix, Ex-Lax Unflavored.
C. B. Fleet Co., Inc., Lynchburg, Va. 24505	Fleet Phospho-Soda, Fleet Phospho-Soda Flavored, Fleet Enema, Fleet Enema Pediatric.
Forset Laboratories, Inc., New York, N.Y. 10022.	Mel-o-Lax.
Gray Pharmaceutical Co., Norwalk, Conn. 06586.	X-Prep Liquid, X-Prep Powder.
Hoechst Roussel Pharmaceuticals, Inc., Somerville, N.J. 08876.	Doxan, Doxidan, Doxinate, Doxinate Solution, Surfak.
ICI, United States, Inc., Wilmington, Del. 19899.	Dialose, Dialose Plus, Effersyllium Instant Mix.
Lewis Howe Co., Saint Louis, Mo. 63102	Milk of Magnesia (concentrated), Nature's Remedy Juniors, Nature's Remedy Regular.
Marcen Laboratories, Inc., New Rochelle, N.Y. 10801.	Acelax.
Merit Remedy Co., Dayton, Ohio 45405	Gall-Solve, Merit Cathartics.
Miles Laboratories, Inc., Elkhart, Ind. 46514	Decholin.
National Magnesia Co., Inc., Brooklyn, N.Y. 11227.	Citrate of Magnesia.
Parke, Davis and Co., Detroit, Mich. 48232	Alophen Pills, Cascara Sagrada Aromatic, Cascara Sagrada Fluid-extract Aromatic, Cascara Sagrada Extract Filmseal, Cas-Evac, Desicol, DeS-S, D-S-S Plus, Geriplex, FS, Geriplex FS, Geriplex FS Liquid, Glycerin Suppositories, Milk of Magnesia, USP, Siblin, Siblin Tablets, Tabron.
Pharmaseal Laboratories, Inc., Irwindale, Calif. 91706.	Oil Retention Enema, Sigmol Enema.
Plough, Inc., Memphis, Tenn. 38101	Correctol, Feen-A-Mint, Feen-A-Mint Chewing Gum, Saraka.
The Purdue Frederick Co., Norwalk, Conn. 06856.	Gentlax Granules, Gentlax-S, Gentlax Tablet, Senokap DSS Capsules, Senokot, Senokot Granules, Senokot Suppositories, Senokot Syrup, Senokot with Psyllium.
Riker Laboratories, Inc., Northridge, Calif. 91234.	Dorbane, Dorbanthyl, Dorbantyl Forte.
Sandoz Pharmaceuticals, East Hanover, N.J. 07936.	Glysennid.
Scott Laboratories, Inc., Corpus Christi, Tex. 78408.	Castor Oil, Citrate of Magnesia, Glycerine.
Searle Laboratories, Chicago, Ill. 60680	Metamucil Instant Mix, Metamucil Powder.
E. R. Squibb & Sons, Inc., New Brunswick, N.J. 08903.	Castor Oil, Glycerine Suppositories, Milk of Magnesia, Milk of Magnesia Tablets, Mineral Oil, Mint-O-Mag.
Sterling Drug Inc., New York, N.Y. 10016	Andrews Salts, Caroid and Bile Salts, Dr. Caldwell Senna Laxative, Fletcher's Castoria, Haley's M-O, Mil Par, Mucilose Flakes, Mucilose Granules, Mucilose Powder, Phillips' Milk of Magnesia, Phillips' Milk of Magnesia Tablets, Sal Andrews.
Stuart Pharmaceuticals (See ICI United States, Inc.).	
The Upjohn Co., Kalamazoo, Mich. 49001	Bile Salts-Phenophthalein Compound, Casakol Capsules, Casyllium, Hydrolose Syrup, Imbicoll with Vitamin B1, Imbicoll with Cascara, Phenolax, Polykol.
USV Pharmaceutical Corp., Tuckahoe, N.Y. 10707.	Neo-Cultol.
Warner Lambert Co., Morris Plains, N.J. 07950.	Cellothyl, Veracolate.
Warren Teed Pharmaceutical, Inc., Columbus, Ohio 43215.	Modane, Modane Mild.

Whitehall Laboratories, Inc., New York, N.Y. 10017.	Petro Syllium No. 1 Plain, Petro Syllium No. 2 with Phenolphthalein, Preparation H Regulator.
J. B. Williams Co., Inc., Cranford, N.J. 07016	Serutan Concentrated Powder, Serutan Concentrated Powder, Fruit Flavored, Serutan Toasted Granules.
Wyeth Laboratories, Inc., Philadelphia, Pa. 19101	Cascara Petrogalar, Glycerin Suppositories, Adult, Glycerin Suppositories for Infants and Young Children, Petrogalar, Phenolphthalein Petrogalar.

In addition, the following firms made related submissions:

Firm	Submissions
American Cyanamid Co, Pearl River, N.Y. 10965.	Dioctyl Sodium Sulfosuccinate.
Merrick Medicine Co., Waco, Tex. 76703	Rhubarb Fluidextract.

B. LABELED INGREDIENTS CONTAINED IN SUBMITTED PRODUCTS

Agar
Aloe
Aloin
Belladonna extract
Bile, desiccated whole
Bile salts
Bisacodyl
Bismuth subnitrate
Bran tablets
Calicum hydroxide
d-Calcium pantothenate
Capsicum
Caroid (digestive enzyme from *Carica papaya*)
Carrageenan (*Chondrus crispus*)
Cascara sagrada
Cascara sagrada bark
Cascara sagrada extract
Cascara sagrada fluid extract
Casanthranol
Castor oil
Citric acid, anhydrous
Danthron
Dehydrocholic acid
Dioctyl calcium sulfosuccinate
Dioctyl potassium sulfosuccinate
Dioctyl sodium sulfosuccinate
Disodium phosphate
Frangula
Ginger
Glycerin
Guar gum
Ipecac powder
Karaya (sterculia)
Magnesium citrate, anhydrous tribasic
Magnesium hydroxide
Magnesium sulfate dihydrate
Malt soup extract
Methylcellulose
Mineral oil
Monosodium phosphate
Oxgall
Papain
Phenolphthalein
Phenolphthalein, yellow
Plantago ovata husk
Plantago seed
Podophyllum resin (podophyllin)
Poloxalkol (polykol, polymers of ethylene and propylene oxide)
Potassium carbonate
Prune concentrate dehydrate
Prune powder
Psyllium, hemicellulose of
Psyllium hydrophilic mucilloid (psyllium hydrocolloid)
Psyllium seed husks, blond
Psyllium seed husks
Psyllium seed
Rhubarb fluidextract
Senna
Senna concentrate
Senna fruit extract
Sennosides A and B
Sodium acid pyrophosphate
Sodium biphosphate
Sodium carbonate
Sodium carboxymethylcellulose
Sodium citrate, anhydrous tribasic
Sodium oleate
Sodium phosphate
Sorbitol
Tartaric acid
Thiamin
Vitamins (multivitamins) and minerals

The Panel also undertook a review of the following:

Bran, dietary
Calomel
Laxative resins (colocynth, elaterin, gamboge, ipomea and jalap)
Polycarbophil

C. CONSTIPATION AND THE USE OF OTC LAXATIVES

In Dorland's Medical Dictionary "constipation" is defined simply as "infrequent, or difficult evacuation of the feces" (Ref. 1). The Panel is unable to improve upon this simple definition.

In the United States, preoccupation with the bowel seems to be the concern of a significant proportion of our population judging from the inordinately large number of laxative agents available and by the significant expenditure for OTC laxatives (Refs. 2 and 3). The Panel is of the opinion that a large segment of the population is not only "bowel-conscious" but also has many misconceptions of normal bowel function. The laity is under the impression that serious and health endangering consequences will occur if the bowel is not evacuated daily.

The Panel is of the opinion that there is widespread overuse of self-prescribed laxatives. Extensive advertising by the pharmaceutical industry has contributed to this problem. The Panel is aware that the FDA is limited in its jurisdiction to package labeling and not to advertising. However, the Panel is concerned that control of package labeling alone may be insufficient in assuring proper use of laxative agents. The Panel is hopeful that as a result of this review that all forms of advertising will be monitored by those having the appropriate jurisdiction, to insure that adequate warning and cautionary statements as found in product labeling will be carried over and incorporated in all advertising and promotional activities for these products.

Only recently have quantitative data become available to better define the normal bowel habits in man. In one study of 115 healthy adult men, stool weight, consistency, and time of evacuation were recorded on 3,267 stools. The ages of the subjects ranged from 20 to 57 years. The average stool weight was 123.6 grams; average interval between stools was 27.6 hours, with a range of 9 to 57 hours. Subjective estimates of consistency showed that 46 percent of the stools were firm; 36 percent semiformed, 15 percent soft or mushy, and 3 percent loose, watery or diarrhetic (Ref. 4). From a social and psychological viewpoint, the subjects in this study cannot be considered representative of the normal population because they were prisoners in a minimal custody Federal Correction Institution. However, the Panel considers the data of value in defining bowel habits under controlled conditions.

In another study, 1,055 industrial workers in the greater London area were interviewed regarding bowel habits. This group was composed of 655 women and 400 men. Also included in this study, were 400 patients of a family practitioner in Northwest London, including 134 males and 266 females who had no known diseases of the gastrointestinal tract. The ages of the patients ranged from 1 year to over 70. It was found that 99.3 percent of the industrial workers and 98.25 percent of the patients were within the frequency limits of 3 bowel movements per week to 3 bowel movements per day (Ref. 5). From these results, it is suggested that fewer than 3 bowel movements per week or more than 3 bowel movements per day are unusual. No simple correlation was observed between bowel habits and age.

There was a positive correlation between increasing bowel frequency and the subject's opinion of the stool being "loose." The proportion of subjects who took laxatives increased with age in both groups studied (Ref. 5). The frequency limits suggested by this study are potentially biased, as 20 percent of all subjects interviewed took a laxative more than once a week. However, the Panel considers the data a contribution in the study of bowel habits in the population.

The terms "laxative", "cathartic", and "purgative" are frequently confused. All three terms denote agents that act to promote evacuation of the bowel; the difference between the terms is largely one of degree. The terms "cathartic" and "purgative" are interchangeable and are best defined as agents which quickly produce bowel evacuation and obvious alteration of stool consistency (Ref. 6). These actions in a laxative agent are less pronounced. Large doses of a laxative may produce a cathartic effect. For purposes of simplicity and consistency only the term "laxative" will be used in this report.

Prolonged laxative use can seriously impair normal bowel function. Use of laxatives for acute abdominal pain, vomiting, and other digestive symptoms can lead to serious complications. The Panel is of the opinion that simple constipation most often results from improper diet, inadequate fluid intake, possibly in-

sufficient exercise and/or from a change of habits due to travel. There are few valid indications for the use of laxatives. Relief for simple constipation often may be achieved by proper diet, including foods with adequate fiber content, adequate fluid intake, and the prompt response to the urge to evacuate the bowels. The Panel is concerned because many people are using laxatives that don't need them (Refs. 4 and 5).

REFERENCES

(1) Dorland's Illustrated Medical Dictionary, 24th Ed., W. B. Saunders Company, Philadelphia, p. 338, 1965.

(2) Danhof, Ivan E., "Methods of Clinical Evaluation of Laxative Agents," Proceedings of a Conference sponsored by the Scientific Development Committee of the Proprietary Association, Washington, DC, 1972.

(3) Sehnert, K. W., "Review of Pharmacology of Bowel Evacuants and Laxatives," Nebraska State Medical Journal, 50:54–58, 1965.

(4) Rendtorf, R. C. and M. Kashgarian, "Stool Patterns of Healthy Adult Males," Diseases of the Colon and Rectum, 10:222–228, 1967.

(5) Connell, A. M., C. Hilton, G. Irvine, J. E. Lennard-Jones and J. J. Misiewicz, "Variation of Bowel Habit in Two Population Samples," British Medical Journal, 2:1095–1099, 1965.

(6) Webster's New Collegiate Dictionary, G & C Merriam Company, Springfield, MA 1973.

D. LABELING OF LAXATIVES

The Panel reviewed the general and specific labeling requirements previously adopted by the Food and Drug Administration for OTC laxative preparations. These requirements provide for labeling information concerning the identity of ingredients, directions for use, and general and specific warnings. The Panel concurs that these requirements are appropriate for OTC laxative preparations and the labeling will be discussed elsewhere in this document.

After review of all labels of OTC laxative preparations submitted, the Panel recommends the following additional requirements:

1. *Indications.* The indications for use of a laxative should be simple and clearly stated. If the product is taken for specific indications such as to increase the frequency of bowel movements, to soften the stool, or to increase the bulk of the stool, the label should so state. The directions for use should be clear and provide the user a reasonable expectation of the results anticipated from use of the product. Statements of indications for use should be specific and confined to the conditions the product is recommended for such as infrequent, difficult, or painful passage of stools. No reference should be made, or implied, regarding the alleviation or relief of symptoms unrelated to the condition that is an indication for use of the product.

2. *Ingredients.* Laxative products should contain only active ingredient(s) plus such inactive ingredients as may be necessary for formulation. The label should state in metric units the quantity of each active ingredient contained in the recommended dose, e.g., teaspoonful, tablet, etc.

A product containing more than 1.0 mEq (23 mg) sodium per maximum daily dose should be labeled as to the sodium content per dosage unit. Furthermore, if the product contains more than 15 mEq (345 mg) sodium in the maximum recommended daily dose, the label should state: "Do not use this product except under the advice and supervision of a physician if you are on a low salt diet." And in addition, "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

If the product contains more than 25 mEq (975 mg) potassium in the maximum recommended daily dose, labeling should state: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

If the product contains more than 50 mEq (600 mg) magnesium in the maximum recommended daily dose, the labeling should state:

Do not use this product except under the advice and supervision of a physician if you have kidney disease.

The Panel strongly recommends that all inactive ingredients be listed with or without a statement of their quantity, since the consumer may need to know for a variety of reasons, the ingredient in a product. However, the product cannot be promoted on the basis of its inactive ingredients, nor can the label emphasize the inclusion of the inactive ingredients.

3. *Mode of action.* The Panel reviewed and concurred with the regulation (21 CFR 1.102a) for over-the-counter drug and device identity labeling in package form which states:

a. "The principal display panel of an over-the-counter drug or device in package form shall bear as one of its principal features a statement of the identity of the commodity.

b. "Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category (categories) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. Such statements shall be placed in direct conjunction with the most prominent display of the proprietary name or designation and shall employ terms descriptive of general pharmacological category (categories) or principal intended action(s); for example, 'laxative', 'antidiarrheal', 'emetic', 'antiemetic', etc. The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part.

c. "The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed."

Thus a prominent and conspicuous statement must be made of general pharmacologic action. In addition, the Panel recommends that the label contain a clear indication of the category of laxative as described below in paragraph E with the specific modes of action when known so that the consumer's expectation is correct; for example, a bulk forming laxative promotes the evacuation of the bowel by increasing bulk volume and water content of the stools.

4. *Effectiveness and claimed advantages.* Effectiveness must be defined without vague or unsupported claims. Phrasing that promises general benefits in good health or well being or warns against the hazards of constipation is unproven and thus unacceptable. Undocumented claims that laxatives relieve "indigestion," "excessive belching," "after-meal discomfort," "headaches," or "biliousness" foster the notion among the laity that such symptoms are caused by constipation. Such claims are not supported by scientific evidence and thus are not acceptable. The Panel has no objection to statements regarding the source of the laxative ingredient. However, the suggestion that a laxative is somehow "natural" because of its source is misleading, because it implies that the product or ingredient is a "natural way" to induce laxation. It is not considered "natural" to take any laxative.

The Panel found no evidence for claims that any laxative has a particular advantage for individuals simply on the basis of sex, age, or other demographic characteristics. However, bulk-forming laxatives may be justified in individuals who consume a diet low in fiber content.

Reference to palatability should not be used to support claims of effectiveness or to promote frequent and continued use, nor should it dominate the label.

5. *Directions for use.* The label should include a clear statement of the usually effective, minimum and maximum dose per time interval, broken down by age groups, and if appropriate, may be followed by "except under the advice and supervision of a physician." It is axiomatic and should be emphasized that the smallest dose of a laxative that is effective is the optimal dose to use.

6. *Warnings.* The Panel has reviewed the current regulation (21 CFR 369.20) regarding labeling of laxatives which states:

WARNING.—Do not use when abdominal pain, nausea, or vomiting are present. Frequent or prolonged use of this preparation may result in dependence on laxatives.

Mercury preparations should have added to the 'frequent use' statement, the words 'and serious mercury poisoning.'

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

CAUTION.—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

The Panel found it difficult to clearly define the word "dependence" as it appears in the regulation, and recommends deletion of the following warning on all laxative labels: "Frequent or prolonged use of this preparation may result in dependence on laxatives." Specific warnings concerning laxative dependency is listed with the Panel's recommendations for each class of laxative ingredient.

The Panel concluded that the warning regarding mercury is now inappropriate since the Panel has recommended removal of such preparations from OTC status. (See discussion for Calomel below in the Category II laxative active ingredient statement.) Warnings for reactions considered by the Panel to be of sufficient frequency or severity will be listed with the Panel's recommendation regarding each class of active ingredients. The warning should be accompanied by specific instructions for avoiding specific side effects (e.g., labels of bulk-forming laxatives should state "drink a full glass of liquid with each dose," and directions should a side effect occur (e.g., "stop medication at once and consult a physician").

The label must also contain a warning as follows:

If you have noticed a sudden change in bowel habits that persists over a period of 2 weeks, consult a physician before using a laxative. If the recommended use of this product for 1 week has had no effect, discontinue use and consult a physician.

The reason for this recommendation is that a sudden change in bowel habits may be due to serious disease (e.g., cancer, stricture), and the continued use of a laxative may delay diagnosis of such conditions. The Panel is of the opinion that the available scientific evidence shows that very few indications warrant the use of any laxative beyond 1 week, except under the advice of a physician.

E. Definitions and Classification of Active Ingredients

The Panel adopted the definitions identified below and elected to classify the active ingredients of laxative products on the basis of the usually accepted pharmacological classes as follows:

1. *Adequate liquid intake.* The ingestion of a full glass (8 oz.) of liquid with each dose.

2. *Age (dosage) range.* Infant (not more than 2 years), child (2 years and over but not more than 12 years), and adult (12 years and over).

3. *Bulk forming laxative.* An agent that promotes the evacuation of the bowel by increasing bulk volume and water content of the stools.

4. *Constipation.* Infrequent, or difficult bowel movement.

5. *Hyperosmotic laxative.* An agent that attracts water into the stool.

6. *Laxative.* Any agent used for the relief of constipation.

7. *Lubricant laxative.* An agent that lubricates the contents of the intestinal tract, thus promoting easier bowel movements.

8. *Oral Dosage.* The dosage range (minimum and maximum amounts) that is generally recognized as safe and effective by mouth.

9. *Rectal dosage.* The dosage range (minimum and maximum) that is generally recognized as safe and effective by rectum.

10. *Saline laxative.* An agent that increases water in the intestine thereby promoting bowel movement.

11. *Short-term use.* Use of a laxative for no longer that a 1 week period.

12. *Stimulant laxative.* An agent that promotes bowel movement by one or more direct actions on the intestine.

13. *Stool softner laxative.* An agent that penetrates and softens the stool.

It is recognized that the mode of action of some ingredients is unknown or different from that described in some textbooks and older literature. For example, it is now known that at least some "stimulant" laxatives promote laxation by means other than "stimulating" peristalsis. Nevertheless, the traditional classification is used for simplicity, and the mode of action, when known, is described for each ingredient.

The Panel found that many laxative products contained more than one active ingredient. In some of these products, the amount of one or more of the active ingredients is considered irrational in that the amount of the ingredient is as little as one-tenth of the recommended effective dose. The Panel concluded that any ingredient causing laxation at an appropriate dosage is considered to be an active agent.

F. Review of Active Ingredients

The Panel reviewed all claimed active ingredients which were the subject of submissions made to and accepted by the Panel. In addition, the Panel reviewed bran (dietary), calomel, laxative resins (colocynth, elaterin, gamboge, ipomea and jalap) and polycarbophil. The Panel considered all pertinent data and information in arriving at its conclusions and recommendations.

1. *Conditions under which laxative products are generally recognized as safe and effective and are not misbranded.* After carefully reviewing all data available to the Panel the following laxative ingredients identified below were classified as safe and effective and not misbranded:

Bulk Forming Laxatives

Bran, Dietary
Cellulose derivatives, semi-synthetic (methylcellulose, sodium carboxymethylcellulose)
Karaya (Sterculia Gum)
Malt Soup Extract
Polycarbophil
Psyllium Preparations
- Plantago seeds
- Plantago ovata husks
- Psyllium, hemicellulose of
- Psyllium, hydrophilic mucilloid (psyllium hydrocolloid)
- Psyllium seed
- Psyllium seed, blond
- Psyllium seed husks

Stimulant Laxatives

Anthraquinones
- Aloe
- Cascara sagrada preparations
  - Aromatic cascara fluidextract
  - Casanthranol
  - Cascara sagrada bark
  - Cascara sagrada fluidextract
  - Cascara sagrada extract
- Danthron
- Senna preparations
  - Senna leaf powder
  - Senna fluidextract
  - Senna fruit extract
  - Senna syrups
  - Sennosides A and B, crystalline
  - Senna pod concentrate

Bisacodyl
Castor oil
Dehydrocholic acid
Phenolphthalein (white or yellow)

Saline Laxatives

Magnesium salts
- Magnesium citrate
- Magnesium hydroxide
- Magnesium sulfate

Phosphate preparations (combined)
- Disodium Phosphate
- Monosodium Phosphate
- Sodium Biphosphate
- Sodium Phosphate

Hyperosmotic Laxatives

Glycerin
Sorbitol

Lubricant Laxatives

Mineral oil, emulsified
Mineral oil, plain

Stool Softener Laxatives

Sulfosuccinate preparations
- Dioctyl Calcium Sulfosuccinate
- Dioctyl Potassium Sulfosuccinate
- Dioctyl Sodium Sulfosuccinate

Miscellaneous Laxative

Released Carbon Dioxide

(a) *Active ingredients classified as bulk-forming laxatives.* The Panel is of the opinion that bulk-forming laxatives are among the safest of laxatives. These agents are generally not absorbed from the digestive tract. They increase the frequency of bowel movements and soften stools by holding water in the stool. Most bulk-forming laxatives require the ingestion of a glassful of liquid with each dose to minimize the risk of obstruction of the digestive tract which has rarely been caused by these agents. Examples of useful labeling information describing the mode of action for purposes of labeling include "Promotes evacuation of the bowels by increasing bulk volume and water content of stools" and "Increases the frequency of bowel movements and softens stools by holding water in the stool."

(1) *Bran, dietary.* The Panel concludes that bran is safe and effective in the amounts (approximately 6 to 14 grams per day) usually taken in the diet when accompanied with adequate fluid intake and believes it unnecessary to impose a specific dosage limitation at this time.

Bran can be obtained from a number of sources but usually is derived from the milling of wheat. Wheat bran consists largely of hemicellulose, cellulose and

"crude fiber" of uncertain chemical composition. When fed to animals and man as bran, these components escape digestion and result in decreased intestinal transit time and increased stool bulk, weight and water content.

Bran's laxative action seems related to its hydrophilic properties and to the direct action on the colon of undefined substances produced by the bacterial action on the bran.

Dietary fiber seems to play the major role in the action of bran. The role of fiber in the gut is not precisely understood because of the incomplete knowledge of its composition and the inadequate techniques for measuring each component.

Bran-rich breakfast cereals and wholewheat bread are convenient sources of crude fiber: 100 grams of bran flakes (various brands) contain between 2.7 to 6.5 grams of crude fiber and one slice of wholewheat bread contains 1–2 grams. As with other bulk laxatives, intestinal obstruction may occur if bran is given for constipation in patients with partial obstruction of the digestive tract.

Bran tablets, as opposed to dietary bran, are classified in Category III. (See discussion of Bran Tablets below).

REFERENCES

(1) Payler, D. K., "Food Fibre and Bowel Behavior," Lancet, 1:1394, 1973.

(2) Cummings, J. H., "Progress Report: Dietary fibre," Gut, 14:69–81, 1973.

(3) The Medical Letter, "Laxatives and Dietary Fiber," 15:98–100, 1973.

COMMENTS REGARDING DIETARY FIBER

Recent epidemiological studies indicate that the low fiber content in the refined foods of technologically advanced countries may contribute to the high prevalence of diverticular disease of the colon, the irritable bowel syndrome, appendicitis, and colonic cancer in these countries. There are references to the usefulness of bulk laxatives in the treatment of diverticulosis and irritable bowel syndrome. The rationale for the use of bulk-forming agents in these conditions is purported to be related to increased intraluminal pressures which occur in the large bowel in patients with diverticulosis and irritable bowel syndrome. The pressure within the bowel (lumen) is related to the tension of the muscles in the wall of the bowel as well as the diameter of the lumen of the bowel cavity. The pressure within the bowel lumen increases as the tension of the muscles of the bowel wall increases but decreases as the radius (one-half the diameter) of the lumen increases. These relationships are known as the Law of LaPlace and are expressed in the following formula:

$$P = t/r$$

where P is intraluminal pressure, t is tension of the bowel wall, and r is the radius of the bowel lumen. Thus, intraluminal pressure elevations could theoretically be lowered by increasing the radius of the lumen by bulk producing agents. Conclusive studies testing this hypothesis have not yet appeared.

REFERENCES

(1) Irving, D. and B. S. Draser, "Fibre and Cancer of the Colon," British Journal of Cancer, 28:462–463, 1973.

(2) Burkitt, D. P., "The Aetiology of Appendicitis," British Journal of Surgery, 58:695–699, 1971.

(3) Painter, N. S. and D. P. Burkitt, "Diverticular Disease of the Colon: A Deficiency Disease of Western Civilization," British Medical Journal, 2:450–454, 1971.

(4) The Medical Letter, "Laxatives and Dietary Fiber," 15:98–100, 1973.

(5) Eastwood, M. A., N. Fisher, C. T. Greenwood and J. B. Hutchinson, "Perspectives on the Bran Hypothesis," Lancet, 1:1029–1033, 1974.

(6) Burkitt, D. P., A. R. P. Walker, and N. S. Painter, "Dietary Fiber and Disease," Journal of the American Medical Association, 229:1068–1073, 1974.

(7) Painter, N. S., "Below the Belt," Lancet, 2:381–382, 1971.

(2) *Cellulose derivatives, semi-synthetic.* The Panel concludes methylcellulose and sodium carboxymethylcellulose to be safe and effective in amounts usually taken orally: 4 to 6 grams per day when accompanied with adequate fluid intake. The dosage for children over 6 years is 1 gm to 1.5 gm per day when accompanied by adequate fluid intake.

The hydrophilic cellulose derivatives, methylcellulose and sodium carboxymethylcellulose, when mixed with water produce a clear to opalescent viscous colloidal suspension with a pH of approximately 7.0. In the colon, the solution loses water to form a gel which increases the bulk of stool. Cellulose has been shown to bind digitalis, nitrofurantoin and salicylate although the clinical significance of this is not yet defined. As with other bulk-forming laxatives, esophageal and large bowel obstructions and fecal impactions have been described in man following the ingestion of methylcellulose with insufficient quantities of liquid. No data are available on the absorption of the 6.5–9.5 percent sodium of sodium carboxymethylcellulose, although edema has been reported in the unsuccessful attempted treatment of obesity with 90 grams of sodium methoxycellulose (255–375 mEq Na) per day.

LABELING

Bulk-forming laxatives should be clearly labeled stressing the importance of adequate fluid intake (drinking a full glass (8 oz.) of liquid) with each dose. The label should also carry a warning against use of the product if the user is taking a drug containing salicylates or a prescription drug containing digitalis or nitrofurantoin. The labeling should state: "This product may combine with certain other drugs. Do not take this product if you are presently taking salicylates or a prescription drug."

REFERENCES

(1) AMA Drug Evaluations, 2nd Edition, American Medical Association, Chicago, p. 800, 1973.

(2) Crane, M. G., J. J. Harris, R. Herber, S. Shankel and N. Specht, "Excessive Fluid Retention Related to Cellulose Ingestion: Studies on Two Patients," Metabolism, 18:945–960, 1969.

(3) Gray, H. and M. L. Tainter, "Colloid Laxatives Available for Clinical Use," Journal of Digestive Disease, 8:130–133, 1941.

(4) Littman, A., "Nutritional and Gastrointestinal Effects of Poorly Absorbed Carbohydrates in Man," Draft of unpublished paper included in OTC Volume 030134.*

(5) GRAS (Generally Recognized as Safe) Food Ingredients-Cellulose and Derivatives, Informatics, Inc., Rockville, Md., FDA 72-104, Dec. 15, 1972.

(6) The Pharmacopeia of the United States of America, 18th Revision, The United States Pharmacopeial Convention, Inc., Bethesda, Md., p. 613, 1970.

(3) *Karaya (sterculia gum).* The Panel concludes karaya to be safe and effective in amounts usually taken orally: 5 to 10 grams per day when accompanied with adequate fluid intake.

Karaya is a hydrophilic vegetable gum obtained from the barks of various species of sterculia and cochlospermum. These substances are indigestible polysaccharides which act by absorbing water and increasing the bulk of the stool. These vegetable gums exert little systemic effect. For example, up to 3 grams per kilogram of karaya has been fed to rats (which is the highest dose that could be physically administered to rats) without systemic effect. However, rare cases of allergic reactions and urticaria in man caused by karaya have been reported.

LABELING

The label should stress the importance of drinking a full glass of liquid immediately with each dose. The labeling should state: "Drink a full glass (8 oz.) of liquid immediately with each dose."

PROFESSIONAL LABELING

Professional labeling should contain a warning that rare cases of allergic reactions and urticaria caused by karaya have been reported. Also, inadequate fluid intake may cause large bowel obstructions.

REFERENCES

(1) Ivy, A. C. and B. L. Isaacs, "Karaya Gum as a Mechanical Laxative," American Journal of Digestive Diseases and Nutrition, 5:315–321, 1938.

(2) The Merck Index, 8th Ed., Merck and Company, Inc., Rahway, New Jersey, p. 533, 1968.

(3) Darlington, R. C., "Laxatives," Handbook of Non-prescription Drugs, American Pharmaceutical Association, Washington, D.C., pp. 62–76, 1973.

(4) Ireson, J. D. and G. B. Leslie, "An In Vitro Investigation of Colloidal Bulk-forming Laxatives," The Pharmaceutical Journal, 205: 540, 1970.

(4) *Malt soup extract.* The Panel concludes malt soup extract to be safe and effective in amounts usually taken orally: infants (not more than 2 years), 6 to 32 grams, and adults, 12 to 64 grams, when accompanied with adequate fluid intake (full glass (8 oz.) of liquid).

*Cited OTC Volumes refer to the submissions made by interested persons pursuant to the call for data notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614). The volumes are on file in the office of the Hearing Clerk, Food and Drug Administration, Room 465, 5600 Fishers Lane, Rockville, MD 20852.

Malt soup extract is obtained from partially germinated grain of one or more varieties of barley containing amylolytic enzymes. The evaporated aqueous extract constitutes malt extract. The powdered malt soup extract contains 73 percent maltose, 7 percent protein, and 1.5 percent potassium. In addition, there are small quantities of calcium, phosphorus, magnesium and vitamins of the B Group and C. Although the Panel considered malt soup extract with the bulk-forming laxatives, the Panel is aware that increase in fecal volume probably is not the sole mechanism of action. Precisely how malt soup extract produces increased softness of the stool is not clearly understood. It has been well documented that malt soup extract will lower fecal pH, and it is purported to exert its beneficial effect as a result of the altered pH. It seems likely that the reduced fecal pH occurs as a result of bacterial conversion of maltose into lactic acid, pyruvic acid, and carbon dioxide.

LABELING

Although reduction in stool pH has also been cited as the reason for the claimed effectiveness of malt soup extract in reducing the symptoms of pruritis ani, the Panel concludes that there is insufficient evidence to support the claim that malt soup extract is effective when used alone in the treatment of pruritis ani. (See discussion of malt soup extract below in Category III statement.)

REFERENCES

(1) Calloway, N. O., "Clinical Investigation of Fecal pH in Geriatric Constipation: Corrective Therapy," Journal of the American Geriatric Society, 12:368–372, 1964.

(2) Crawford, O. W. and N. O. Calloway, "Clinical Study of Fecal pH in Pediatric Constipation," Illinois Medical Journal, 128:320–322, 1965.

(3) Brooks, L. H. "Further Studies of the Management of Pruritus Ani," Diseases of the Colon and Rectum. 12:193–195, 1969.

(4) OTC Volume 090018.[1]

(5) *Polycarbophil.* The Panel concludes that polycarbophil is safe and effective in amounts usually taken orally: infants (not more than 2 years) 0.5 to 1.0 gram, children (2 to 5 years) 1.0 to 1.5 grams, children (6 to 12 years) 1.5 to 3.0 grams and adults 4 to 6 grams per day as a laxative (or when used as an antidiarrheal preparation).

Polycarbophil, a hydrophilic polyacrylic resin (polyacrylic acid crosslinked with divinyl glycol) has a marked capacity for binding water and absorbs about 60 times its original weight. This property is the basis for its use as an intestinal hydrosorptive agent.

The seemingly paradoxical utilization of this hydrosorptive agent in the treatment of both diarrhea and constipation is based on its modifying effect on abnormal fecal consistency. In diarrheal states, it is presumed the hydrophilic agent absorbs free fecal water forming a gel in the lumen of the intestine. In constipation, the agent retains water intraluminally and opposes dehydrating forces in the bowel. The water-retaining capacity of polycarbophil is considerably greater than that of methylcellulose or psyllium mucilloid. The degree of hydrophilia (cubic centimeters/gram) of polycarbophil in synthetic intestinal juice is about 120, while for psyllium, methylcellulose and agar-agar the values are 30, 36, and 14, respectively.

In animal studies the ingestion of polycarbophil has been shown to be free of toxicity, to be nonabsorbable, to have no effect on digestive enzymes, to have no influence on nutritional status, and to be metabolically inactive.

LABELING

"Drink a full glass (8 oz.) of liquid with each dose."

REFERENCES

(1) Grossman, A. J., R. C. Batterman and P. Leifer, "Polyacrylic Resin: Effective Hydrophilic Colloid for the Treatment of Constipation," Journal of the American Geriatric Society, 5:187–192, 1957.

(2) Roth, J. L. A., "Effect of Polycarbophil as Enteral Hydrosorbent in Diarrhea," *American Journal of Digestive Diseases,* 5:965–971, 1960.

(3) Pimparker, B. D., F. F. Faustian, J. L. A. Roth and H. L. Bockus, "Effect of Polycarbophil on Diarrhea and Constipation," Gastroenterology, 40:397–404, 1961.

(4) Rutledge, M. L., M. M. Willner and J. T. King, "Calcium Polycarbophil in Acute Childhood Diarrhea," Clinical Pediatrics, 2:61–63, 1963.

(5) Winkelstein, A., "Effect of Calcium Polycarbophil (CARBOFIL[R]) Suspension on Gastrointestinal Transit Time," Current Therapeutic Research, 6:572–583, 1964.

(6) *Psyllium preparations [plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophilic mucilloid (psyllium hydrocolloid), psyllium seed, psyllium seed (blond)], psyllium seed husks.* The Panel concludes psyllium preparations to be safe and effective in amounts usually taken orally (2.5 to 30.0 grams per day) provided the unit dose is taken with a full glass (8 oz.) of liquid and believes it is unnecessary to impose a specific daily dosage limitation at this time. The dosage for children over 6 years is 1.25 to 15.0 grams per day with the same fluid intake requirement.

Psyllium preparations are obtained from the seeds of various species of *Plantago,* i.e., *P. psyllium, P. ovata,* and *P. indica.* The dried ripe seeds have a high content of mucilage which acts by imbibing water and increasing the bulk of the feces. The hydrophilic mucilloid of psyllium preparations is a hemicellulose that is indigestible, nonabsorbable and presumably nonallergenic.

Experimentally, it has been demonstrated that renal tubular pigmentation, the nature of which has not been identified, occurs in animals fed large quantities of the whole ground psyllium seed (*P. psyllium* and *P. indica*). Blond psyllium seed (*P. ovata*) and the purified hydrophilic mucilloid do not cause renal pigmentation. Despite the presence of the renal tubular pigment, urea clearance in treated rats was not different from that found in untreated control rats. In man, phenolsulfonphthalein excretion and urinalysis were normal in 9 human subjects who ingested 7 to 14 grams of psyllium agar flakes daily for 2 to 7 years. It is the opinion of the Panel that the renal pigmentation is probably harmless. Chronic ingestion of psyllium products will cause an increase in bile salt excretion in the feces in the rat and man. In addition, a slight reduction in serum cholesterol has been observed in man. The theoretical complication of increased gallstone formation due to a reduced bile salt pool has not been described.

Esophageal, gastric, small intestinal and rectal obstruction due to accumulation of mucilaginous derivatives of psyllium preparations have been described on several occasions. The common denominator in most cases has been insufficient water intake or underlying organic disease which resulted in compromise of the intestinal lumen. Considering the widespread use of psyllium products, the incidence of esophageal and intestinal obstruction is extremely rare.

LABELING

The label must state "Drink a full glass (8 oz.) of liquid with each dose."

REFERENCES

(1) Souter, W. A., "Bolus Obstruction of Gut After Use of Hydrophilic Colloid Laxatives," British Medical Journal, 1:166–169, 1965.

(2) Tirsch, H. S. and S. Rosenfeld, "Correction of Constipation in Severely Incapacitated Invalids and in Patients with Neurologic Disease," American Journal of Gastroenterology, 31:702–705, 1959.

(3) Stanley, M., D. Paul, D. Gacke and J. Murphy, "Comparative Effects of Cholestyramine, Metamucil and Cellulose on Bile Salt Excretion in Man," Gastroenterology, 62:810, 1972.

(4) Fingl, E., "Cathartics and Laxatives," Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan, New York, p. 1026, 1970.

(b) *Active ingredients classified as stimulant laxatives.* The Panel is of the opinion that the so called "stimulant" group of laxative preparations should be used only occasionally, and not more than daily for a week, for the relief of simple constipation.

LABELING

In addition to specific labeling requirements for the individual ingredients listed below, it must be stated on the label of this group of laxatives that

Prolonged or continued use of this product can lead to laxative dependency and loss of normal bowel function. Serious side effects from prolonged use or overdose may occur;

and

This product should be used only occasionally, but, in any event, no longer than daily for 1 week, except on the advice of a physician.

(1) *Anthraquinones.* The Panel concludes the following anthraquinone to be safe and effective in the following amounts usually taken orally in laxative products for occasional use only:

Anthraquinone	*Usual Dose*
Aloe	120 to 250 mg daily for adults; 40 to 80 mg daily for children 6 to 8 years, and 80 to 120 mg daily for 8 to 15 years. (Not recommended for children under 6 years).
Cascara Sagrada Preparations:	
Aromatic Cascara Fluidextract	2 to 6 ml daily (infants not more than 2 years: 1–2 ml/dose).
Casanthranol	30 to 90 mg daily.
Cascara Sagrada Bark	300 mg to 1 gm daily.
Cascara Sagrada Extract	200 to 400 mg daily.
Cascara Sagrada Fluidextract	0.5 to 1.5 ml daily.

The usual dose for infants under 2 years is ¼ the adult dose and for children (2 to 12 years) ½ the adult dose of cascara preparations.

Danthron	75 to 150 mg daily (No pediatric dose recommended for children under 13 years).
Senna Preparations (single dose):	
Senna Fluidextract	2 ml.
Senna Leaf Powder	0.5 to 2 gm.
Senna Pod Concentrate	0.6 to 1 gm (1–4 times daily).
Senna Fruit Extract	3.4 to 4 gm.
Senna Syrup	8 ml.
Sennosides A & B, Crystalline	12 to 36 mg.

The usual childhood dose of the senna preparations is ⅛ of the adult dose for infants under 2 years, ¼ of the adult dose for children 1 to 5 years, and ½ of the adult dose for children 6 to 12 years of age.

The laxative action of aloe, cascara sagrada, and senna is attributed to hydroxyanthraquinone derivatives that exist in the plants as glycosides and, in the case of the synthetic compound danthron, as the free anthraquinone. The laxative action of the anthraquinones is limited mainly to the large intestine where the glycosides in the plant derivatives arrive intact and are subsequently hydrolyzed by colonic microflora to free anthraquinone. The precise mechanism by which these compounds promote bowel movement is not known. Proposals that suggest the active constituents act by a direct irritant effect on the mucosa or that they stimulate intramural nerve plexi lack experimental confirmation.

Danthron is partially absorbed from the upper gastrointestinal tract and a large part of the drug is metabolized by the liver. The metabolic products are excreted by the kidneys, sometimes causing a harmless discoloration of the urine as occurs with all anthraquinones. Anthraquinone also is excreted in the milk of nursing mothers but in insufficient amounts to cause laxation in the nursing infant. Melanotic pigmentation of the mucous membrane of the colon has been observed in persons who have taken anthraquinone drugs for years. This pigmentation is thought to be benign and is reversible after the medication is discontinued.

LABELING

Labeling should include statements identified above for stimulant laxatives. Professional labeling for senna preparations may also include "for the preparation of the colon for X-ray and endoscopic examination."

REFERENCES

(1) AMA Drug Evaluations, 2nd Ed., Publishing Sciences Group, Acton, Mass., p. 801, 1973.

(2) Greenhalf, J. O. and H. S. D. Leonard; "Laxatives in the Treatment of Constipation in Pregnant and Breast-feeding Mothers," Practitioner, 210:259–263, 1973.

(3) Jones, F. A. and E. W. Godding, "Management of Constipation," Blackwell Scientific Publications, London, p. 62–64, 1972.

(4) Travell, J., "Pharmacology of Stimulant Laxatives," Annals of the New York Academy of Sciences, 58:416–425, 1954.

(2) *Bisacodyl.* The Panel concludes that bisacodyl is safe and effective in the amounts usually taken orally (5–15 milligrams daily at bedtime) and rectally (10 milligrams suppository) for occasional use. The usual oral dose is 0.3 mg/Kg/day or 5 mg for children over 3 years of age. The rectal dose is 5 mg for children under 2 years.

Bisacodyl, (4,4'-(2-pyridylmethylene) diphenol diacetate), when in contact with the colonic mucosa, after either oral or rectal administration, promotes evacuation by inducing mass movements in the colon. The agent is considered a "contact" laxative owing to the fact that its action may be blocked by mucosally applied local anesthetics. After rectal administration, it is usually effective within 15 minutes to 1 hour. Bisacodyl is very poorly absorbed, if at all.

The action of bisacodyl is said to be limited to the colon by acting on the mucosa or the submucosal plexi of the large bowel. However, studies in animals indicate bisacodyl may inhibit sodium and potassium adenosine triphosphatase thereby limiting sodium and water reabsorption in the small intestine. It may also inhibit tyrosine and glucose absorption resulting in intraluminal retention of osmotically attracted water in the small bowel as well as inducing active secretory processes in the colon. With excessive use, or accidental overdose, severe side effects have been reported including diarrhea with metabolic acidosis, muscular weakness due to hypokalemia, and metabolic alkalosis leading to tetany in the presence of persistent hypokalemia.

LABELING

The label of the enteric coated tablets of bisacodyl must state: (1) "Do not chew." (2) "Do not give to children under 3 years of age or to persons who cannot swallow without chewing." (3) "Do not take this product within 1 hour after taking an antacid and/or milk." (4) "This product may cause abdominal discomfort, faintness, rectal burning and mild cramps." Labeling for both tablets and suppositories should state: "Store in a cool place at temperature not above 86° F (30° C)."

PROFESSIONAL LABELING

The Panel concludes that additional indications for professional labeling may include for use in preparation of the patient for surgery or for preparation of the colon for x-ray and endoscopic examination.

REFERENCES

(1) Anon: "Purgatives," British Medical Journal, 4:543–544, 1969.

(2) Cooke, W. T., "Laxatives and Purgatives," Practitioner, 206:77–80, 1971.

(3) Ewe, K., "Effect of Laxatives on Intestinal Water and Electrolyte Transport," European Journal of Clinical Investigation, 2:283, 1972.

(4) Rider, J. A., "Treatment of Acute and Chronic Constipation with Bisoxatin Acetate and Bisacodyl: Double-blind Crossover Study." Current Therapeutic Research, 13:386–392, 1971.

(5) Goldfinger, P., "Hypokalemia, Metabolic Acidosis, and Hypocalcemic Tetany in a Patient Taking Laxatives. A Case Report." Journal of Mount Sinai Hospital, 36:113–116, 1969.

(3) *Castor oil.* The Panel concludes castor oil to be safe and effective in amounts (15 to 60 milliliters) taken orally as a single dose. The usual dose for infants (not more than 2 years) is 1 to 5 ml and for children (2 to 12 years) 5–15 ml.

The laxative action of castor oil is due to ricinoleic acid which is produced when castor oil is hydrolyzed to the fatty acid in the small intestine by pancreatic lipase. The precise mode by which ricinoleic acid promotes bowel movement is not known, although recent experimental evidence indicates that it causes the colon to secrete water and electrolytes. There is no experimental evidence to support the assumption that the laxative acts to increase peristalsis through a direct irritant effect on the intestinal mucosa.

Some castor oil may be absorbed from the gastrointestinal tract; its systemic effect and metabolic fate are unknown. Ricinoleic acid is also absorbed and it is metabolized in a manner similar to other fatty acids. Its single action usually results in a complete clearance of the lower bowel which makes it useful to prepare the patient for proctoscopy or for x-ray studies of the gastrointestinal tract.

Castor oil affects the small intestine and regular use may cause excessive loss of water, electrolyte and unabsorbed nutrients. These potential side effects preclude its repeated administration as a therapeutic agent in the management of constipation.

LABELING

The label of castor oil containers must state: (1) "For the treatment of isolated bouts of constipation." (2) "Not to be used on a daily basis except under the direction of a physician." (3) "Castor oil affects the small intestine and regular use may cause excessive loss of water, and body salts, which can have debilitating effects." Professional labeling may also include "for the preparation of the colon for x-ray and endoscopic examination."

REFERENCES

(1) AMA Drug Evaluations, 2nd Ed., American Medical Association, Chicago, p. 801, 1973.

(2) Jones, F. A. and E. W. Godding, "Management of Constipation," Blackwell Scientific Publications, London, p. 57, 1972.

(3) "Report of NAS-NRC Drug Efficacy Study Group," Published in the Federal Register of May 24, 1972 (37 FR 10521).

(4) Watson, W. C., R. S. Gordon, Jr., A. Karmen and A. Jover, "Absorption and Excretion of Castor Oil in Man." Journal of Pharmacy and Pharmacology, 15:183–188, 1963.

(5) Phillips, S. F., "Diarrhea: A Current View of the Pathophysiology," Gastroenterology, 63:495–518, 1972.

(6) Christensen, J. and B. W. Freeman, "Circular Electromyogram in the Cat Colon: Local Effect of Sodium Ricinoleate," Gastroenterology, 63:1011–1015, 1972.

(4) *Dehydrocholic acid.* The Panel concludes that dehydrocholic acid is safe and effective as a laxative when given in recommended doses of 750 to 900 milligrams per day. The Panel has no data to support a recommended pediatric dose and accordingly should not be used in any child under 12 years of age.

Dehydrocholic acid is the oxidation product of cholic acid, a natural bile acid. It differs from the natural bile acids and their conjugates in at least two respects: (a) it does not readily form micelles (small aggregates of bile acids, fats, and phospholipids necessary for normal fat absorption) and (b) it is a potent hydrocholeretic (increases the volume and water content of bile). Animal toxicity studies have disclosed a remarkably high LD_{50} (14.7 gm/kg in rats). Chronic administration of doses as high as 5 gm/kg/day in dogs failed to produce hepatoxicity and no hepatic damage was found in rats fed 333 mg/kg daily for 32 days. In man, reports of the oral and intravenous administration of dehydrocholic acid for a variety of conditions have failed to disclose consistent or serious toxicity (with the exception of rare anaphylactic reactions following the intravenous administration of this substance for the measurement of circulation times).

The mechanism by which dehydrocholic increases the frequency of bowel movements is unkown. There is no experimental basis for the early literature references to "bilitary constipation" or the relief of constipation due simply to the hydrocholeretic action of dehydrocholic acid. It is possible that this bile acid has a direct effect on the colonic mucosa to inhibit the absorption of sodium and water and stimulate the secretion of sodium bicarbonate and water as has been demonstrated with naturally occurring bile acids.

LABELING

There is no evidence in support of the claim that dehydrocholic acid relieves, "indigestion," "excessive belching," "after meal discomfort," or "the sensation of abdominal fullness." These claims constitute mislabeling and dehydrocholic acid is placed in Category II with respect to these claims.

REFERENCES

(1) Berman, A. L., E. Snapp, A. C. Ivy and A. J. Atkinson, "The Effect of Long-Continued Ingestion of Oxidized Bile Acids on the Dog and Rat." American Journal of Digestive Diseases, 7:280–284, 1940.

(2) King, J. C., "Practical Ambulatory Therapy of Functional Constipation," American Journal of Digestive Diseases, 22:102–108, 1955.

(5) *Phenolphthalein (white or yellow).* The Panel concludes phenolphthalein to be safe and effective in the amounts 30 to 270 milligrams daily for adults, 15 to 20 milligrams per day for children (2 to 5 years), and 30 to 60 milligrams for children 6 years and older usually taken orally in laxative products for occasional use only. The drug is not recommended for use in children less than 2 years of age unless under the advice and supervision of a physician.

Phenolphthalein exerts its primary laxative action on the colon, but may also increase the activity of the small intestine. The main mode of action appears to be as a noncompetitive inhibitor of the enzymes, sodium and potassium adenosine triphosphatase, resulting in failure of salt and water absorption. The glucuronide and disulfide derivatives of phenolphthalein have no effect on enzymatic activity. Yellow phenolphthalein is said to be about three times as potent as white phenolphthalein, but this is not adequately supported by clinical studies. Up to 15 percent of a therapeutic dose may be absorbed and excreted by the kidney, giving a pink color to alkaline urine. The major side effects of phenolphthalein, which occur infrequently, are excessive laxation or electrolyte depletion in chronic use and various skin reactions including nonspecific rashes and pigmentation.

LABELING

In addition to the general requirements for labeling as a laxative, the following specific caution must appear: "If a skin rash appears, do not use this or any other preparation containing phenolphthalein."

REFERENCES

(1) Phillips, R. A., A. H. G. Love, T. G. Mitchell and E. M. Neptune, Jr., "Cathartics and the Sodium Pump," Nature, 206:1367–1368, 1965.

(2) Chignell, C., "The Effect of Phenolphthalein and Other Purgative Drugs on Rat Intestinal (Na^++K^+) Adenosine Triphosphatase," Biochemical Pharmacology, 17:1207–1212, 1968.

(3) Ditkowsky, S., and F. Steigmann, "Phenolphthalein in Childhood: Dosage and Efficacy," Journal of Pediatrics, 45:169–170, 1954.

(4) Savin, J. A., "Current Causes of Fixed Drug Eruptions," British Journal of Dermatology, 83:546–549, 1970.

(c) *Active ingredients classified as saline and hyperosmotic laxatives.*—(1) *Saline laxatives.* Although the saline laxatives (magnesium and phosphate ions) have long been assumed to act by the hyperosmotic effect of poorly absorbed ions within the small bowel, recent evidence suggests that saline laxatives exert a complex series of actions on the gastrointestinal tract. The Panel recognizes that the following commentary may undergo significant revision on the basis of current and future research into the mechanisms of action of the saline laxatives. Further, the Panel concludes that the saline laxatives should be restricted to occasional use only, as serious electrolyte disturbances have been reported with their long-term or daily use.

LABELING

The label should contain a warning concerning prolonged usage such as, "For occasional use only. Do not take longer than 1 week. Serious side effects from prolonged use or overdosage may occur."

(i) *Magnesium salts.* The Panel concludes that the following magnesium salts are safe and effective in the amounts taken orally in laxative products for occasional use:

Magnesium Salt—Usual daily dose (taken in divided doses).

Magnesium Citrate—11–16 gm (77–141 mEq Mg^{++}) or for children 2 to 5 years 2.5 to 5 gm, 6 years and older 5 to 10 gm.

Magnesium Hydroxide—2.4–4.8 gm (82–164 mEq Mg^{++}) or for children 2 to 5 years 0.4 to 1.2 gm, for children 6 years and older 1.2 to 2.4 gm.

Magnesium Sulfate—10–30 gm (81–243 mEq Mg^{++}) or for children 2 to 5 years 2.5 to 5 gm, 6 years and older 5 to 10 gm.

Magnesium salts are one of a group of the saline laxatives classically thought to exert a laxative effect by osmotically attracting water into the intestinal lumen. Current work suggests that the mechanism of action may be due in large part to the release of the gastrointestinal hormone cholecystokinin-pancreozymin (CCK–PZ) and its subsequent stimulation of the motor and secretory activity in the gastroentestinal tract. Most studies suggest a minimally effective dose of magnesium is approximately 80 mEq, although lower doses may, in the future, be shown to be effective for activity unrelated to any osmotic action.

Absorption of administered magnesium is approximately 15 to 30 percent, which may cause systemic toxicity in the presence of renal insufficiency.

Anhydrous Magnesium Citrate is usually formulated in combinations of citric acid and anhydrous sodium citrate; these latter two substances are considered sequestering agents that allow magnesium to be held in solution as a soluble complex ion. Citric acid and anhydrous sodium citrate are not considered laxative agents in themselves and should not be claimed as active ingredients.

Magnesium hydroxide is occasionally promoted as both an antacid and a laxative. This dual claim is permissible owing to the activity of this compound, but the public should be aware that when used regularly as an antacid, magnesium hydroxide causes significant laxation. Claims of superior laxation on the basis of the antacid properties are not allowed because the Panel is not aware of any scientific data that establishes a relationship between acid secretion and constipation.

LABELING

For those products in which the maximal daily dose exceeds 50 milliequivalents of magnesium, the label should contain a statement such as, "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

Labeling of the magnesium citrate solution should indicate the need for storage in a cold place (refrigerator temperature) to retard decomposition.

SODIUM WARNING LABEL

See laxative labeling statement (paragraph D) above for sodium warning.

REFERENCES

(1) Welt, L. G. and W. B. Blythe, "Cations: Calcium, Magnesium, Barium, Lithium and Ammonium," "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman MacMillan, New York, pp. 811–813, 1970.

(2) Seed, J. C. and R. Harris, "Some Factors in the Design of Aperient Studies," Annals of the New York Academy of Science, 58:426–437, 1954.

(3) Harvey, R. F. and A. E. Read, "Saline Purgatives Act by Releasing Cholecystokinin," Lancet, 2:185–187, 1973.

(4) Montilla, E., "Treatment of Chronic Constipation With An Emulsion of Milk of Magnesia and Mineral Oil." Clinical Medicine, 73:75–77, 1966.

(ii) *Phosphate Salts.* The Panel concludes that each of these phosphate salts is safe and effective in amounts taken orally or rectally in a single dose of the following ingredients:

Phosphate Salt	Usual daily dose of all ingredients combined (gm)	
	Oral	Rectal
Disodium Phosphate	1.9-3.8	3.8
Monosodium Phosphate	8.3-16.6	16.6
Sodium Biphosphate	9.6-19.2	19.2
Sodium Phosphate	3.6-7.2	7.2

The usual oral dosage for children 5 to 10 years of age: ¼ of the adult dose, children 10 years and older: ½ the adult dose of phosphate salts. The usual rectal dosage for children over 2 years of age is ½ of the adult dosage of phosphate salts.

The oral phosphate salts are considered to be rapidly acting laxatives whose mechanism of action may involve more complex activity in the gastrointestinal tract than that of a hyperosmotic agent. When given as an enema rectally, four ounces of the hypertonic solution containing approximately 26 grams of phosphate salt is also considered effective although the extent to which effectiveness reflects the volume of liquid introduced rectally is unknown. The amount of total sodium contained in the effective and safe range is 88 to 176 milliequivalents. The amount of sodium absorption from the enema varies from 1.6 to 31 milliequivalents of sodium; the extent of sodium absorption from the oral preparations is unknown. By either route, there is risk of acute elevation of sodium concentration in the serum and dehydration, particularly in children with megacolon. Elevated levels of serum phosphates and decreased levels of serum calcium have been reported with prolonged use or in patients with renal disease.

LABELING

The labeling for saline laxatives discussed above should be included. The label should also contain a warning against use in the presence of kidney disease. The label should also contain a warning against use by children under the age of 6 for oral preparations and by children under the age of 2 years for rectal preparations, except under the advice of a physician.

SODIUM WARNING LABEL

See laxative labeling statement (paragraph D) above for sodium warning.

PROFESSIONAL LABELING

The labeling provided to health professionals (but not to the general public) for all phosphate laxatives should provide the total dose of sodium in mEq (mg). per standard dose. The label should carry the following warnings: "Do not use in patients with megacolon, as hypernatremic dehydration may occur. Use with caution in patients with impaired renal function as hyperphosphatemia and hypocalcemia may occur."

REFERENCES

(1) Fonkalsrud, E. and J. Keen, "Hypernatremic Dehydration from Hypertonic Enemas in Congenital Megacolon," Journal of the American Medical Association, 199:584–586, 1967.

(2) The National Formulary, 12th Ed., The American Pharmaceutical Association, Washington, D.C. p. 372, 1965.

(3) Page, S. G., C. R. Riley and H. B. Haag, "A Comparative Clinical Study of Several Enemas," Journal of the American Medical Association, 157:1208–1210, 1955.

(4) Rosenfield, H. H., L. Burke and H. Rubin, "Disposable Enema Unit in Obstetrics," Obstetrics and Gynecology, 222–225, 1958.

(5) Zumóff, B. and L. Hellman, "Rectal Absorption of Sodium from Hypertonic Sodium Phosphate Solutions," Sloan Kettering Institute for Cancer Research, New York, N.Y., Draft of unpublished paper included in OTC Volume 0900—.

(6) McConnell, T. H., "Fatal Hypocalcemia from Phosphate Absorption from Laxative Preparation," Journal of the American Medical Association, 216:147–148, 1971.

(2) *Hyperosmotic Laxatives*—(i) *Glycerin.* The Panel concludes that glycerin is safe and effective in the amounts usually used rectally as an aid in evacuation of the bowel: 3 grams as a suppository; 5 to 15 milliliters as an enema. Children under 6 years 1 to 1.5 gm as a suppository or 2 to 5 ml as an enema.

Glycerin is a clear, colorless trihydroxy alcohol which is miscible with water and alcohol. Three possible modes of action of glycerin on the rectal mucosa have been proposed: (1) Being hypertonic, it causes mild dehydration of the tissues resulting in reflex defecation; (2) it is locally irritating and produces reflex defecation; (3) possessing hygroscopic properties, it softens fecal material and hydrates hardened dry feces.

Moderate doses orally or parenterally (in proper dilution) are safe and cutaneous application in copious amounts does not produce systemic effects. Owing to its sweet taste, it has been used as a sweetening agent. When taken orally, it is rapidly absorbed and metabolized providing calories. Large doses orally can exert toxic effects and may lead to symptoms including restlessness, vomiting, loose stools, fever, convulsive seizures, hemoglobinuria, progressive narcosis, and circulatory failure. The Panel, therefore, concludes that glycerin is unsafe at the effective dose level as an oral laxative.

Compounds related to glycerin, with the exception of propylene glycol, are much more toxic than the parent compound and may cause nephro- and hepatotoxicity.

The use of glycerin as rectal suppositories in adults and children is effective in producing a bowel movement, usually within 30 minutes, in the majority of children and adults with only minimal incidence of side effects including rectal discomfort, rectal burning or griping, and cramping pain. Glycerin administered rectally is considered to be safe but may produce in some individuals rectal mucosal hyperemia, minimal hemorrhage, and mucorrhea.

LABELING

The labeling should state: (1) "For rectal use only and not for oral use. Large doses of glycerin if taken orally can lead to serious toxic effects." (2) "Glycerin administered rectally may produce in some individuals rectal discomfort or a burning sensation."

REFERENCES

(1) Staples, R., A. Misher and J. Wardell, Jr., "Gastrointestinal Irritant Effect of Glycerin as Compared with Sorbitol and Propylene Glycol in Rats and Dogs," Journal of Pharmaceutical Sciences, 56:398–400, 1967.

(2) Sloviter, H. A. and R. M. Tietze, "Effects of the Intravenous Administration of Glycerol Solutions to Animals and Man," Journal of Clinical Investigation, 37:619–626, 1958.

(3) Pinter, G. G. and D. B. Zilversmit, "Mechanism of Hemolysis After Intravenous Glycerol Administration," American Journal of Physiology, 198:895–898, 1960.

(4) Barowsky, H., "A Rectal Suppository for Inducing Lower Bowel Evacuation. Its Comparative Effectiveness to the Glycerin Variety," American Journal of Gastroenterology, 39:183–186, 1963.

(5) Brocklehurst, J. C., "Treatment of Constipation and Fecal Incontinence in Old People," Practitioner, 193:779–782, 1964.

(ii) *Sorbitol.* The Panel concludes that sorbitol is safe and effective in amounts usually administered rectally (120 milli-

liters as a 25 to 30 percent solution) in laxative products for occasional use (Children 2 years and older 30 to 60 ml in same concentration, administered rectally).

Sorbitol is a poorly absorbed polyalcohol of the hexose sugar, sorbose. Because of its limited absorption from the gastrointestinal tract, if given orally in sufficient quantities, it promotes an osmotic diarrhea. The oral laxative minimum effective dose in man appears to be about 50 grams. This dose is used occasionally to produce laxation in patients with some complicated disease, but is not approved for use as an oral laxative in OTC products. When administered rectally as a hypertonic solution, it promotes defecation.

Sorbitol given orally has been shown in animals to be less irritating to the intestinal mucosa than glycerin, but the observed changes are qualitatively similar and dose and concentration dependent.

LABELING

"For rectal use only."

REFERENCES

(1) Adcock, L. H. and C. H. Gray, "The Metabolism of Sorbitol in the Human Subject," Biochemical Journal, 65:554–560, 1957.

(2) Staples, R., A. Misher and J. Wardell, Jr., "Gastrointestinal Irritant Effect of Glycerin as Compared with Sorbitol and Propylene Glycol in Rats and Dogs," Journal of Pharmaceutical Sciences, 56:398–400, 1967.

(3) Prescott, L. G., "Pharmacokinetic Drug Interaction," Lancet, 2:1239–1243, 1969.

(4) Stempien, S. J., "Double-Blind Evaluation of Sorbitol, Phosphate, and Dextrose Enemas at Sigmoidoscopy," Gastroenterology, 36:830–831, 1959.

(5) Agostini, L., P. F. Down. J. Murison and O. M. Wrong, "Faecal Ammonia and pH During Lactulose Administration In Man: Comparison With Other Cathartics," Gut, 13:859–866, 1972.

(d) *Active ingredients classified as stool softener and lubricant laxatives.* The active ingredients as stool softener laxatives and lubricant laxatives are particularly useful when the stools are hard and dry or when disease of the anus and rectum exist that make the passage of a firm stool painful. These products should be used only occasionally or no longer than a week when taken daily as they may interfere with the absorption of a number of nutrients including some vitamins. If relief of the condition for which the product is taken is not obtained in a week, the user should consult a physician. The following ingredients are considered, by the Panel, to be safe and effective when taken as directed.

(1) *Stool softener laxatives*—(i) *Dioctyl sulfosuccinate preparations.* The Panel concludes that the following dioctyl sulfosuccinate preparations are safe and effective in amounts usually taken orally or rectally in laxative products.

Sulfosuccinate	*Usual daily dose*
Dioctyl calcium sulfosuccinate (oral)	50–360 mg/day (25 mg for infants under 2 years, 50–150 mg/day for children).
Dioctyl potassium sulfosuccinate (rectal)	50–250 mg/day (100 mg/day for children).
Dioctyl Sodium sulfosuccinate (oral)	50–360 mg/day (20–50 mg for infants under 2 years, 50–150 mg/day for children).

The mechanism of action of dioctyl sodium sulfosuccinate (DSS) salts is not completely understood. Published literature based on in vitro studies suggests that they act by a detergent action which lowers surface tension at the oil-water interface permitting water and lipid to penetrate the fecal mass and soften the stool. Absorption of DSS does occur in the duodenum and jejunum. The clinical significance of intestinal absorption of DSS has not been determined.

Recent evidence suggests that the laxative properties of DSS may be explained by its ability to stimulate secretion of electrolytes and water in the colon. The effect is associated with an increased concentration of cyclic adenosine monophosphate in the colonic mucosal cells exposed to DSS.

Significant toxicity in the human has not been attributed to DSS when used alone as a laxative. Hepatic toxicity has occurred when DSS was used in combination with oxyphenisatin, but this drug combination is no longer being marketed.

Published reports available to the Panel concerning studies made in many types of constipated patients show DSS to be effective in softening the stool. Only minimal and insignificant side effects have been attributed to its use.

In spite of the reported record of safety, DSS possesses potent detergent properties and the Panel recognizes that it might facilitate gastrointestinal or hepatic cell uptake of other drugs, thereby, potentiating their activity. The absorption of mineral oil (a lubricant laxative described elsewhere in this document) may be enhanced by DSS, and therefore, these agents should not be taken concurrently. The doses of DSS and dioctyl calcium sulfosuccinate (DCS) should be as small as possible to give the desired result.

Current information does not warrant a need to restrict the use of DSS, DCS, or dioctyl potassium sulfosuccinate (DPS), but reevaluation may be needed as additional data become available.

LABELING

Because of possible drug interaction, the label should contain a statement such as:

WARNING.—Do not take this product if you are presently taking a prescription drug or mineral oil.

The label should also contain a statement such as:

CAUTION.—This product should be used only occasionally, but in any event no longer than daily for 1 week.

REFERENCES

(1) Dujovne, C. A., and D. W. Shoeman, "Toxicity of a Hepatotoxic Laxative Preparation in Tissue Culture and Excretion in Bile in Man," Clinical Pharmacology and Therapeutics, 13:602–608, 1972.

(2) Hyland, C. M. and J. D. Foran, "Dioctyl Sodium Sulphosuccinate as a Laxative in the Elderly," Practitioner, 200:698–699, 1968.

(3) Donowitz, M. and H.J. Binder, "Dioctyl Sodium Sulfosuccinate (DSS) Stimulates Large Intestinal Water and Electrolyte Secretions: Mechanism of Laxative Action?," Gastroenterology, 66:A184/838, 1974.

(4) Phelps, D. K. "Effect of Dioctyl Sodium Sulfosuccinate on Bowel Function in Mental Patients," Journal of the Indiana State Medical Association, 51:646–649, 1958.

(5) Sanders R. C. and F. W. Wright, "Colonic Preparation: A Controlled Trial of Dulcodos, Dulcolax and Senokot DX," British Journal of Radiology, 43:245–247, 1970.

(2) *Lubricant laxatives*—(i) *Mineral oil, plain.* The Panel concludes mineral oil preparations to be safe and effective in the amounts usually administered orally only at bedtime (adults, 15 to 45 milliliters, and children over 6 years 10 to 15 milliliters) and rectally (adults, 120 milliliters, and children 6 years of age and older—60 milliliters) provided the specific directions and limitations are carefully followed.

Mineral oil, a mixture of colorless, tasteless, liquid aliphatic hydrocarbons obtained from petroleum, is a laxative agent that acts by a lubricating effect on the intestinal mucosa and a lubricating or softening action on fecal material. It is non-irritating, not digested by endogenous gastrointestinal enzymes, and minimally absorbed.

Side effects with the proper use of mineral oil are few. Absorption of a number of dietary nutrients including fat soluble vitamins may be impaired by concurrent ingestion of mineral oil. Thus, mineral oil should be taken orally at bedtime, when the stomach is empty. Administration of mineral oil may lower prothrombin levels probably secondary to impaired vitamin K absorption and regular use in pregnancy may predispose to hemorrhagic disease of the newborn. As the absorption of mineral oil may be enhanced by dioctyl sodium sulfosuccinate (a stool softener described elsewhere in this document), these agents should not be taken concurrently. With chronic use and particularly with excess dosage, anal leakage, and dermatologic reactions may ocur.

On very infrequent occasions, mineral oil may be aspirated and cause lipid pneumonitis particularly in young children and debilitated elderly persons. Deposition of mineral oil in various tissues may simulate neoplasms. Mineral oil should not be given to patients with esophageal or gastric retention.

LABELING FOR ORAL PREPARATIONS

The label must state: "Caution: To be taken only at bedtime. Do not take for more than 1 week. Do not administer orally to infants or children under 6 years of age, to pregnant women, to bedridden or aged patients, to persons with difficulty in swallowing, recent vomiting or regurgitation, or abdominal pain ex-

cept on the advice and supervision of a physician.

Because of possible drug interaction, the label should contain a statement such as: "Do not use this product if you are currently taking a stool softener laxative." (See dioctyl sodium sulfosuccinate section of this document for explanation).

(ii) *Mineral oil emulsion.* The Panel concludes certain mineral oil emulsions are safe and effective in amounts usually administered orally twice a day with the first dose taken on arising and the second dose taken at bedtime and neither dose at mealtimes (adults 15 to 45 ml of mineral oil component of emulsion, children over 6 years of age 0.25 to 5 ml of mineral oil component of emulsion). Emulsification of mineral oil by magnesium hydroxide or other agents reduces the size of oil droplets, and there is evidence that this properly results in enhanced penetration of mineral oil into the fecal mass. Emulsification would theoretically enhance intestinal absorption but the Panel is unaware of evidence that this occurs.

LABELING FOR ORAL PREPARATIONS

The Panel concludes that the labeling which applies to plain mineral oil, should also apply to mineral oil emulsion with the exception of the bedtime ingestion limitation for plain mineral oil. That limitation should be modified to permit a twice daily dosage regimen for mineral oil emulsion with the first dose taken on arising and the second dose taken at bedtime and neither dose at mealtime.

LABELING FOR RECTAL PREPARATIONS

The precautions listed above for oral administration do not apply to rectal administration of mineral oil.

LABELING FOR HEALTH PROFESSIONALS

Professional labeling may contain as additional indications: "For the preparation of the colon for x-ray and endoscopic examination."

Labeling shall contain the following: "Side effects with the proper use of mineral oil are few. However, with chronic use and particularly with excess dosage, excessive laxation, anal leakage and dermatologic reactions may occur. Owing to its property as a lipid solvent, liquid paraffin (mineral oil) may interfere with the absorption of pro-vitamin A, vitamin A, and vitamin D leading to impairment of calcium and phosphorus metabolism. This occurs only under conditions of chronic usage. Administration of mineral oil may lower prothrombin levels, probably secondary to impaired vitamin K absorption, and regular use in pregnancy may predispose to hemorrhagic disease of the newborn. Because of possible interference with nutrition, mineral oil should not be ingested in close proximity to meals. These side effects occur very rarely and then only with chronic and abusive use."

REFERENCES

(1) AMA Drug Evaluations, 1st Ed., AMA Council on Drugs, American Medical Association, Chicago, pp. 598–601, 1971.

(2) Martin, E. W., Hazards of Medication, J. B. Lippincott Co., Philadelphia, pp. 577 and 686, 1971.

(3) Anderson, N. P., "Contact Dermatitis; Its Relation to Petroleum Products," Industrial Medicine and Surgery, 23:270–273, 1953.

(4) Steigmann, F., H. Popper, H. Dyniewica and I. Maxwell, "Critical Levels of Mineral Oil Affecting the Absorption of Vitamin A," Gastroenterology, 20:587–594, 1952.

(5) Javert, C. T. and C. Macri, "Prothrombin Concentration and Mineral Oil," American Journal of Obsterics and Gynecology, 42:409–414, 1941.

(6) Poppel, M. H. and C. K. Bangappa," "The Induction of a Disordered Motor Function Pattern in the Small Bowel by the Administration of Mineral Oil," American Journal of Roentgenology, 83:926–927, 1960.

(7) Salm, R. and E. W. Hughes, "A Case of Chronic Paraffin Pneumonitis," Thorax, 25: 762–768, 1970.

(8) Nairn, R. C. and M. F. A. Woodruff, "'Paraffinoma' of the Rectum," Annals of Surgery, 141:536–540, 1955.

(e) *Active ingredient classified as a miscellaneous laxative—(1) Released carbon dioxide from combined sodium biphosphate anhydrous, sodium acid pyrophosphate and sodium bicarbonate.* The Panel concludes that rectal suppositories which release carbon dioxide are safe and effective in the amounts usually used rectally once a day as an aid in evacuation of the bowel (no pediatric dosage for children under 12 years).

The suppository dosage form contains 1.2 gm to 1.5 gm sodium biphosphate anhydrous, 0.04 gm to 0.05 gm sodium acid pyrophosphate and 1.0 gm to 1.5 gm sodium bicarbonate, and works through the production of carbon dioxide (approximately 230 ml) in the rectum. The active ingredient, carbon dioxide, is produced by the action of water on these ingredients. The expanding gas induces a gentle pressure in the rectum thereby promoting bowel movement. The suppository should be placed under a water tap for about 30 seconds or immersed in a cup of water for at least 10 seconds prior to rectal insertion.

LABELING

The product should be labeled for rectal use only. To facilitate the release of carbon dioxide, the labeling should state: "Do not lubricate with mineral oil or petrolatum jelly, prior to rectal insertion." In addition, the following warning should be included:

WARNING.—Rectal bleeding, or failure to evacuate may indicate a serious condition and a physician should be consulted.

REFERENCES

(1) Hamilton, W., and W. Walker, "Carbon Dioxide Suppositories as Preparation for Sigmoidoscopy," Journal of the National Medical Association, 57(6):496–7, 1965.

(2) Slotkin, R., "A Study of the Vacuett Suppository in the Pediatric Patient," Journal Pediatrics, 66(5): 954–6, 1965.

(3) Welsh, J., "Preparation of Outpatients for Proctoscopic Examination," The Journal of the Oklahoma State Medical Association, 6:467–9, 1968.

(4) Barowsky, H., "A Rectal Suppository for Inducing Lower Bowel Evacuation," American Journal Gastroenterology, 39(2): 183–6, 1963.

(5) Blumberg, N., "A New Suppository for Functional Constipation," Medical Times, 91(1):45–7, 1963.

(6) Culp, C., "Bowel Preparation for Proctosigmoidoscopy," Nebraska State Medical Journal, 50(2):79–82, 1965.

2. *Conditions under which laxative products are not generally recognized as safe and effective or are misbranded.* After carefully reviewing all data submitted, as well as additional evidence provided by the Food and Drug Administration and consultants to the Panel and the results of an extensive literature search, the Panel concluded that some OTC laxative ingredients should be removed from the market because of the lack of data supporting their safety. The Panel found no scientific basis or even sound theoretical reasons for claimed effectiveness of a number of ingredients used in OTC laxatives. In addition, certain labeling claims were considered misbranding. Statements and suggestions that laxatives "improve well being" or "promote good health" are unproven and unacceptable. "Irregularity" as an indication for use is misleading because "regularity" of bowel movement is not essential to health or well being. Laxative products are not appropriate for use solely on the basis of a lack of "regularity," because variability of frequency of bowel movements is normal within the limits referred to elsewhere in this document. All undocumented claims such as "stimulates colonic peristalsis," "acts naturally," and "promotes gentle movements" are unacceptable.

The Panel concludes that the following ingredients, labeling, and combination drugs involved should be removed from the market unless and until further scientific testing supports their use:

ACTIVE INGREDIENTS

Calomel
Carrageenan, degraded
Podophylum resin (podophyllin)
Other laxative resins
- Colocynth
- Elaterin
- Gamboge
- Ipomea
- Jalap

COMBINATIONS WITH NONLAXATIVE ACTIVE INGREDIENTS

Belladonna extract (belladonna alkaloids)
Bismuth subnitrate
Capsicum
Carold papain
Ginger
Ipecac powder
Thiamin, multivitamin preparations, and minerals

LABELING CLAIMS FOR SPECIFIC INGREDIENTS

Bile acids and ox bile
Dehydrocholic acid
Magnesium compounds

a. *Active ingredients*—(1) *Calomel (mercurous chloride).* The Panel concludes that calomel is unsafe and unreliable as a laxative.

No data on calomel were submitted to the Panel for review. However, a review of the presently available literature by the Panel requires classification of this compound in Category II and merits special comment, especially with regard

to the conclusion that it is unsafe to use as a laxative (Ref. 1).

Calomel is relatively insoluble; however, in the presence of alkali and bile in the intestine, it is oxidized to some extent to mercuric ion, which is responsible for the toxicity of the drug (Refs. 2 and 3). In the event that calomel fails to produce prompt laxation, appreciable amounts of mercury may be absorbed and cause systemic mercury poisoning (Refs. 2, 3, and 4). Autopsies of two women who had been chronic users of calomel-containing laxatives revealed renal tubular and cerebellar damage and chronic colitis. In addition to having kidney failure and necrosis of the colon, the two patients before death had central nervous system manifestations such as personality change and failure of cognition, and at autopsy elevated mercury levels in the kidneys, brain, and colon (Refs. 5 and 6). In infants, administration of calomel has caused a severe febrile, (erythematous disease known as acrodynia (pink disease) (Refs. 3, 4, and 7).

REFERENCES

(1) AMA Drug Evaluations, "Laxatives and Agents Affecting Fecal Consistency," 2d Ed., American Medical Association, Chicago, p. 799, 1973.

(2) Fingl, E., "Cathartics and Laxatives," The Pharmacological Basis of Therapeutics, Edited by Goodman, L. S. and A. Gilman, 4th Ed., MacMillan, New York, p. 1028, 1970.

(3) Barrett, F. R., "Calomel and Pink Disease: Preliminary Report," Medical Journal of Australia, 44:714–716, 1957.

(4) Barrett, F. R., "A Biochemical Approach to Calomel-Induced Mercurialism and to the Etiology of Pink Disease," Medical Journal of Australia, 44:242–245, 1957.

(5) Davis, L. E., J. R. Wands, S. A. Weiss, D. L. Price and E. F. Girling, "Central Nervous System Intoxication from Mercurous Chloride Laxatives," Archives of Neurology, 30:428–431, 1974.

(6) Wands, J. R., S. W. Weiss, J. H. Yardley and W. C. Maddrey, "Poisoning Due to Laxative Abuse," American Journal of Medicine, 57:92–101, 1974.

(7) Jones, F. A. and E. W. Godding, "Management of Constipation," Blackwell Scientific Publication, London, p. 55, 1972.

(2) *Carrageenan, degraded (Chondrus crispus, Irish moss)*. The Panel concludes that, owing to potential hazards associated with absorbed degraded carrageenan, this material cannot be considered safe on the basis of current evidence.

Native carrageenans which are used in foods possess molecular weights within the range of 100,000 to 800,000. If the cross-linkages of the polymer are broken, degraded carrageenans with molecular weights less than 30,000, are formed. In most animal species tested, native carrageenans (See Category III discussion below) are poorly absorbed, but degraded carrageenans are much more amenable to absorption, especially in herbivorous animals. When added to the drinking water of guinea pigs and rabbits, degraded carrageenans caused diarrhea, severe colonic ulceration, hyperplasia of the intestinal mucosa, and weight loss (Refs. 1 through 6). Degraded carrageenan in the drinking water ingested by Rhesus monkeys was extensively deposited in the reticuloendothelial cells and was still present in Kupffer cells 6 months after cessation of carrageenan administration (Ref. 7).

Owing to the observation that degraded carrageenan may inhibit the proteolytic activity of gastric enzymes, the material has been used in man in the treatment of peptic ulcer (Refs. 5 and 9). Because many of these studies were poorly controlled, the significance of these observations is open to question.

The parenteral administrations of carrageenan produces a wide variety of effects. These include, among others, the following: induction of irritation, inflammation, and edema; granuloma formation; release of kinins, probably by activation of the plasmin system; hypotension; anticoagulation; inhibition of complement fixation; and inhibition of immediate and delayed hypersensitivity reactions (Ref. 5).

REFERENCES

(1) Watt, J., and R. Marcus, "Ulcertative Colitis in Rabbits Fed Degraded Carrageenan," Journal of Pharmacy and Pharmacology, 22:130–131, 1970.

(2) Watt, J. and R. Marcus, "Carrageenan-Induced Ulceration of the Large Intestine in the Guinea Pig," GUT, 12:164–171, 1971.

(3) Watt, J. and R. Marcus, "Hyperplastic Mucosal Changes in the Rabbit Colon Produced by Degraded Carrageenan," Gastroenterology, 59:760–768, 1970.

(4) Anon, "Articles of General Interest: Carrageenan," Food and Cosmetics Toxicology, 9:561, 1971.

(5) DiRosa, M., "Biological Properties of Carrageenan," Journal of Pharmacy and Pharmacology, 23:89–102, 1972.

(6) Fabian, R. J., R. Abraham, F. Coulston, and L. Golberg, "Carrageenan-Induced Squamous Metaplasia of the Rectal Mucosa in the Rat," Gastroenterology, 65:265–276, 1973.

(7) Abraham, R., L. Golberg, and F. Coulston, "Uptake and Storage of Degraded Carrageenan in Lysosomes of Reticuloendothelial Cells in the Rhesus Monkey, Macaca mulatta," Experimental and Molecular Pathology, 17: 77–93, 1972.

(8) Benitz, K. F., L. Golberg, and F. Coulston, "Intestinal Effects of Carrageenan in the Rhesus Monkey," Food and Cosmetics Toxicology, 2: 565–575, 1973.

(9) Evans, P. R. C., S. Nowell, and I. A. P. Thomas, "Blind Trial of a Degraded Carrageenin and Aluminum Hydroxide Gel in the Treatment of Peptic Ulceration," Postgraduate Medical Journal, 4: 48–52, 1965.

(3) *Podophyllum resin* (podophyllin). The Panel concludes that podophyllin is unsafe for use as a laxative because of its potential embryotoxicity and systemic toxicity.

Although podophyllum resin (podophyllin) is official in the U.S. Pharmacopeia (Ref. 1), the ingredient is described only as a cytotoxic agent in the topical treatment of condylomata acuminata (Ref. 11).

Podophyllin and its chief constituent, podophyllotoxin, interfere with normal cell division in animals (Refs. 2 through 4). Because of its inhibitory effect on dividing cells, there is concern that podophyllin may produce an adverse effect on the human embryo and/or fetus. A number of investigators have tested podophyllin or podophyllotoxin in pregnant mice and rats (Refs. 4 through 8) and have demonstrated that these drugs cause a significant incidence of fetal resorption (mortality) and/or fetal growth retardation and that podophyllotoxin interrupts pregnancy in rabbits (Ref. 5). Thus, podophyllin is considered to be a strong embryocidal and fetal growth retarding agent in animals (Ref. 7).

However, the drug has not been shown to produce a significant incidence of gross morphologic (teratogenic) defects in animal fetuses (Refs. 4 through 8). Similarly, the clinical evidence that podophyllin has teratogenic properties in man is equivocal. According to one clinical report (Ref. 9), a patient ingested herbal "slimming" tablets during the first trimester of pregnancy and eventually delivered a baby having multiple deformities involving the thumb, radius, and ear. The "slimming" tablet contained in addition to podophyllin (30 mg), three other plant extractives whose teratogenic potential is unknown. In another case (Ref. 10), severe peripheral neuropathy and intrauterine death occurred in a young woman in the 32d week of pregnancy following the application of podophyllin (1.8 gm) to the vulva for the treatment of warts.

Podophyllin is reported to possess a high systemic toxicity (Ref. 11). For example, in one study, the oral LD_{50} of podophyllin in mice was found to be 60 mg/kg, and the subcutaneous LD_{50} of podophyllin in rats was determined to be 24 mg/kg (Ref. 12). Symptoms of podophyllin-induced toxicity in animals include diarrhea, acute enteritis, rapid and labored breathing, hindlimb paralysis, and convulsions (Ref. 12). Because of the well documented toxic effects of podophyllin in animals and because podophyllin has the potential to cause significant embryotoxicity and systemic toxicity in man, the Panel concludes that this drug is unsafe for use as a laxative.

REFERENCES

(1) The Pharmacopeia of the United States of America, 18th Rev., The United States Pharmacopeial Convention, Inc., Bethesda, Md., p. 512, 1970.

(2) King, L. S. and M. Sullivan, "The Similarity of the Effect of Podophyllin and Colchicine and Their Use in the Treatment of Condylomata Acuminata," Science, 104:244–245, 1946.

(3) Tuchmann-Duplessis, H., "The Action of Anti-Tumour Drugs on Gestation and on Embryogenesis, "Teratology, Edited by Bertelli, A. and L. Donati, Excerpta Medica Foundation, Amsterdam, p. 78, 1969.

(4) Joneja, M. G. and W. C. LeLievor, "In vivo Effects of Vinblastine and Podophyllin on Dividing Cells of DBA Mouse Fetuses," Canadian Journal of Genetics and Cytology, 15:491–495, 1973.

(5) Didcock, K. A., C. W. Picard, and J. M. Robson, "The Action of Podophyllotoxin on Pregnancy," Journal of Physiology, 117:65P–66P, 1952.

(6) Thiersch, J. B., "Effect of Podophyllin (P) and Podophyllotoxine (PT) on the Rat Litter in utero," Proceedings of the Society of Experimental Biology and Medicine, 113: 124–127, 1963.

(7) Joneja, M. G. and W. C. LeLievor, "Effects of Vinblastine and Podophyllin on DBA

Mouse Fetuses," Toxicology and Applied Pharmacology, 27:408–414, 1974.
(8) Dwornik, J. J., "Effect of Podophyllin and Temperature in Skeletal Development of the Holtzman Albino Rat," Doctoral Thesis submitted to University of Manitoba, 1969 is included in OTC Volume 090135.
(9) Cullis, J. E., "Congenital Deformities and Herbal 'Slimming Tablets,'" Lancet, 2: 511–512, 1962.
(10) Chamberlain, M. J., A. L. Reynolds, and W. B. Yeoman, "Toxic Effect of Podophyllum Application in Pregnancy," British Medical Journal, 3:391–392, 1972.
(11) Goodman, L. S. and A. Gilman, The Pharmacological Basis of Therapeutics, 2nd Ed., Macmillan Co., N.Y., pp. 1029 and 1052, 1955.
(12) Sullivan M., R. H. Follis, Jr., and M. Hilgartner, "Toxicology of Podophyllin," Proceedings of the Society of Experimental Biology and Medicine, 27:269–272, 1951.

(4) *Other laxative resins (colocynth, elaterin, gamboge, ipomea, jalap).* The Panel concludes that these plant products are unsafe for use as laxatives because of their potential toxicity.

These plant resins contain active ingredients (usually glycosides) which are released in the intestines. These plant principles are profoundly irritant to the intestines and produce profuse watery stools, which may be blood-tinged, and cause considerable colic (Refs. 1 through 3). Overdose may lead to severe prostration (Ref. 1). Because of the strong action of these irritant principles on the small intestine, their injudicious and long-continued use may lead to nutritional deficiencies, potassium depletion and dehydration (Refs. 1 through 3).

Although these resinous laxatives are not widely used today, the Panel is aware that some OTC laxative mixtures contain these products (Ref. 4). There are no adequate clinical studies to demonstrate that there are safe and effective laxative doses of these irritant resins.

REFERENCES

(1) Fingel, E., "Cathartics and Laxatives," Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S., and A. Gilman, MacMillan, NY, p. 1029, 1970.
(2) Bonnycastle, D. D., "Cathartics and Laxatives," Drill's Pharmacology in Medicine, Edited by J. R. Dipalma, 4th Ed., McGraw-Hill, NY, p. 981, 1971.
(3) Macgregor, A. G., "Purgative and Laxatives," British Medical Journal, 2:1423, 1960.
(4) Darlington, R. C., "Laxatives," Handbook of Non-Prescription Drugs, Edited by G. B. Griffenhagen, 2nd Ed., American Pharmaceutical Association, Washington, DC, p. 41, 1971.

b. *Combinations with nonlaxative active ingredients.* Some OTC laxative products contain nonlaxative ingredients which do not contribute to laxation and in some instances, greatly increase risk of side effects. Other products contain nonlaxative active ingredients for which the Panel can find no scientific or medical rationale. The Panel concludes that the following nonlaxative active ingredients in combination with laxatives are irrational combinations and are not appropriate therapy for a significant portion of the population.

(1) *Combinations containing nonlaxative active ingredients that increase the likelihood of side effects and/or reduce the safety of the product.—Belladonna extract (belladonna alkaloids).* The Panel concludes that the use of belladonna extract or other anticholinergic agents in combination with oral laxatives constitutes irrational and unsafe therapy.

Belladonna extract, which is extracted from the leaves of *Atropa belladonna*, contains atropine and other anticholinergic alkaloids (Ref. 1). The usual quantity of belladonna extract contained in a unit dose of a product is 8 milligrams (equivalent to 0.1 milligram belladonna alkaloids). Belladonna extract is sometimes combined with laxative mixtures containing anthraquinone compounds, presumably to counteract potential griping action of these laxatives (Ref. 2). However, due to short duration of action (2 to 3 hours) of belladonna extract, the use of this anticholinergic plant drug for this purpose is irrational because its antispasmodic action on the intestine will have subsided before the laxative action (18 to 24 hours) of the anthraquinone is manifest (Refs. 2 and 3).

The addition of belladonna extract to laxative products increases the risk of toxic side effects. The Panel is aware of serious poisoning in children who accidentally ingested laxatives that contain belladonna alkaloids (Ref. 4).

REFERENCES

(1) Swinyard, E. A. and S. C. Harvey, "Gastrointestinal Drugs," Remington's Pharmaceutical Sciences, 14th Ed., Mack Publishing Company, Easton, Pennsylvania, p. 796, 1970.
(2) Fingl, E., "Cathartics and Laxatives," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan, New York, pp. 811–813, 1970.
(3) Bonnycastle, D. D., "Cathartics and Laxatives," Drill's Pharmacology in Medicine, 4th Ed., Edited by DiPalma, J. R., McGraw-Hill, N.Y., p. 981, 1971.
(4) Palmisano, P. A., American Academy of Pediatrics, Subcommittee on Accidental Poisoning, Personal Communication to the Food and Drug Administration, October 29, 1973.

(2) *Combinations of laxative and nonlaxative ingredients for which there is no medical or scientific rationale.*

(i) *Bismuth Subnitrate.* The Panel concludes that the use of bismuth subnitrate or other bismuth salts in combination with laxatives constitutes irrational therapy.

There is no scientific evidence to indicate that bismuth salts contribute to the efficacy or safety of laxative preparations. Bismuth is considered in some textbooks as an astringent and adsorbent, and is discussed by the Panel under antidiarrheals.

REFERENCES

(1) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Adsorbtable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Anticeborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan, New York, p. 990, 1970.

(ii) *Capsicum.* The Panel concludes that the addition of capsicum to laxative products is irrational therapy.

Capsicum is said to be a colonic irritant that produces a sensation of heat (Ref. 1); the agent does not produce cutaneous hyperemia. The use of capsicum as a carminative is based entirely on subjective evidence. The Panel is unaware of any scientific data or even sound theoretical reasoning to indicate that capsicum should be considered an active laxative agent.

REFERENCES

(1) The United States Dispensatory and Physicians' Pharmacology, 26th Ed., Edited by Ozol, A., R. Pratt and M. D. Altschule, J. B. Lippincott Co., Philadelphia, p. 237, 1967.

(iii) *Caroid-papain.* The Panel concludes that the addition of caroid-papain or other proteolytic enzymes to laxative agents is irrational therapy.

Caroid-papain, derived from *Carica papaya*, is a mixture of proteolytic enzymes containing papain, bromelin, and ficin, which possess the property of digesting collagen (Refs. 1 and 2). These agents are thought to be innocuous to viable tissues and hence may be considered safe. The Panel is unaware of any scientific data or even sound theoretical reasoning to indicate that caroid-papain should be considered an active laxative agent.

REFERENCES

(1) Miller, J. M. and B. Goldman, "Preliminary and Short Report: The Digestion of Collagen," Journal of Investigative Dermatology, 30:217–219, 1958.
(2) Sherry, S. and A. P. Fletcher, "Proteolytic Enzymes: A Therapeutic Evaluation," Clinical Pharmacology and Therapeutics, 1: 202–226, 1960.

(iv) *Ginger.* The Panel concludes that, though this material has found wide use and ready acceptance as an aromatic carminative and flavoring agent, no studies have indicated its effect as a laxative agent.

Ginger, the dried rhizone of *Zingiber officinale*, contains a volatile oil, a nonvolatile mixture of substances possessing pungent principles collectively termed gingerol, and an acrid resin (Refs. 1 and 2). It has been advocated for use in man as a carminative for flatulence (Refs. 2 and 3). In addition, it has been used in veterinary medicine as a carminative for atonic indigestion as well as spasmodic colic, and has been added to veterinary purgatives to prevent griping (Ref. 1). There is no evidence of which the Panel has been made aware that ginger possesses laxative properties or is active in man.

REFERENCES

(1) Redgrove, H. S., "Some Notes on Ginger," Pharmacy Journal and Pharmacist, 125:54, 1930.
(2) Grieve, M., "A Modern Herbal," Hafner Press, Vol. 1, pp. 353–354, 1959.
(3) Glatzel, H., "Treatment of Dyspeptic Disorders with Spice Extracts," Hippokrates, 40:916, 1959 (Ger.).

(v) *Ipecac powder.* The Panel concludes that the use of ipecac in any amounts in combination with laxatives constitutes irrational therapy.

Powdered ipecac, which is obtained from the plant *Cephaelis ipecacuanha* contains a number of emetic alkaloids, including emetine and cephaeline (Ref. 1). Powdered ipecac is now added to some laxative mixtures that contain belladonna extract, on the assumption that the emetic will induce vomiting in the event of an overdose of the laxative mixture. The Panel concludes this is irrational therapy. Furthermore, the quantity of powdered ipecac used in OTC laxative products would not provide an emetic dose, even if 100 dosage units of the laxative product were ingested (Ref. 1).

REFERENCES

(1) The Pharmacopeia of the United States of America, 18th Rev., The United States Pharmacopeial Convention, Inc., Mack Printing Co., Easton, PA, p. 345, 1970.

(vi) *Thiamin, multivitamin preparations, and minerals.* The Panel concludes that the addition of various vitamins and minerals, including trace elements, to laxative products is irrational concurrent therapy and places such combinations in Category II.

An extensive review of the available literature failed to reveal any evidence that the addition of various vitamins, minerals, and trace elements to laxative preparations contribute to a laxative effect. The Panel does not recognize any significant target population that requires laxatives and vitamins concurrently. The Panel does not recognize the use of vitamins for purposes of laxation or the inclusion of vitamins in laxative products as adjunctives to the laxative action of the product. The Panel further concurs that constipation and vitamin needs ordinarily bear no relationship to each other. The rationale of addition of vitamins and minerals intended as nutritional supplements becomes questionable due to the laxative action abrogating the bioavailability of the supplement.

Data in one study in which a combination laxative product containing thiamin was compared with control (no laxatives) are unconvincing in terms of supporting the effectiveness of the combination product, and no evaluation of thiamin alone was undertaken (Ref. 1).

The Panel concludes that the concurrent use of vitamins in OTC laxative products is irrational therapy.

REFERENCES

(1) Long, A. E., "Postpartum Bowel Function," Obstetrics-Gynecology, 11:415–420, 1958.

c. *Labeling claims for specific ingredients.* The Panel concludes the following labeling claims are untrue and represent misbranding.

(1) *Dehydrocholic acid.* There is no evidence in support of the claim that dehydrocholic acid relieve's indigestion, excessive belching, after meal discomfort or the sensation of abdominal fullness. These claims constitute mislabeling and dehydrocholic acid is placed in Category II with respect to these claims. (See discussion of dehydrocholic acid which appears above in stimulant laxative statements.)

(2) *Bile salts (acids and ox bile).* Claims that these agents will "relieve headaches and biliousness" due to constipation are misleading and undocumented. Bile acids and ox bile are placed in Category II for these claims. (See discussion of bile salts (acid) and ox bile which appears below in claimed laxative active ingredients in Category III.)

(3) *Magnesium hydroxide.* Magnesium hydroxide is occasionally promoted as both an antacid and a laxative. This dual claim is permissible owing to the activity of this compound, but the public should be aware that when used regularly as an antacid, magnesium hydroxide causes significant laxation. However, the Panel is not aware of any scientific data that establishes a relationship between acid secretion and constipation. Therefore, claims of superior laxation on the basis of the antacid properties are not acceptable. (See discussion of Magnesium Compounds which appears above in saline laxative statement.)

3. *Conditions for which the available data are insufficient to permit final classification at this time.* The Panel concludes that adequate and reliable scientific evidence is not available to permit final classification of the claimed active ingredients and labeling listed below:

BULK FORMING LAXATIVES

Agar
Bran tablets
Carrageenan, native (Chondrus crispus)
Guar gum

STIMULANT LAXATIVES

Aloin
Bile salts (acid) and ox bile
d-Calcium pantothenate
Frangula
Prune concentrate dehydrate and prune powder
Rhubarb; Chinese
Sodium oleate

SALINE AND HYPEROSMOTIC LAXATIVES

Tartaric acid and tartrate preparations

STOOL SOFTENERS

Poloxalkal (polykol)

LABELING CLAIM FOR SPECIFIC INGREDIENT

Malt soup extract

The Panel believes it reasonable to allow 2 years for the development and review of evidence to permit final classification of these ingredients and the claims made for them. Marketing need not cease during this time if adequate testing is undertaken. If data regarding adequate effectiveness and safety are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed as active ingredients in over-the-counter products but may be permitted as inactive ingredients if the amount employed is necessary for the pharmaceutical formulation of the product. Some ingredients may be present in products in quantities which are pharmacologically inactive by virtue of being subclinical doses. In these cases the ingredients may be included for pharmaceutical necessity such as improving the stability or palatability of the product. However, it is the opinion of the Panel that if an ingredient was originally claimed by the sponsor to be active, it cannot then also be claimed inactive and included for formulation purposes unless the following are documented: the absolute necessity for inclusion in the pharmaceutical formulation, the safety of the quantity in the finished product, and the inactivity of the quantity in the finished product.

The Panel has given careful consideration to the types of studies and types of data to be required for removing a claimed active laxative ingredient from Category III and placing it in Category I. See data required below for laxative ingredient evaluation. In general, to demonstrate effectiveness, the design of the study should have a sound scientific basis (e.g., a randomized, double-blind, cross-over study comparing claimed active ingredients to placebo), the clinical trial should be carefully controlled (e.g., consideration given to selection of subjects representative of general population as well as diet, activity, travel, etc. of subjects being studied), and quantitative measurement of various parameters appropriate for the claimed effects of the ingredient (e.g., stool frequency, stool weight, stool water content, stool consistency, etc.). To demonstrate safety, appropriate toxicological studies in experimental animals (preferably primate) and man are required as outlined elsewhere.

a. *Claimed active ingredients classified as bulk-forming laxatives*—(1) *Agar.* The Panel concludes agar is safe in amounts usually taken orally in laxative products but is unable to document effectiveness when used alone in any dose.

Agar is the dried, hydrophilic, colloidal substance extracted from *Gelidium cartilagineum* and related red algae (Refs. 1 through 3 and 5). It is rich in indigestible hemicellulose, is nonabsorbable, and apparently does not cause irritation to the gastrointestinal mucosa. Agar will absorb at least five times its weight of water at 25° C. On absorbing water, it forms a gel and theoretically increases the bulk of the stool. The claimed mechanism of laxative action is considered to be the mechanical stimulus of distention (Ref. 4). It is a common ingredient in a variety of proprietary laxatives and is probably used as an emulsifying and stabilizing agent. When used in these preparations, the amount of agar is too small to contribute to the laxative effect of the preparation.

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

Well-designed and carefully controlled clinical trials are needed to demonstrate that agar is a safe and effective bulk-forming laxative. It would be helpful to compare agar to a known effective bulk former and determine the oral dose required to produce significant changes in stool weight, volume, consistency, and water content. Regarding safety, fluid intake required to prevent obstruction of or impaction in the digestive tract should

be determined. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Fingl, E., "Cathartics and Laxatives," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan, New York, p. 1026, 1970.

(2) Aviado, D. M., Pharmacologic Principles of Medical Practice, 8th Ed., The Williams and Wilkins Co., Baltimore, p. 942, 1972.

(3) Swinyard, E. A. and S. C. Harvey, "Pharmaceutical Necessities," Remington's Pharmaceutical Sciences, 14th Ed., Mack Publishing Co., Easton, Pa., p. 1344, 1970.

(4) AMA Drug Evaluations, 2d Ed., American Medical Association, Chicago, p. 800, 1973.

(5) The Pharmacopeia of the United States of America, 17th Rev., The United States Pharmacopeial Convention, Washington, D.C., pp. 17–18, 1965.

(2) *Bran tablets.* The Panel concludes that there is insufficient evidence that bran in the form of tablets is an effective laxative.

The Panel has concluded that dietary bran is safe and effective as a laxative when taken in sufficient quantities (approximately 6 to 14 grams per day). Bran tablets weighing 1 gram contain 0.5 gram of granulated bran. There is insufficient evidence that compressed tablets containing processed bran produce the same laxative effect as dietary bran contained in cereals and whole wheat bread. (See discussion above for bran (dietary) in laxative active ingredients in Category I.)

DATA PERTINENT FOR EFFECTIVENESS

Uncontrolled studies of the effectiveness and safety of bran tablets have been reviewed (Ref. 1). While they demonstrate safety, the Panel concludes that evidence of effectiveness remains equivocal. A carefully controlled, double-blind clinical trial is needed to determine if bran tablets are more effective than placebo in increasing the frequency of bowel movement and/or softening their consistency. Objective methods for quantitating frequency and consistency should be employed in such a study. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCE

(1) OTC Volumes 090100 through 090103.[3]

(3) *Carrageenan, native (Chondrus crispus, Irish moss).* The Panel concludes that although native carrageenan is safe in amounts not exceeding 3.5 grams per day, definitive evidence is lacking with respect to laxative action in man.

Carrageenan is a macromolecular hydrocolloid obtained from red algae, generally from *Chondrus crispus.* Material with similar composition and physical properties has been isolated from other genera of red seaweed such as *Eucheuma* and *Gigartina.* The carrageenan from each source differs slightly as to its property. These properties are related to the amount of the two major components (designated kappa and lambda), that are separable on the basis of selective solubility in potassium chloride solutions and proportions of galactose, anhydrogalactose and sulphated galactose units.

Native carrageenan is widely used in the food industry because of its ability to combine with protein and is used as a stabilizer and as a demulcent and for its gelling properties. Food and Agriculture Organization/World Health Organization recommendations allow up to 50 mg/kg as the acceptable daily intake (ADI) in man (Ref. 1).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

Well designed and carefully controlled clinical trials are needed to demonstrate that carrageenan is a safe and effective bulk forming laxative. It would be helpful to compare carrageenan to a known effective bulk former and determine the oral dose required to produce significant changes in stool weight, volume, consistency, and water content. Regarding safety, fluid intake required to prevent obstruction of or impaction in the digestive tract should be determined. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Anon: "Articles of general interest: Carrageenan," Food and Cosmetic Toxicology, 9:561–580, 1971.

(2) Abraham, R., L. Golberg, and P. Coulston, "Uptake and Storage of Degraded Carrageenan in Lysosomes of Reticuloendothelial Cells in the Rhesus Monkey, Macaca mulatta," Experimental and Molecular Pathology, 17:77–93, 1972.

(4) *Guar gum.* The Panel concludes that guar gum is safe in amounts usually taken orally but is unable to document effectiveness of this agent when used alone at any dose.

Guar gum, a polysaccharide containing polymers of d-galactose and d-mannose (i.e., a galactomannan) is derived from the endosperm seed layer of the guar plant. Galactomannans have a high affinity for water. They presumably swell when hydrated in vivo as they clearly do in vitro (Ref. 1). The hydrophilic capacity is related to the particle size in which the plant seeds are ground and to the pH of the medium to which it is exposed. Optimum hydration occurs in solutions with a pH range of 7.5 to 9.0. According to information submitted by companies which market the preparations, the laxative formulations contain particles of a size designed for minimum hydration duration the first few hours after ingestion during which time the material moves through the esophagus, stomach and upper small bowel. It is also claimed that more rapid dispersal and maximal bulk effect occurs after the agent has reached the lower intestinal tract (Ref. 2). This property would theoretically reduce the hazard of obstruction in the esophagus, stomach, and upper intestine that has rarely been associated with other bulk laxatives. There is no documentation that this is of more than theoretical advantage.

The conclusion that guar gum is safe is based largely on its widespread use in food products such as cheese, salad dressings, ice cream, sherbets, and frozen desserts and its recognition as safe as a food ingredient (Ref. 3). Partially controlled studies in which guar gum was given in combination with senna concentrate failed to demonstrate side effects that could not be attributable to the senna (Ref. 4).

The hydrophilic properties of guar gum would support the belief that it should act as other bulk forming laxatives if given in sufficient doses. The marketed preparations contain 1 gram of guar gum and there is no proof that such a quantity alters stool character or frequency in man or animals.

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

Well-designed and carefully controlled clinical trials are needed to demonstrate that Guar Gum is a safe and effective bulk-forming laxative. It would be helpful to compare Guar Gum to a known effective bulk former and determine the oral dose required to produce significant changes in stool weight, volume, consistency, and water content. Regarding safety, fluid intake required to prevent obstruction or impaction in the digestive tract should be determined. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Chudzikowski, R. J., "Guar Gum and its Applications," Journal of the Society of Cosmetic Chemists, 22: 43–60, 1971.

(2) OTC Volume 090084.[3]

(3) Krantz, J. C.: "Testimony Presented at the Hearings Before the Administrator, Federal Security Agency, in the matter of the standards of identity for cheese, 1947."

(4) Barcomb, A. E., "Management of Functional Constipation," Western Medicine, 7: 323–325, 1966.

b. *Claimed active ingredients classified as stimulant laxatives.*—(1) *Aloin.* The Panel concludes that there are insufficient clinical data to establish an effective and safe laxative dose for aloin.

Aloin is a microcrystalline powder consisting of a mixture of active principles, chiefly barbaloin and isobarbaloin, obtained from aloe. The drug may vary in chemical composition according to the variety of aloe from which it is obtained (Ref. 1). Although a method for the bioassay of aloin in rats has been reported (Ref. 2), there is no published information on methods presently used by manufacturers to standardize aloin for laxative action.

Aloin is usually used in combination with other laxative ingredients such as phenolphthalein or cascara sagrada (Ref. 3), and thus, there is a paucity of clinical data concerning its effectiveness as a laxative when used alone.

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

In addition to the general requirements outlined elsewhere, appropriate dose-response studies in man are needed that will clearly establish an effective and safe laxative dose for this plant extract. It would be helpful to compare aloin with another known effective stimulant laxa-

tive to determine if the incidence and severity of undesirable side effects such as cramping and griping is greater with aloin. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) The National Formulary, 11th Ed., Mack Printing Co., Easton, Pa., p. 17, 1960.
(2) Lister, R. E. and R. R. A. Pride, "The Characterisation of Crystalline and Amorphous Aloin," Journal of Pharmacy and Pharmacology, 11:278T–282T, 1959.
(3) Darlington, R. C., "Laxatives," Handbook of Non-Prescription Drugs, Edited by G. B. Griffenhagen and L. L. Hawkins, American Pharmaceutical Association, Washington, D.C., p. 54, 1971.
(4) Fingl, E., "Cathartics and Laxatives." The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan, N.Y., p. 1028, 1970.

(2) *Bile salts (acids) and ox bile.* The Panel concludes that there is insufficient evidence that natural bile acids taken orally as a laxative are effective and safe.

Bile acids induce diarrhea if they escape reabsorption at the terminal ileum and reach the colon in sufficient concentrations. Deoxycholic acid inhibits the absorption of water and sodium by the colon of the rat, and colonic perfusion with the dihydroxy bile acids, deoxycholic and chenodeoxycholic acid in man induces secretion of sodium and water (Ref. 1). Recent studies with the feeding of cholic acid and chenodeoxycholic acid in attempts to dissolve cholesterol gallstones in man disclosed that diarrhea was common when either agent was ingested in amounts exceeding 1.5 grams daily but did not occur at doses below 0.5 gram (Refs. 2 through 4). These studies indicate that bile acids in sufficient quantities can cause diarrhea, which is not necessarily equivalent to the conclusion that smaller or equal doses are effective in relieving constipation.

One limited controlled study demonstrated that cholic acid, 0.25 gram three times daily, but not placebo or bisacodyl, significantly increased fecal frequency in five subjects with chronic constipation (Ref. 5).

The composition of ox bile resembles that of human bile. The only preparation submitted for review contains only 51 milligrams of ox bile per dose. This quantity of ox bile is far below the quantity of bile acids known to produce diarrhea following the ingestion of cholic acid or chenodeoxycholic acid (more than 0.5 gram daily).

It is anticipated that the question of safety of chronic administration of chenodeoxycholic acid at two dose levels will be settled by the National Cooperative Gallstone Study. This study, supported by the National Institutes of Health, will provide data, collected over a 3-year period from 900 patients in 10 Medical Centers, to determine the safety and effectiveness of chenodeoxycholic acid in dissolving gallstones in man. Additional studies are needed to document effectiveness of bile acids in constipated subjects.

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

In the case of bile acids, carefully controlled, double-blind studies are especially needed to show that bile acid administration significantly increases the frequency of bowel movements and stool water content. Since ox bile contains significant quantities of lithocholic acid, doses which might be shown to be effective must also be shown to be safe. (See data pertinent below for laxative ingredient evaluation.)

LABELING

Claims that these agents will relieve headaches and "biliousness" due to constipation are misleading and undocumented. Bile acids and ox bile are placed in Category II for these claims.

REFERENCES

(1) Mekhjian, H. S., S. F. Phillips and A. F. Hofmann, Colonic Secretion of Water and Electrolytes Induced by Bile Acids: Perfusion Studies in Man," Journal of Clinical Investigation, 50:1569–1577, 1971.
(2) Danzinger, R. G., A. F. Hofmann, L. J. Schoenfield and J. L. Thistle, "Dissolution of Cholesterol Gallstones by Chenodeoxycholic Acid," New England Journal of Medicine, 286:1–8, 1972.
(3) Thistle, J. L., Personal Communication, 1974, included in OTC Volume 090134.[1]
(4) Schoenfield, L. J., Personal Communication, 1974, included in OTC Volume 090134.[1]
(5) Hepner, G. W. and A. F. Hofmann, "Cholic Acid Therapy for Constipation. A controlled Study," Mayo Clinic Proceedings, 48:356–358, 1973.
(6) Seed, J. C. and R. Harris, "Some Factors in the Design of Aperient Studies." Annals of the New York Academy of Sciences, 58:426–434, 1954.
(7) Shaftel, H. E. "Modulated Laxative Action for the Geriatric Patient," Journal of the American Geriatric Society, 1:549–556, 1953.
(8) Hofmann, A. F.; Personal Communication, 1974.
(9) Palmer, R. H., "Bile Acids, Liver Injury, and Liver Disease," Archives of Internal Medicine 130:606–617, 1972.
(10) Heywood, R., et al., "Pathological Changes in Fetal Rhesus Monkey Induced by Oral Chenodeoxycholic Acid," Lancet, 2:1021, 1973.
(11) "Six Month Oral Toxicity Study in Rhesus Monkeys with Chenodeoxycholic Acid." Performed at Huntington Research Center for Weddel Pharmaceuticals Limited, England, FDA Files.
(12) "Acute and Subacute Oral Toxicity Studies in Animals with Chenodeoxycholic Acid." Conducted at International Research and Development Corp. for the National Cooperative Gallstone Study. FDA Files.

(3) *d-Calcium pantothenate.* The Panel concludes that d-calcium pantothenate is safe in amounts usually taken orally, but the evidence currently available with respect to laxative action is contradictory and additional studies are necessary to evaluate its laxative potential.

While d-calcium pantothenate serves a number of important metabolic functions, the full import of this substance on functions of the gastrointestinal tract has not been fully elucidated. The addition of pantothenic acid to diets fed to pantothenic acid deficient dogs corrected the 50 percent decrease observed in gastro-intestinal motility and the 40 to 60 percent decreases demonstrated in carbohydrate and protein digestion and absorption (Ref. 1). There is no evidence currently available supporting the concept that these functions would be enhanced in subjects with normal pantothenic acid levels. The therapeutic use of pantothenic acid has been reported as being of no value while others observed that 50 milligrams of pantothenate i.m. 1 to 3 times daily improved post-operative ileus (Ref. 2). There are no carefully controlled clinical trials that demonstrate the effectiveness of d-calcium pantothenate as a laxative (Refs. 3 through 5).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

Data are needed first, to demonstrate that d-calcium pantothenate does indeed produce laxation as determined by quantitative measurements outlined elsewhere in this notice. If evidence of laxation is demonstrated, data are needed to determine a dose-response relationship. Additionally, the effectiveness of d-calcium pantothenate should be compared to a known effective stimulant laxative or stool softener. Data regarding safety are needed as outlined elsewhere in this document. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Bly, C. G., F. W. Heggeness and E. S. Nasset, "The Effects of Pantothenic Acid and Inositol Added to Whole Wheat Bread on Evaluation Time, Digestion and Absorption in the Upper Gastrointestinal Tract of Dogs," Journal of Nutrition, 26: 161–173, 1943.
(2) Haycock, C. E., W. A. Davis and T. V. Morton, Jr., "The Effect of d-Pantothenyl Alcohol upon Postoperative Discomfort," American Journal of Surgery, 97: 75–78, 1959.
(3) Paljakka, H., "The Effect of Oral Panthothenic Acid on Intestinal Function of Aged Persons," Duodecim, 76:209–213, 1960.
(4) Casassa, P. M., "Pantothenol in the Therapy of Chronic Constipation in the Aged." Acta Gerontology, 3:15–22, 1953.
(5) Aubin, C., "Study and Dissociation of the Laxative Effect of the Combination of Calcium Pantothenate-Danthron." Doctoral Thesis, College of Medicine of Paris, Paris, France, 1970, included in OTC Volume 090134.[1]

(4) *Frangula.* The Panel concludes that there are insufficient clinical data to establish an effective and safe laxative dose for frangula.

Frangula is the dried bark of *Rhamnus frangula* and contains hydroxymethylanthraquinone derivative which resemble the anthraquinones found in aloe, cascara sagrada, and senna. The chief constituent in frangula is the glycoside frangulin which consists of an anthraquinone (emodin) in combination with a sugar (rhamnose) (Refs. 1 and 2). There is no published information on how frangula bark preparations are standardized for laxative action.

Frangula bark is used in OTC laxative products in combination with other

laxative ingredients, usually a bulk forming agent such as sterculia gum or psyllium (Ref. 3).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

There are no clinical studies with frangula bark that provide sufficient evidence to establish an effective and safe laxative dose for this plant product. Appropriate dose-response studies in man are needed to determine a dosage range of frangula bark that produces effective laxation with minimal side effects.

In addition, evidence should be provided that the laxative potency of frangula bark can be standardized so that a reproducible degree of laxation will be produced by different batches of frangula bark.

Data regarding safety are needed as outlined elsewhere in this report. (See paragraph I below for data pertinent for laxative ingredient evaluation).

REFERENCES

(1) Gunton, J. A. and G. D. Beal, "A Reinvestigation of the Proximate Composition of *Rhamnus frangula*," Journal of the American Pharmaceutical Association, 11:669–682, 1922.

(2) Longo, R., "Separation and Determination of the Hydroxyanthraquinones of Frangula," Bollettino Chimico Farmaceutica, 104:369–372, 1965.

(3) Darlington, R. C., "Laxatives," Handbook of Non-Prescription Drugs, Edited by Griffenhagen, G. B., and L. L. Hawkins, American Pharmaceutical Association, Washington, DC, p. 54, 1971.

(5) *Prune concentrate dehydrate and prune powder.* The Panel does not challenge the general belief that prunes exert a laxative effect but concludes there is insufficient evidence to document effectiveness of prune concentrate and prune powder when used alone at any dose.

The chemical nature and mechanism of action of laxative ingredients in prunes, including prune concentrate dehydrate and prune powder, are unknown. An initial claim that prune juice contains diphenylisatin (Ref. 1), which is chemically related to oxyphenisatin, has not been confirmed by other investigations (Ref. 2).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

There are no clinical studies with prune concentrate dehydrate and prune powder that provide sufficient evidence to establish an effective laxative dose for this plant product. Appropriate dose-response studies in man are needed to determine a dosage range of prune concentrate dehydrate and prune powder that produces effective laxation.

In addition, evidence should be provided that the laxative potency of prune concentrate dehydrate and prune powder can be standardized so that a reproducible degree of laxation will be achieved by differing batches of prune concentrate dehydrate and prune powder. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Baum, H. M., R. G. Sanders and G. J. Straub, "The Occurrence of Diphenylisatin in California Prunes," Journal of American Pharmaceutical Association (Scientific Edition), 40:348–349, 1951.

(2) Hubacher, M. H. and S. Doernberg, "Laxatives II. Relationship Between Structure and Potency," Journal of Pharmaceutical Sciences, 53:1067–1072, 1964.

(3) Stern, F. H., "Constipation-An Omnipresent Symptom: Effect of A Preparation Containing Prune Concentrate and Cascarin," Journal of the American Geriatric Society, 14:1153–1155, 1966.

(6) *Rhubarb, Chinese.* The Panel recognizes that Chinese rhubarb (*Rheum officinale*) contains derivatives which are related to active laxative agents but concludes that there is insufficient reliable scientific evidence to permit final classification of this plant product.

Chinese Rhubarb contains several hydroxymethylanthraquinones derivatives which are chemically similar to those found in aloe, cascara sagrada, and senna. In contrast to these anthraquinone type laxatives, however, rhubarb also contains astringent ingredients such as rheotannic acid and gallic acid. The Panel found no reliable scientific data that evaluated the influence of these astringents on the anthraquinone ingredients (Refs. 1 and 2). Moreover, there are no dose response studies in man that establish an effective and safe dose for Chinese Rhubarb. In the case of Chinese Rhubarb, the Panel's concern with safety relates only to the known side effects common with all anthraquinones; American Rhubarb, which is used extensively in foods, is devoid of anthraquinone derivatives. (Ref. 1).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

There are no clinical studies with Chinese Rhubarb that provide sufficient evidence to establish an effective and safe laxative dose for this plant product. Appropriate dose-response studies in man are needed to determine a dosage range of Chinese rhubarb that produces effective laxation with minimal side effects.

In addition, evidence should be provided that the laxative potency of Chinese Rhubarb can be standardized so that a reproducible degree of laxation will be achieved by differing batches.

Data regarding safety are needed as outlined elsewhere in this report. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) AMA Drug Evaluations, 1st Ed. American Medical Association, Chicago, Illinois, p. 597, 1971.

(2) Sollman, T., A Manual of Pharmacology, 8th Ed., W. B. Saunders, Philadelphia, p. 211, 1957.

(7) *Sodium oleate.* The Panel concludes that sodium oleate is safe in the amounts usually taken orally in laxative preparations. However, the Panel was unable to find any evidence supporting the claim that sodium oleate produces laxation. Sodium oleate, a fatty acid salt, has been shown to influence the gastrointestinal tract of animals. (Refs. 1 through 3).

In one experimental study using an in vitro preparation of adult feline colon and electromyographic techniques, sodium oleate and sodium ricinoleate were compared. It was found that sodium ricinoleate produced electromyographic changes similar to those observed in spontaneous and castor oil-induced diarrhea in cats. Sodium oleate had no such effect (Ref. 3).

DATA PERTINENT FOR EFFECTIVENESS

Data are needed first, to demonstrate that sodium oleate produces laxation as determined by quantitative measurements outlined elsewhere in this report. If evidence of laxation is demonstrated, data are needed to determine a dose-response relationship. Additionally, sodium oleate should be compared with a stimulant laxative of known effectiveness. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Rochman, N. D., P. E. Lear, L. Picker, O. Mandell, "Inhibition of Gastric Secretion in the Rat with Sodium Oleate," Journal of Surgical Research, 9:213–215, 1969.

(2) Kowalecki, K., "Effect of Prolonged Intravenous Infusion of Oleate Sodium on Spontaneous and Histamine Stimulated Gastric Secretion in Rats," Archives Internationales de Physiologie et de Biochimie, 78: 971–977, 1970.

(3) Christensen, J. and B. W. Freeman, "Circular Muscle Electromyogram in the Cat Colon: Local Effect of Sodium Ricinoleate," Gastroenterology, 63:1011–1015, 1972.

(c) *Claimed active ingredients classified as saline and hyperosmotic laxatives*—(1) *Tartaric acid and tartrate preparations.* The Panel concludes that there are insufficient data to establish a safe and effective dose for the tartrates.

The laxative action of the tartrates is purportedly due to the slow absorption of sodium tartrate and resulting osmotic retention of water in the intestine, but recent experiments with the saline laxatives would indicate potentially more complex mechanisms of action. The Panel was concerned that information on the metabolic fate of tartrates, as well as data on the mechanism of action, is lacking. Although 20 percent of an oral dose may appear in urine, the remaining 80 percent has not been demonstrated in the feces, and no definitive work on the fate of tartrate in the body has been done (Refs. 1, 4, and 5). Evidence exists concerning a dose-response relationship of tartrates of nephrotoxicity. Up to 1.2 percent of tartrate in the diet of rats for 2 years apparently was not harmful, but 1.5 percent was toxic. Toxicity in rabbits occurred at 250 mg/kg, and in dogs ingesting 0.99 gm/kg per day (Refs. 1 and 2). Tartrates are ubiquitous in the human diet which would suggest safety. However, a death has been reported following the oral ingestion of 30 grams of tartaric acid (Ref. 6). The Food and Agriculture Organi-

zation/World Health Organization Expert Committee on Food Additives in its eighth report recommended a conditional limit of 6–20 mg/kg/day of tartaric acid (Ref. 3).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

The Panel knows of no studies that use modern tracer methods to determine the absorption, metabolism, and excretion of these compounds, or any quantitative description of their systemic effects and implications for renal functions. Such data are required to determine the safety of tartrates. The Panel concludes that the usual daily dose of tartrates (e.g., 5–10 grams) in laxative preparations is probably safe, but in order to justify an additional exposure for the public to tartrates in the form of a laxative, definitive, well designed studies of effectiveness and establishment of safety are necessary. (See paragraph I below for data pertinent for laxative ingredient evaluation).

REFERENCES

(1) Underhill, F. P., C. S. Leonard, E. G. Gross and T. C. Jaleski, "Studies on the Metabolism of Tartrates: II. The Behavior of Tartrate in the Organism of the Rabbit, Dog, Rat and Guinea Pig," Journal of Pharmacology and Experimental Therapeutics, 43:359–380, 1931.

(2) Krop, S. and H. Gold, "On the Toxicity of Hydroxyacetic Acid After Prolonged Administration: Comparison With its Sodium Salt and Citric and Tartaric Acids," Journal of the American Pharmaceutical Association (Scientific Edition), 34:86–89, 1945.

(3) Food and Agriculture Organization/World Health Organization Expert Committee of Food Additives, Eighth Report, Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Food Colours and Some Antimicrobials and Antioxidants, World Health Organization Technical Report Series, Number 309, 1965.

(4) Bauer, C. W. and R. W. Pearson, "A Comparative Study of the Metabolism in the Human Body of Some Isomers of Tartaric Acid," Journal of the American Pharmaceutical Association (Scientific Edition), 46: 575–578, 1957.

(5) Finkle, P., "The Fate of Tartaric Acid in the Human Body," Journal of Biological Chemistry, 100:349–355, 1933.

(6) Robertson, B. and L. Lonnel, "Human Tartrate Nephropathy: Report of a Fatal Case," Acta Pathologica et Microbiologica Scandinavica, 74:305–310, 1968.

d. *Claimed active ingredients classified as stool softeners or lubricants*—(1) *Poloxalkol (Polykol)*. The Panel concludes that while evidence is available suggesting that poloxalkol is safe, the evidence attesting to laxative action in man is sparse and equivocal.

Poloxalkol, an oxyalkene polymer, is a relatively tasteless nonionic surface active agent. The chemical is said to produce effects similar to dioctyl sodium sulfosuccinate, but the two drugs have not been subjected to a careful clinical comparison. Animal studies suggest that poloxalkol possesses low toxicity (Ref. 1); however, it may increase the absorption of mineral oil and the possibility of untoward effects. While the wetting properties of poloxalkol make it potentially useful as a stool softener (Ref. 2), the action is usually slow and may require several days before an effect becomes apparent.

The drug has been clinically evaluated in children (Refs. 3 and 4), young adults with serious neurologic disorders enforcing nonambulation (Ref. 5), and elderly subjects complaining of constipation. The administration of the medication showed a 3-to-5 day latency and apparent effect, and was well tolerated with few side effects (Ref. 5 and 7). Several clinical evaluations in children and older patients failed to include the use of placebos, were poorly controlled, relied almost exclusively on subjective appraisal, or involved the testing of combination products (Refs. 1 and 5 through 7).

DATA PERTINENT FOR EFFECTIVENESS

While the product appears to be safe based on animal studies and limited clinical evaluations, well-controlled, double-blind studies utilizing objective measurements in addition to subjective appraisals are necessary to establish unequivocally that this agent is a stool softener in man. Owing to the low toxicity and potential usefulness of this medication in man, the Panel urges that such definitive studies be undertaken. (See paragraph I below for data pertinent for laxative ingredient evaluation.)

REFERENCES

(1) Hardouin, J. P., and J. Aubrion, "Experimental and Clinical Study of a New Therapeutic Agent for Constipation: A Polyoxyethylene and Polyoxypropylene Polymer," La Presse Medicale, 67:1543–1550, 1959 (French).

(2) Cooke, W. T., "Laxatives and Purgatives," Practitioner, 206:77–80, 1971.

(3) Salvador-Diaz, O., "A Humectant Agent for Constipation in Children," La Semana Medica, 142:439–441, 1973 (Spanish).

(4) Rodriquez-Farina, R. N., "Poloxalcol. Humectant Agent in the Treatment of Constipation in Children," La Semana Medica, 143:788–790, 1973 (Spanish).

(5) Vincent (no initial), Girous (no initial), The Treatment of Chronic Constipation of Immobilization by a Polymer of Poly-Oxyethylene and Poly-Oxy-Propanediol 1–2, Lyon Med., 202:1079, 1959.

(6) Dugger, J. A., "Poloxalkol in the Treatment of Constipation in Children," Journal of the Michigan State Medical Society, 59: 1211, 1960.

(7) Christopher, L. J., "A Controlled Trial of Laxatives in Geriatric Patients," Practitioner, 202:821, 1969.

e. *Labeling claims for specific ingredient—Malt soup extract.* Although reduction in stool pH has also been cited as the reason for the clinical effectiveness of malt soup extract in reducing the symptoms of pruritus ani, the Panel concludes that there is insufficient evidence to support the claim that malt soup extract is effective when used alone in the treatment of pruritus ani.

G. PRODUCTS COMBINING MULTIPLE LAXATIVE INGREDIENTS

1. *General statements.* a. The Panel has followed the regulation (21 CFR 330.10(a)(4)(iv)) which states:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and when the combination, when used under adequate direction for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

b. The Panel concludes that, in general, the fewer the ingredients, the safer and more rational the therapy. The Panel believes that the interests of the consumer are best served by exposing the user of OTC drugs to the fewest ingredients possible at the lowest possible dosage regimen consistent with a satisfactory level of effectiveness.

c. The Panel concludes that OTC drugs should contain only such inactive ingredients as are necessary for pharmaceutical formulation.

2. *Requirement of significant contribution.* The Panel has determined that each claimed active ingredient in the combination must make a significant contribution to the claimed effect. In the absence of data showing the minimum dose necessary to achieve the intended laxative effect, the amount of ingredient present in laxative products must be at least equal to the currently accepted minimum dose level for such active ingredients as set forth elsewhere in this document.

The Panel found it impossible to develop a formula for establishing a level, below the minimum effective dose level for an ingredient as a single entity, at which it could reliably be stated that each laxative ingredient would make a contribution to a combination drug product. This may be possible with other agents such as antacid combination products where the contribution of each antacid can be determined by chemical titration. Laxatives are believed to have a minimum effective dose below which there are few measurable responses. The Panel recognizes that it is possible that some ingredients may be proved to contribute to the effectiveness of a combination product in amounts below the generally recognized minimum effective daily dose. However, because of the numerous variables involved (e.g., different laxative categories, differing modes of action, etc.), the Panel could not select one lower level of an active ingredient which may be assumed to be effective in a combination product.

Moreover, the Panel could not establish the percent of contribution that an active ingredient must make to the effectiveness of the product in order for that contribution to be considered "significant." The Panel concluded that where a combination product is permitted, as discussed below, it is sufficient to demonstrate in well-controlled clinical trials (Section I below—Data Required for Laxative Ingredient Evaluation) that each of the ingredients makes a statistically significant contribution to the claimed effect. As long as "statistical significance" is shown, the Panel concludes that the contribution toward laxa-

tion will also have been shown to be clinically "significant."

3. *Safety.* In its consideration of active ingredients, the Panel reviewed the safety and effectiveness of all the combinations submitted. All combinations that meet the criteria for Category I as set forth below, are considered safe.

The combination of dioctyl sodium sulfosuccinate and mineral oil is considered unsafe and is assigned to Category II because absorption of mineral oil may be enhanced by dioctyl sodium sulfosuccinate (Ref. 1).

4. *Effectiveness.* Combination products are regarded as effective if each active ingredient is present in the product within the dosage range set by the Panel for each Category I active laxative ingredient, as set forth elsewhere in this document. If the quantity of active ingredient is below the recognized effective dose range, the product containing the ingredient(s) is placed in Category III and testing is required for effectiveness.

The Panel considers it important that the minimum effective dose be established for each ingredient in a combination product. Data should be developed by appropriate well-controlled clinical studies to demonstrate the effectiveness as a laxative of a dosage level for any ingredient that is below the minimum set by the Panel for that ingredient when used alone.

Where the ingredients and the dosages are the same as those of the combination products this Panel has classified in Category I, further testing will not be required. Where the ingredients are different from those that have already been found safe, such testing will be required.

5. *Single active ingredients.* OTC drugs containing safe and effective single ingredients are preferred to those having multiple active ingredients because of the reduced risks of toxic effects, synergistic effects, allergic and/or idosyncratic reactions, and possible unrecognized and undesirable drug interaction(s).

It is an established medical principle to give only those medications, preferably as single entities, necessary for the safe and effective treatment of the patient. This principle applies equally to self-medication. To add needlessly to the patient's medication increases the risk of adverse reactions.

6. *Limitation of ingredients in combination products.* The Panel recognizes that combining 2 active ingredients may in some circumstances be desirable. For example, in an individual whose bowel movements are both painful and infrequent a product combining a stimulant laxative with a stool softener may be rational.

On the basis of the ingredients reviewed, the Panel could find no medical justification for combining 3 or more active laxative ingredients in a single product.

The Panel states its concern that even if situations are identified that suggest use of more than 2 active laxative ingredients, the benefit-to-risk ratio might be narrowed, and this is not in the best interest of the consumer of OTC laxatives. Therefore, products containing more than 2 active laxative ingredients are classified as Category II products and would require evaluation through the new drug procedures.

7. *Active ingredients not reviewed by the Panel.* Each claimed active ingredient must be an ingredient that has been reviewed by the Panel. If a product contains an active ingredient that has not been reviewed by the Panel and consequently not found in this document, such ingredient is automatically classified as a Category II ingredient, i.e., it is not generally recognized as safe and/or effective. Appropriate animal and human testing and prior approval by the Food and Drug Administration is required before a product containing such an ingredient may be marketed.

8. *Review of submitted combination products.* The Panel considered only those combination products submitted pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) and included above in paragraph A. The Panel recognizes that other combination products may be in the market place but it has either no knowledge of such products, or insufficient data with respect to such products to make a reasonable judgment of safety and/or effectiveness.

Accordingly, the Panel recommends that any new combination, or any presently marketed combination not submitted to this Panel, which is not within the combinations recognized by the Panel as safe as set forth below, be evaluated through the new drug procedures, or be the subject of an appropriate petition to the Commissioner to review or amend the OTC laxative monograph.

9. *Combinations containing nonlaxative ingredients.* Products combining laxative ingredient(s) with other ingredients having nonlaxative pharmacologic effects are considered irrational, unless it can be shown that there is a significant target population requiring concurrent treatment of symptoms that require laxative(s) and nonlaxative(s) in combination. Among such combinations reviewed, the Panel could find neither a rational basis nor a significant target population that would warrant such concurrent therapy.

Nonlaxative ingredient(s) may be present as inactive ingredients in a laxative product as an aid to formulation or to palatability. However, the presence of such ingredient(s) must not be emphasized or identified as active ingredients in the labeling or in the advertisement of such product(s).

10. *Combinations allowable as Category I.* The Panel recognizes the particular combinations set forth below as safe and effective combinations and bases its opinion on the submitted material, and the Panel's expertise. Based on the combinations submitted and within the categories defined by the Panel the following are allowed, pursuant to the criteria developed by the Panel for determining Category I combinations, which combinations are set forth below:

ORAL DOSAGE FORMS

a. Dioctyl calcium sulfosuccinate and danthron.
b. Dioctyl sodium sulfosuccinate and casanthranol.
c. Dioctyl sodium sulfosuccinate and danthron.
d. Dioctyl sodium sulfosuccinate and phenolphthalein.
e. Cascara sagrada and aloe.
f. Cascara sagrada and magnesium hydroxide.
g. Cascara sagrada and phenolphthalein.
h. Malt soup extract and blond psyllium seed.
i. Malt soup extract and blond psyllium seed husks.
j. Mineral oil and casanthranol.
k. Mineral oil and cascara sagrada.
l. Mineral oil and cascara sagrada fluid extract.
m. Mineral oil, emulsified and magnesium hydroxide.
n. Mineral oil and phenolphthalein.
o. Mineral oil and psyllium seed.
p. Plantago ovata husk and methyl cellulose.
q. Phyllium and senna concentrate.
r. Senna concentrate and dioctyl sodium sulfosuccinate.
s. Sodium carboxymethylcellulose and dioctyl sodium sulfosuccinate.

RECTAL DOSAGE FORMS

a. Glycerin and dioctyl potassium sulfosuccinate.
b. Sorbitol and dioctyl potassium sulfosuccinate.

11. *Criteria for determining Category I combinations.* To qualify as a Category I combination, i.e., one that is generally recognized as safe and effective, each of the following conditions must be met:

a. The combination is limited to two Category I active laxative ingredients.

b. The specific combination of active laxative ingredients is found on the list set forth above for allowable combinations.

c. Each ingredient in the subject combination must be present within the dosage range for a Category I active laxative ingredient, as set forth elsewhere in this document.

d. The Panel developed the following concept as a reasonable means of expressing the sum of the percentage amounts of the effective dosage range (EDR) of each active ingredient which must not exceed 100, as calculated by the following formula:

$$\frac{L \max d - EDR\ (\min)}{EDR\ (\max) - EDR\ (\min)} \times 100 = \%\ \text{EDR of each ingredient}$$

where: $L \max d$ is the labeled maximum daily dosage obtained from the labeling information for the product, *EDR* (min) is the minimum effective dosage range set by the Panel and *EDR* (max) is the maximum effective dosage range set by the Panel.

The purpose of the above formula is two-fold:

(1) to assist the manufacturer in determining which combination products require reformulation and/or testing;

(2) to encourage the use of ingredients in amounts at the minimum end of the dosage range rather than at the maximum effective range dosage.

Example: A liquid oral dosage form, laxative combination containing a stimulant laxative (326 mg. senna concentrate per teaspoonful), and a bulk former (1.0 grams psyllium per teaspoonful), having a label dosage of 1 or 2 teaspoonfuls 2 times a day.

I. Maximum daily dosage obtained from labeling for:

(1) senna concentrate—(326 mg x 2) x 2=1304 mg or 1.3 gm

(2) psyllium—(1.0 gm x 2) x 2=4.0 gm

II. Daily dose range for each Category I ingredient set by panel:

senna concentrate—1 to 4 gm daily

psyllium—2.5 to 30 gm daily

III. Calculation of percentage amount of:

senna concentrate

$$\frac{1.3-1.0}{4-1}=\frac{0.3}{3}\times 100=10\%$$

psyllium

$$\frac{4-2.5}{30-2.5}=\frac{1.5}{27.5}\times 100=5.45\%$$

Conclusion: The sum of the EDR percentages does not exceed 100 percent and therefore the combination is in Category I.

12. *Criteria for Category II combination products.* A combination is classified by the Panel as a Category II product, i.e., one that is not generally recognized as safe and or not generally recognized as effective, if any of the following apply:

a. The combination contains 3 or more active laxative ingredients, e.g., mineral oil, phenolphthalein, plantago seed; sodium carboxymethylcellulose, dioctyl sodium sulfosuccinate, casanthranol.

b. The combination contains 2 active laxative ingredients each of which is safe and effective when used alone, but in combination is found to be not safe e.g., mineral oil and dioctyl sodium sulfosuccinate.

c. The combination contains any ingredient that is listed elsewhere in this document as a Category II ingredient.

d. The combination contains any ingredient in an amount equal to the maximum dosage set by the Panel for such ingredient and contains another ingredient in an amount above the minimum dosage set by the Panel for such other ingredient.

e. The combination is such that the sum of the percentage amounts of each ingredient exceeds 100 percent. (See "Criteria for determining Category I' combinations" above, for an explanation of the method for calculating the percentage amount of each ingredient).

f. The combination contains any active laxative ingredient that has not been reviewed by the Panel and accordingly not listed in this document.

13. *Criteria for Category III combination products.* A combination is classified as a category III combination if any of the following apply:

a. If one or both Category I ingredient(s) fall below the minimum dosage set for each respective ingredient.

b. If one or both ingredients are Category III ingredients, as set forth elsewhere in this document for single active laxative ingredients.

14. *Criteria for reclassification of Category III combinations to Category I combinations.* a. For any combination found in paragraph 10, ". . . combinations allowable as Category I . . .," where one or both ingredients fall below the minimum effective level as set forth elsewhere in this document for such respective ingredient(s), tests must be performed to substantiate the effectiveness of any such ingredient alone and in the respective combination.

The Panel recommends that such testing be performed and evaluated through the new drug procedures or suitable petition to the Commissioner for appropriate modification of the monograph to permit such lower dosage level(s) of ingredient(s) present in an allowable combination.

b. (1) Any combination that contains one or both ingredients in Category III, as set forth elsewhere in this document, must be tested to satisfy Category I requirements for each such ingredient.

(2) Two Category I ingredients in a combination not found in paragraph 10, ". . . combinations allowable as Category I . . .," must petition the Commissioner for an appropriate amendment to the monograph or proceed through the NDA procedures.

REFERENCES

(1) Martin, E. W., Hazards of Medication, J. B. Lippincott Co., Philadelphia, pp. 577 and 686, 1971.

H. INACTIVE INGREDIENT IN LAXATIVES

Laxative products frequently contain a number of inactive laxative ingredients, some of which are used in the formulation of the preparation. The Panel recommends that inactive ingredients be listed on the label with or without the amounts contained in a recommended dose. The availability of sodium, potassium, and magnesium in the maximum recommended daily dose should be stated on the label. (See labeling discussion above for laxative products.) Special warnings on the label should be provided for patients with heart disease and renal disease.

The inactive ingredients identified below are added to laxative preparations to enhance their formulation or to contribute to the effervescent qualities of some preparations and should not be listed as an active laxative ingredient.

CALCIUM, POTASSIUM, AND SODIUM SALTS

Calcium hydroxide
Potassium carbonate
Sodium acid pyrophosphate
Sodium bicarbonate
Sodium biphosphate, anhydrous
Sodium carbonate
Sodium citrate

I. DATA PERTINENT FOR LAXATIVE INGREDIENT EVALUATION

The Panel has given considerable thought to the problem of demonstrating that a laxative is safe and effective. When a drug is available for widespread use, as in OTC products, its safety and effectiveness must be well documented by toxicological data, data on the absorption, distribution, fate and excretion of the drug, the pharmacological effects of the drug, and the mechanism of action. The drug must also meet certain effectiveness standards.

The Panel recommends that information such as the following be obtained when relevant and pertinent to the drug under study: standardization of plant derivative, toxicologic data, absorption, distribution, fate, and excretion (ADFE) data, mechanism of action, and effectiveness standards.

1. *Standardization of plant derivative laxatives.* The Panel reviewed several ingredients which are plant derivatives of varying degrees of refinement. In some cases, the crude product was a known, accepted laxative agent, but the degree to which any extracted derivatives were active was unknown (e.g., prune powder and prune concentrate). In other cases, the Panel could assume some measure of activity for the refined extract, but data were unavailable to establish effectiveness and safety.

The Panel adopts the position that an extract or derivative of a well-established crude laxative product is not efficacious or safe ipso facto. The Panel requires evidence of effectiveness and safety for the crude as well as the refined product, and data sufficient to establish dosing parameters.

The Panel recommends that the following additional information be submitted to ensure standardization of plant derivative ingredients:

a. A description of the source of material used for extraction and any refining process that it may have undergone.

b. An outline of the extraction procedure and the analyses used to establish the identity of the products.

c. Controlled clinical trials establishing effectiveness and safety and appropriate dosing regimens of the crude as well as the extracted ingredient alone.

2. *Toxicological data.* A variety of toxicological data can be obtained to demonstrate that a laxative is safe. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the safety of their products. The Panel recommends that data such as the following be obtained in animal studies and in clinical studies in man. Certain data on human subjects, such as lethal doses and chronic toxicity, will only be available from poison control centers, hospitals, or medical centers, or medical examiners. However, the Panel considers such data important and attempts should be made to obtain them.

a. *Preclinical Animal Studies.* (1) The oral LD_{50} established in no less than two animal species.

(2) Determinations of histologic and biochemical alterations in animals given lethal doses acutely or low doses chronically.

(3) Studies of effects on fertility, teratogenicity and embryolethality, delivery, and nursing offspring may also be indicated.

b. *Clinical studies in man.* (1) Biochemical tests of liver and renal func-

tion and measurement of serum electrolytes after a therapeutic dose.

(2) Chronic toxicity studies in man, especially in relation to altered function and cytological changes of the mucose of the intestinal tract of man.

(3) Adverse drug reactions should be well documented. Substantial effort should be made to have physicians document side effects, especially those of a serious nature as allergic reactions, intestinal obstruction or impaction, syncope, etc.

(4) Minimal lethal dose by single oral ingestion or in divided doses when such data are available from accidental or deliberate overdosing.

(5) Maximal tolerated dose from single oral ingestion, or divided multiple oral ingestions, when such data are available from accidental or deliberate overdosing.

3. *Absorption, distribution, fate and excretion (ADFE) as determined by currently accepted methods.* Many laxatives claimed to escape intestinal absorption have been found subsequently to be absorbed and excreted in substantial quantities. Since ADFE bears directly on the safety of drugs and occasionally on the mechanism of action of laxatives, appropriate data should be provided for all active ingredients and their active metabolic products. The methods for obtaining these data are established and are not different from those used in the study of ADFE of other drugs. Data such as the following would provide sufficient information regarding ADFE. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding ADFE of the products:

a. The percentages of various oral doses of the drug which are absorbed in man.

b. The percentages of various oral doses which are excreted in the urine in man.

c. The percentages of various oral doses of the drug which are excreted in breast milk.

d. The metagolic fate in man of absorbed but unexcreted drug.

e. The fate of unabsorbed drug in man.

f. The net bioavailability of the drug in man.

g. The ingredients and metabolic products associated with fecally excreted drug and/or its unabsorbed intraluminal biotransformation products.

h. The ingredients and metabolic products associated with renally excreted drug and/or its renally excreted biotransformation product.

4. *Effects.* Effectiveness requires that the desired pharmacologic effect of the drug under study be laxation. The Panel recognizes that the mechanism of action of many safe and effective drugs is unknown. Nevertheless, for laxatives, a number of excellent models exist that can be used in such studies. For example, in vitro studies of water incorporated into colloid laxatives demonstrates the hydrophilic properties of such laxatives—a property easily confirmed in man by demonstrating that stools contain the colloid and an increased percentage of water. The perfused animal intestine and everted intestinal loop preparations can be employed to demonstrate alterations in intestinal absorption and secretion. Methods are available for measuring alterations of sodium and potassium adenosine triphosphatase activity in animal intestinal preparations. Similarly, preparations are available for assessing the effects of laxatives on smooth muscle contractility. In man it is also feasible to measure alterations in intestinal absorption and secretion associated with laxative use and to detect changes in intraluminal pressures. These are only a few of the methods that can be employed to clarify the mechanism of action of laxatives. It is recommended that data such as the following be obtained. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the mode of action of their products:

a. Effects of oral drug on jejunal secretion and the flux of ions and water at the levels of the jejunum, ileum, proximal and distal colon.

b. Effects of the oral drug on the absorption of actively transported ions, sugars, and amino acids.

c. Effects of the oral drug on the absorption of carbohydrate, protein, lipids and fat-soluble vitamins.

d. Effects of the oral drug on the absorption of other drugs.

e. Effects of the oral drug on secretion of gastrointestinal enzymes, gastrointestinal hormones, gastrointestinal mucus, and the biliary secretion of bile, bile acids, and cholesterol.

f. Effects on intestinal smooth muscle such as contractility and electromyographic changes.

5. *Effectiveness standards.* Clinical studies in humans should usually be done in both normal and constipated persons with additional studies as indicated for specific target populations such as bedfast persons, postpartum and postoperative subjects, etc. Acceptable clinical criteria of effectiveness would be well-controlled clinical trials using randomized subjects in a double-blind, cross-over technique. "Before treatment" data should be obtained for each subject, besides basic demographic characteristics. These should include information on: (a) Diet, (b) Other medications, (c) Any other preexisting conditions which would bias analyses and (d) Pretreatment stool frequency, weight, volume, water content, transit time, etc.

One treatment group should receive a placebo for comparison purpose. If the identity of the drug cannot be masked or a suitable placebo cannot be devised, control and treatment periods should be of sufficient duration to allow the subject or patient to serve as his/her own control. Ingredients should be tested alone and in appropriate combinations. Appropriate statistical evaluations of observed effects are necessary. In addition to frequency and consistency, there are many other appropriate parameters that can be measured quantitatively to assess laxative effectiveness. Some of these parameters are more appropriate for one type of laxative than another. Thus, for a bulk-forming laxative, the following parameters would be appropriate: Volume, weight, percent water content, consistency, fecal solids, and bulk density. For stimulant laxatives, it would be more appropriate to quantitate transit time, frequency, electrolytes, and bile salt content, fecal excretion rate and stool water.

The Panel concurs that the following parameters of laxation, determined quantitatively, are appropriate for evaluating the effectiveness of drugs to produce laxation. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the effectiveness of their products:

a. *Frequency.* The Panel recognizes that frequency of stool evacuation is quite variable among normal, healthy individuals and may range from three bowel movements per day to three per week. Frequency should be expressed in number of evacuations per unit time such as 24 hours or per week, etc.

b. *Consistency.* Consistency should be evaluated in some objective manner in addition to the subject's sensation of ease of passage or the observer's description of the stool as liquid, soft, hard, etc. Since major changes in the consistency of stool (and other materials) may occur with little change in either percent water or total stool weight, the Panel recommends a quantitative determination of consistency. There are few rheologic studies of colonic content (Ref. 1), but instrumentation used to quantitate the consistency of compounds, such as bread doughs, various pastes, and soils might be appropriate. If a tube viscometer is used, consistency is expressed in terms of shear rate and if a penetrometer is used, consistency is expressed in terms of kilograms per square centimeter.

c. *Volume.* The volume of stool evacuated during a unit time period is easy to determine and is usually expressed in milliliters or cubic centimeters per 24 hours or other time period. Average normal is 150 ml/24 hours.

d. *Weight.* Weight is expressed in grams per 24 hours or other unit time period. Weight is independent of consistency and important in determining the effectiveness of bulk-forming laxatives. Average normal is 110 to 130 grams per 24 hours.

e. *Water content.* Water content of the feces is usually expressed as percent water. This parameter is important in determining the effectiveness of stimulant and osmotic saline laxatives. Average normal is 60 to 85 percent.

f. *Fecal solids.* Fecal solids are usually expressed in grams per 24 hours. Average normal is 25 grams/24 hours.

g. *Bulk density.* Bulk density is expressed as unit weight per unit volume,

usually grams per cubic centimeter, and is determined by drying a known volume to constant weight at 105° C. Bulk density is an important parameter in determining the effectiveness of bulk-forming laxatives. Average normal is 0.15 to 0.18 gm/cc.

h. *Transit time.* Transit time may be expressed by either the "time method" or the "distant method" by use of nonabsorbable markers as polyethylene glycol, nonabsorbable color dyes as carmine, and nonabsorbable radioactive materials as chromium. In addition, inert colored plastic beads have been used as a marker to determine transit time. The use of some markers, such as carmine dye, is associated with considerable "streaming" and should be taken into account when markers are used to separate treatment periods. Average normal is 40 to 60 hours for complete transit of the digestive tract.

i. *Fecal excretion rate.* Fecal excretion rate is expressed in weight per unit time, usually grams per hour. Average normal fecal excretion rate is 6 grams per hour.

j. *Stool electrolytes, bile acids (salts), etc.* Feces contain a number of substances that might be appropriate to measure in evaluating laxative agents. Stool electrolytes, particularly sodium, potassium, and chloride, may be markedly altered by laxative agents. Fecal bile salts may be an appropriate parameter to measure with certain laxative agents.

REFERENCES

(1) Picologlou, B. F., P. D. Patel, and P. S. Lykoudis, "Biorheological Aspects of Colonic Activity: Part I. Theoretical Considerations," Biorheology, 10:431–440, 1973.

(2) Picologlou, B. F., P. D. Patel, and P. S. Lykoudis, "Biorheological Aspects of Colonic Activity: Part II. Experimental Investigation of Rheologic Behavior of Human Feces," Biorheology, 10:441–446, 1973.

II. ANTIDIARRHEALS

Pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) requesting the submission of data and information on OTC antidiarrheal drugs, the following firms made submissions relating to the indicated products:

A. DATA AND INFORMATION OF SUBMISSIONS

Firm	Marketed products
Eneglotaria Medicine Co., Inc., of Puerto Rico, Santurce, PR 00907.	Kao-Gest.
Hynson, Westcott and Dunning, Inc., Baltimore, MD 21201.	Lactinex Tablets.
International Pharmaceutical Corp., Warrington, PA 18976.	Dia-Quel.
Lacto Products Co., Milwaukee, WI 53218.	Acidophilus Concentrate.
Merrick Medicine Co., Waco, TX 76703.	Percy Medicine.
Norwich Pharmacal Co., Norwich, NY 13815.	Pepto - Bismol, Pepto - Bismol Chewable Tablets.
Parke, Davis and Co., Detroit, MI 48232.	Pargel.
Purdue Frederick Co., Norwalk, CO 06856.	Parelixir Liquid.
A. H. Robins Co., Richmond, VA 23220.	Donnagel, Donnagel-PG.
William H. Rorer, Inc., Fort Washington, PA 19034.	Parapectolin.
The Upjohn Co., Kalamazoo, MI 49001.	Kao-Con, Kaopectate.
USV Pharmaceutical Corp., Tuckahoe, NY 10707.	Bacid.
Wyeth Laboratories, Inc., Philadelphia, PA 19101.	Kalpec, Kaomagma, Polymagma, Polymagma Tablets.

B. LABELED INGREDIENTS CONTAINED IN SUBMITTED PRODUCTS

Alumina powder, hydrated
Aminoacetic acid
Atropine sulfate
Attapulgite, activated
Bismuth subnitrate
Bismuth subsalicylate
Calcium carbonate, precipitated
Calcium hydroxide
Carboxymethylcellulose
Charcoal, Activated
Homatropine methylbromide
Hyoscyamine sulfate
Kaolin
Lactobacillus acidophilus
Lactobacillus bulgaricus
Opium powder
Opium, tincture of
Paregoric (camphorated tincture of opium)
Pectin
Phenyl salicylate, (salol)
Potassium carbonate
Rhubarb fluidextract
Scopolamine hydrobromide (hyoscine hydrobromide)
Zinc phenolsulfonate

In addition, the panel reviewed the following ingredient: polycarbophil.

C. DIARRHEA AND THE USE OF OTC ANTIDIARRHEAL PRODUCTS

Diarrhea may be defined as the excretion of stools with increased frequency and an increased weight and water content (Ref. 1). Healthy adults may have up to three stools per day (Ref. 2); and the water content may vary from 60 to 85 percent. Individuals with diarrhea excrete more than 200 grams of stool per day containing 60 to 95 percent water (Ref. 1). The major factor contributing to diarrhea is the excess water. It is remarkable that only 80 to 120 milliliters of water are excreted daily in the stool, when one considers that normal daily fluid intake is approximately 2 liters and normal secretions into the digestive tract account for an additional 7 liters. This indicates the extreme efficiency of the normal digestive tract in absorbing water and that excretion of only a few hundred milliliters of water in the stools will contribute to diarrhea.

Water absorption is thought to occur passively in the gut as a result of the absorption of solutes (ions as sodium, potassium, chloride, bicarbonate, etc., and simple products of digestion as glucose, amino acids, etc.). Thus, any condition that interferes with or inhibits normal solute absorption secondarily disturbs water absorption and may result in diarrhea. In a recent excellent review, the pathophysiology of diarrheal states is described and correlated with clinical conditions (Ref. 1). The multiple causes of diarrhea include bacterial and viral infections, parasitic infestations, lack of adequate digestive enzymes, pathological conditions of the intestinal mucosa, various metabolic and hormonal disturbances, increased gastrointestinal motility resulting in decreased transit time, and various surgical operations upon the digestive tract.

Diarrhea, unassociated with fever or blood in the stool, but sometimes associated with symptoms such as loss of appetite, abdominal cramps, nausea and vomiting is common. The Panel concludes that this type of diarrhea for which relief may be sought in OTC antidiarrheal products is a self-limiting disorder and usually lasts about 2 days. The Panel believes that OTC antidiarrheal products provide only symptomatic relief and are most effective in the mildest types of diarrhea.

The Panel has therefore adopted the following definitions:

(1) *Diarrhea.* Abnormally frequent passage of watery stools, self limiting (24 to 48 hours) usually with no identifiable cause.

(2) *Antidiarrheal.* An agent that is effective for the treatment of diarrhea.

REFERENCES

(1) Phillips, S. F., "Diarrhea: A Current View of the Pathophysiology," Gastroenterology, 63:495–518, 1972.

(2) Connell, A. M., C. Hilton, G. Irvine, J. E. Lennard-Jones, and J. J. Misiewicz, "Variation of Bowel Habit in Two Population Samples," British Medical Journal, 2:1095–1099, 1965.

D. LABELING OF ANTIDIARRHEAL PRODUCTS

1. *Indications.* The indications for use of an antidiarrheal should be simple and clearly stated. If the product is taken for specific indications such as to decrease the frequency of bowel movements, or to increase the bulk of the stool, the label should so state. The directions for use should be clear and provide the user a reasonable expectation of the results anticipated from use of the product. Statements of indications for use should be specific and confined to the conditions for which the product is recommended. No reference should be made, or implied, regarding the alleviation or relief of symptoms unrelated to the condition that is an indication for use of the product.

2. *Ingredients.* The label should state in metric units the quantity of each active ingredient contained in the recommended dose, e.g., teaspoonfuls, tablets, etc.

A product containing more than 1.0 mEq (23 mg) sodium per maximum daily dose should be labeled as to the sodium content per dosage unit. Furthermore, if the product contains more than 15 mEq (345 mg) sodium in the maximum recommended daily dose, the label should state:

Do not use this product except under the advice and supervision of a physician if you are on a low salt diet.

And in addition.

Do not use this product except under the advice and supervision of a physician if you have kidney disease.

If the product contains more than 25 mEq (975 mg) potassium in the maximum recommended daily dose, labeling should state: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

If the product contains more than 50 mEq (600 mg) magnesium in the maximum recommended daily dose, the labeling should state: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

The Panel strongly recommends that all inactive ingredients be listed with or without a statement of their quantity.

3. *Directions for use.* The label should contain a clear statement of the usually effective, minimal and maximal dose per time interval broken down by age groups, and if appropriate, may be followed by the statement "except under the advice and supervision of a physician."

4. *Warnings.* The Panel concurs with the regulation (21 CFR 369.20) containing the general warning statement for diarrhea preparations which states:

WARNING—Do not use for more than 2 days or in the presence of high fever or in infants or children under 3 years of age unless directed by a physician.

In addition, the label of antidiarrheal products containing belladonna preparations and preparations of its alkaloids shall also contain the specific warnings for these agents as discussed below for anticholinergics in Category III as antidiarrheals.

Opium-paregoric and other habit-forming drugs should contain the labeling requirements as provided in the regulation (21 CFR 329.10) as discussed below for opiates in Category I as antidiarrheals. The label should clearly state that if diarrhea is associated with high fever, the patient should see a physician.

E. Classification of Active Ingredients

The Panel reviewed all active ingredients which were the subject of submissions made to the Panel. Additionally, the Panel reviewed polycarbophil brought to their attention by the Food and Drug Administration. The Panel considered all pertinent data and information in arriving at its conclusions and recommendations.

In accordance with the regulation (21 CFR 330.10), the Panel's findings with respect to these ingredients are set forth in three categories:

I. Conditions under which antidiarrheal products are generally recognized as safe and effective and are not misbranded.

II. Conditions under which antidiarrheal products are not generally recognized as safe and effective or are misbranded.

III. Conditions for which the available data are insufficient to permit final classification at this time.

The Panel recommends the following for each category of drugs:

1. That the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient to classify such conditions either as generally recognized as safe and effective and not misbranded or as not being generally recognized as safe and effective or would result in misbranding (Category III) be permitted to remain in use for 2 years after the date of publication of the final monograph in the FEDERAL REGISTER, if the manufacturer or distributor of any such drug utilizing such conditions in the interim conducts tests and studies adequate and appropriate to satisfy the questions raised with respect to the particular condition by the Panel.

F. Review of Active Ingredients

In considering the active ingredients in antidiarrheal products, the Panel elected to classify ingredients on the basis of the usually accepted pharmacologic categories of the ingredient in providing relief from diarrhea, i.e., adsorptives, anticholinergics, astringents, opiates, and other active ingredients. Like laxative products, the Panel found that many antidiarrheal products contain more than one active ingredient. Some of these combinations are considered irrational because one or more of the active ingredients is considered too small to contribute significantly to the overall effectiveness of the product. The Panel finds it difficult to substantiate the claims of effectiveness of some antidiarrheal products.

1. *Conditions under which antidiarrheal products are generally recognized as safe and effective and are not misbranded.* After carefully reviewing all data available to the Panel, the following antidiarrheal ingredients were classified as safe and effective and not misbranded:

OPIATES

Opium powder
Opium, tincture of
Paregoric (camphorated tincture of opium)

POLYCARBOPHIL

(a) *Active ingredients classified as opiates*—(1) *Opium powder, tincture of opium, paregoric (camphorated tincture of opium).* The Panel concludes that opiates are safe and effective in the amounts usually taken orally: adults 15 to 20 milligrams opium per unit dose; children (6 to 12 years) 5 to 10 milligrams opium per unit dose or adults 1.5 to 2.0 milligrams morphine per unit dose; children (6 to 12 years) 0.5 to 1.0 milligram morphine per unit dose 1 to 4 times a day in antidiarrheal products for use not to exceed 2 days.

The Panel concurs that preparations containing less than 100 milligrams opium per 100 milliliters should be exempt from the federal requirements (21 CFR 329.20(a)) for prescription of narcotics: *"Provided,* That the preparations * * * contain one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than those possessed by the narcotic drug alone." These preparations should be sold over-the-counter unless limited by state or local laws.

The opiates are generally recognized as effective antidiarrheals at the dose equivalent to 15 to 20 milligrams of opium or 1.5 to 2.0 milligrams of morphine. Morphine increases rhythmical segmenting contractions of both the small intestine and the colon with inhibition of propulsive movements (Ref. 1). The delayed colonic emptying affords clinical relief but may actually retard recovery from infectious (shigellosis) diarrhea (Ref. 2).

The resulting high intraluminal pressure, a possible precursor of diverticular disease, is considered a contraindication to the chronic use of opiates in persons with disorders of gut motility (Ref. 3).

LABELING

In addition to the general warnings required of all antidiarrheals (See labeling statements above for antidiarrheal products), the labeling of products containing opium and its alkaloids should meet the labeling requirements in 21 CFR 329.10 for habit forming drugs which states the following:

WARNING.—May be habit forming.

REFERENCES

(1) Adler, H. F., A. J. Atkinson and A. C. Ivy, "Effect of Morphine and Dilaudid on the Ileum and of Morphine, Dilaudid and Atropine on the Colon of Man," Archives of Internal Medicine, 69:974–85, 1942.

(2) Dupont, H. L. and R. B. Hornick, "Lomotil Therapy of Induced Shigellosis," Clinical Research, 21:598, 1973.

(3) Read, A. E., "Anti-diarrheal Agents," Practitioner, 206:69–76, 1971.

(b) *Other active ingredients*—(1) *Polycarbophil.* The Panel concludes that polycarbophil is safe and effective in amounts usually taken orally (4 to 6 grams per day) in antidiarrheal preparations (or when used as a laxative). The pediatric dose is 0.5 to 1.0 gram for infants not more than 2 years; 1 to 1.5 grams for children (2 to 5 years); and 1.5 to 3.0 grams for children over 5 years.

Polycarbophil, a hydrophilic polyacrylic resin (polyacrylic acid cross-linked with divinyl glycol), is insoluble in water, dilute acids, dilute alkalis, and common

organic solvents. It has a marked capacity for binding water and absorbs about 60 times its original weight. This property is the basis for its use as an internal hydrosorptive agent.

The seemingly paradoxical utilization of this hydrosorptive agent in the treatment of both diarrhea and constipation is based on its modifying effect on abnormal fecal consistency. In diarrheal states, the hydrophilic agent absorbs free fecal water forming a gel in the lumen of the intestine that is incapable of absorbing water at normal rates, and produces formed stools. In constipation, the agent retains water intraluminally and opposes dehydrating forces in the bowel. The water-retaining capacity of polycarbophil is considerably greater than that of methylcellulose or psyllium mucilloid. The degree of hydrophilia (cc/gm) of polycarbophil in synthetic intestinal juice is about 120 while for psyllium, methylcellulose, agar-agar, and carbo gum the values are 30, 36, 14, and 22, respectively.

In animal studies, polycarbophil has been shown to be free of toxicity, to be nonabsorbable, to have no effect on digestive enzymes, to have no influence on nutritional status, and to be metabolically inactive.

Clinical studies in patients with both acute and chronic diarrhea have demonstrated the effectiveness of polycarbophil as an antidiarrheal.

COMMENT

The Panel is of the opinion that there is a great need for more Category I antidiarrheal ingredients and urges industry to develop additional safe and effective antidiarrheal agents.

REFERENCES

(1) Grossman, A. J., R. C. Batterman and P. Leifer, "Polyacrylic Resin: Effective Hydrophilic Colloid for the Treatment of Constipation," Journal of the American Geriatric Society, 5:187–192, 1957.

(2) Roth, J. L. A., "Effects of Polycarbophil as Enteral Hydrosorbent in Diarrhea," American Journal of Digestive Diseases, 5:965–971, 1960.

(3) Pimparker, B. D., F. F. Paustian, J. L. A. Roth and H. L. Bockus, "Effect of Polycarbophil on Diarrhea and Constipation," Gastroenterology, 40:397–404, 1961.

(4) Rutledge, M. L., M. M. Willner and J. T. King, "Calcium Polycarbophil in Acute Childhood Diarrhea," Clinical Pediatrics, 2:61–63, 1963.

(5) Winkelstein, A., "Effect of Calcium Polycarbophil (CARBOFIL®) Suspension on Gastrointestinal Transit Time," Current Therapeutic Research, 6:572–583, 1964.

2. *Conditions under which antidiarrheal products are not generally recognized as safe and effective or are misbranded.* After careful review of all data submitted as well as additional evidence provided by the Food and Drug Administration and the results of a literature search, the Panel found there is no scientific or even sound theoretical basis for claimed efficacy of a number of ingredients used in OTC antidiarrheal preparations. The Panel concludes that the ingredients, labeling, and combination drugs involved should be removed from the market unless further scientific testing supports their use. In addition, the Panel concludes that it is neither truthful nor accurate to make claims regarding multiple indications for some single ingredients or to claim enhanced effectiveness and/or safety in some combinations of ingredients.

The Panel concludes that the following ingredients, labeling, and combination drugs involved should be removed from the market as antidiarrheals unless and until further scientific testing supports their use:

ASTRINGENT

Rhubarb fluidextract

OTHER CLAIMED ACTIVE INGREDIENTS

Aminoacetic acid (glycine)
Potassium carbonate
Scopolamine hydrobromide (hyoscine hydrobromide)

LABELING CLAIMS FOR SPECIFIC COMBINATIONS

Anticholinergic
Antacid

a. *Claimed active ingredient classified as an astringent—(1) Rhubarb Fluidextract.* The Panel recognizes that Chinese rhubarb (*Rheum officinale*) contains derivatives which are related to active laxative agents, but concludes there is no reliable scientific evidence to permit classification of this plant derivative as an antidiarrheal.

Chinese rhubarb contains several hydroxymethyl-anthraquinone derivatives which are chemically similar to those found in aloe, cascara sagrada, and senna. In addition to these anthraquinone type compounds, rhubarb also contains astringent ingredients such as rheotannic acid and gallic acid. The Panel found no reliable scientific data that evaluated the influence of these astringents on the laxative action of the anthraquinone ingredients (Refs. 1 and 2). Moreover, there are no dose response studies in man that establish an effective and safe dose for Chinese rhubarb. It is the Panel's opinion that the claim of Chinese Rhubarb acting as a laxative in high doses due to its anthraquinone like compounds, and as an antidiarrheal in low doses due to its astringent properties, is unfounded and represents misbranding.

In the case of Chinese rhubarb, the Panel's concern with safety relates only to the known side-effects common with all anthraquinones. American rhubarb, which is used extensively in foods, is devoid of anthraquinone derivatives (Ref. 1). It is the opinion of the Panel that Chinese rhubarb in small amounts is inactive as an antidiarrheal, but may contribute to flavoring.

REFERENCES

(1) AMA Drug Evaluations, 1st Ed., American Medical Association, Chicago, IL, p. 597, 1970.

(2) Sollmann, T., A Manual of Pharmacology, 8th Ed., W. B. Saunders, Inc., Philadelphia, p. 211, 1957.

b. *Other claimed active ingredients in antidiarrheal preparations—(1) Aminoacetic acid (glycine).* The Panel concludes that aminoacetic acid (glycine) is safe in the amounts (400 to 800 milligrams daily) taken orally in antidiarrheal preparations but there is no evidence to establish efficacy in diarrhea.

Aminoacetic acid was reviewed by the OTC Antacid Panel, which found glycine to be safe in the amounts usually taken orally (5 grams per day) in antacid preparations (Ref. 1). Animal toxicity studies report excess glycine (10 percent glycine diet) leads to the accumulation of fat in the liver and slower growth rate (Ref. 2).

Aminoacetic acid is described in the National Formulary and other textbooks as a dietary supplement or antacid (Ref. 3 and 4). The Panel recognizes that the small amount of glycine used in antidiarrheal preparations may be included for palatability or as a pharmaceutical necessity. It is the scientific opinion of the Panel that there is no justification to claim glycine an active antidiarrheal ingredient.

REFERENCES

(1) "Proposal Establishing a Monograph for OTC Antacid Products," published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714).

(2) Arnstein, H. R. V., "The Metabolism of Glycine," Advances in Protein Chemistry, 9:17–18, 1954.

(3) The National Formulary, 13th Ed., American Pharmaceutical Association, Washington, D.C., p. 38–39, 1970.

(4) Wilson, C. W., et al., The Textbook of Organic Medicinal and Pharmaceutical Chemistry, 5th Ed., J. B. Lippincott, Philadelphia, p. 803–804, 1966.

(2) *Potassium carbonate.* The Panel concludes that potassium carbonate is safe in amounts usually taken orally in antidiarrheal preparations (3 to 6 grams per day), but there is no evidence that it possesses an antidiarrheal effect.

Although claimed as an active antidiarrheal ingredient, it is the Panel's opinion that potassium carbonate is an inactive ingredient and should be so regarded. The Panel is unaware of any evidence indicating potassium carbonate has antidiarrheal properties. Products containing potassium carbonate should list on the label the available potassium in a recommended dose of the product. If significant amounts are present, specific warnings should be made for patients with renal disease.

REFERENCE

(1) OTC Volume 090005.[1]

(3) *Scopolamine hydrobromide (hyoscine hydrobromide).* The Panel concludes there is insufficient evidence that scopolamine hydrobromide exerts an antidiarrheal effect.

Scopolamine hydrobromide differs quantitatively from atropine in its antimuscarinic action. Scopolamine has more pronounced effects on the central nervous system, ciliary body, iris and various secretory glands while atropine is more effective in reducing intestinal tone and motility (Ref. 1). There is, therefore, little or no rationale for the use of scopolamine in the treatment of diarrhea. The use of the related anticholinergics, atropine sulfate, homatropine methylbromide, and hyoscyamine sulfate is discussed below.

REFERENCES

(1) Innes, I. R. and M. Nickerson, "Drugs Inhibiting the Action of Acetylcholine on Structures Innervated by Postganglionic Parasympathetic Nerves (Antimuscarinic or Atropinic Drugs)," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Company, New York, p. 524–548, 1970.

(c) *Labeling claims for specific combinations*—(1) *Claims for combinations of anticholinergic with opiates.* The Panel concludes that claims for enhanced effectiveness of the opiates through combination with atropine or its derivatives is not supported clinically or theoretically, since large and potentially toxic doses of the anticholinergics are required for partial suppression of the increased tone of the ileum and colon induced by morphine (Ref. 1). For example, the addition, in a non-OTC drug, of atropine at only 1/20 of the usual effective dose (0.025 mg./tablet) to diphenoxylate is widely recognized as an example of additive toxicity without additive therapeutic benefit (Ref. 2).

REFERENCES

(1) Adler, H. F., A. J. Atkinson and A. C. Ivy, "Effect of Morphine and Dilaudid on the Ileum and of Morphine, Dilaudid and Atropine on the Colon of Man," Archives of Internal Medicine, 69:974–85, 1942.

(2) Rosenstein, G., M. Freeman, A. Standard and N. Weston, "Warning: The Use of Lomotil in Children," Pediatrics, 51:132–133, 1973.

(2) *Claims for combinations of antidiarrheals with antacids.* Some antidiarrheal combination products contain various amounts of effective antacid ingredients as calcium carbonate, calcium hydroxide and hydrated alumina powder, as well an antidiarrheal ingredients. It is well known that many effective antacids including those listed above when given in adequate doses for antacid therapy will sometimes cause mild constipation. The fact that these agents may cause constipation when used in antacid therapy, does not constitute a rational basis for the claim that these agents are also effective antidiarrheals. In addition, there is no known relationship between gastric secretion and constipation. Thus, the Panel is of the opinion that it is not rational concurrent therapy for a significant portion of the population for the label to claim both antacid and antidiarrheal properties if the antidiarrheal claim is supported by a nonantidiarrheal ingredient.

(3) *Conditions for which the available data are insufficient to permit final classification at this time.* The Panel concludes that adequate and reliable scientific evidence is not available at this time to permit final classification of the active ingredients listed below:

ADSORBENTS

Attapulgite, activated
Charcoal, activated
Kaolin
Pectin

ANTICHOLINERGICS

Atropine sulfate
Homatropine methylbromide
Hyoscyamine sulfate

ASTRINGENTS

Alumina powder, hydrated
Bismuth salts
Calcium hydroxide
Phenyl salicylate (salol)
Zinc phenolsulfonate

OTHER CLAIMED ACTIVE INGREDIENTS

Calcium carbonate
Lactobacilli
  Acidophilus
  Bulgaricus
Sodium carboxymethylcellulose

LABELING CLAIMS FOR SPECIFIC INGREDIENT

Bismuth subsalicylate

The Panel believes it reasonable to allow 2 years for the development and review of such evidence. Marketing need not cease during this time if adequate testing is undertaken. If data regarding adequate effectiveness and safety are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed as active antidiarrheal ingredients in over-the-counter products but may be permitted as inactive ingredients if the amount employed is shown to be free of pharmacologic or toxic effect and contributes to the pharmaceutical formulation of the product. Some ingredients may be present in products in quantities which are pharmacologically inactive by virtue of being subclinical doses. In these cases, the ingredients may be included for pharmaceutical necessity or convenience, such as improving the stability or palatability of the product. However, it is the opinion of the Panel that if an ingredient was originally claimed by the sponsor to be active, it cannot then also be claimed inactive and included for formulation purposes unless the following are documented: The absolute necessity for inclusion in the pharmaceutical formulation, the safety of the quantity in the finished product, and the inactivity of the quantity in the finished product.

The Panel strongly recommends that all inactive ingredients be listed with or without a statement of their quantity, since the consumer may need to know for a variety of reasons, the ingredient in a product. However, the product cannot be promoted on the basis of its inactive ingredients, nor can the label emphasize the inclusion of the inactive ingredients.

The Panel has given careful consideration to the types of studies and types of data to be required for removing a claimed active antidiarrheal ingredient from Category III and placing it in Category I. (See paragraph I below for data required for antidiarrheal ingredient evaluation.) In general, to demonstrate effectiveness, the design of the study should have a sound scientific basis (e.g., a randomized, double-blind study comparing claimed active ingredients to placebo), the clinical trial should be carefully controlled (e.g., consideration given to selection of subjects representative of general population as well as diet, activity, travel, etc., of subjects being studied), and quantitative measurement of various parameters appropriate for the claimed effects of the ingredients (e.g., stool frequency, stool volume, stool weight, stool water content, stool consistency, etc.). To demonstrate safety, appropriate toxicological studies in experimental animals (preferably primate) and man are required as outlined elsewhere.

(a) *Claimed active ingredients classified as adsorbents*—(1) *Attapulgite, activated.* The Panel concludes activated attapulgite is safe in the amounts taken orally (e.g., 6 to 9 grams per 24 hour period) but there is insufficient evidence to classify it as an effective antidiarrheal.

Attapulgite is a naturally occurring aluminum magnesium silicate, similar to kaolin. It is inert and, presumably, nontoxic when administered orally (Ref. 1). In experimental animals, no LD_{50} could be obtained at 900 times the clinical dose. There have been few clinical studies on the safety or efficacy of attapulgite (Refs. 2 and 3). One well-controlled study showed that a combination of attapulgite and pectin was more effective than a placebo of unknown composition (Ref. 4). The claimed action of attapulgite is apparently due to its adsorptive properties (Ref. 5), i.e., adsorption of bacteria, toxins, etc.

DATA PERTINENT FOR EFFECTIVENESS

The Panel recognizes that attapulgite is generally recognized as safe in the amounts taken orally, but adequate data to establish effectiveness are lacking. Additional in vivo and in vitro studies are needed to establish that the primary mechanism of action is that of adsorption. Additionally, well-designed and carefully controlled clinical studies are necessary to establish the effectiveness of attapulgite when compared to placebo and/or an effective antidiarrheal. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) Gaubert, Y., "A New Intestinal Adsorbent Medication," Quest. Medical, 17:930–934, 1964 (French).

(2) Caroli, J. and J. Plessier, "Clinical Study of Attapulgite," Semaine des Hospitaux de Paris, 40:1685–1689, 1964.

(3) Barr, M., "Activated Attapulgite," Journal of the American Pharmaceutical Association, 19:85–87, 1958.

(4) Vernon, W. G., Attapulgite Efficacy Study included in OTC Volume 090133.

(5) Bartell, P., W. Peirzchala and H. Tint, "The Adsorption of Enteroviruses by Activated Attapulgite," Journal of the American Pharmaceutical Association (Scientific Edition), 49:1–4, 1960.

(2) *Charcoal, activated.* The Panel concludes activated charcoal to be safe in the amounts taken orally, but believes there is a lack of acceptable clinical evidence to establish its effectiveness as an antidiarrheal agent.

Activated charcoal powder is the residue obtained by the destructive distillation of wood pulp, suitably treated to increase its adsorptive power. Important characteristics of activated charcoal that contribute to its adsorptive capacity are small particle size, large total surface area, and low mineral content. The only generally accepted medicinal use for activated charcoal is as an antidote in poisoning (Ref. 1), although it may also

prove useful in the treatment of acute hepatic failure (Ref. 2). In regard to its use as an antidote, the adsorbent has been amply demonstrated to bind a number of chemicals within the gastrointestinal tract and thus, prevent their absorption (Ref. 1). Since activated charcoal in the form of tablets or capsules is sometimes recommended for the management of various gastrointestinal disorders such as flatulence and diarrhea (Ref. 3), it is significant to point out that activated charcoal powder has been demonstrated to be much more effective as an adsorbent than activated charcoal tablets (Ref. 4).

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

The Panel concurs that activated charcoal is a potent adsorptive agent but there are no partially controlled or controlled clinical studies to establish the effectiveness of activated charcoal as an antidiarrheal agent. Effectiveness should be tested in well-controlled clinical trials comparing activated charcoal with a placebo and/or a known effective antidiarrheal. Dose response data should be established, and, if determined, the effects of an effective dose on the gastrointestinal absorption of various drugs commonly used in small doses (e.g. cardiac glycosides, alkaloids and synthetic estrogens) should be determined. Additionally, data are needed to determine whether activated charcoal contains benzpyrene or methylcholanthrene type carcinogens. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) Picchioni, A. L., "Activated Charcoal: A Neglected Antidote," Pediatric Clinics of North America, 17:535–543, 1970.

(2) Gazzard, B. G., et al., "Charcoal Haemoperfusion in the Treatment of Fulminant Hepatic Failure," Lancet, 1:1301–1307, 1974.

(3) Riese, J. A. and F. Damrau, "Use of Activated Charcoal in Gastroenterology: Value for Flatulence and Nervous Diarrhea," Journal of the American Geriatrics Society, 12:500–502, 1964.

(4) Tsuchiya, T. and G. Levy, "Drug Adsorption Efficacy of Commercial Activated Charcoal Tablets in vitro and in Man," Journal of Pharmaceutical Sciences, 61:624–625, 1972.

(3) *Kaolin.* The Panel concludes kaolin is safe in the amounts taken orally (e.g. 12 to 24 grams per dose), but there is insufficient evidence to classify it as an effective antidiarrheal at this time, nor are there data to establish a dose response relationship.

Kaolin is a native hydrated aluminum silicate, powdered and freed from gritty particles. It is a clay and occurs as a soft white or yellowish white powder. Kaolin is considered to act as an adsorbent and protectant and has been used for over 200 years. It is available only in combination with pectin, or with one or more other antidiarrheals. Kaolin Mixture with Pectin, N.F., is a suspension which contains 20 percent kaolin and 1 percent pectin (Ref. 1). The usual dose is 30 milliliters (6 grams of kaolin, 300 milligrams of pectin). Adequately controlled clinical studies demonstrating the effectiveness of kaolin alone or in combination with pectin are not available. It is considered that kaolin adsorbs some toxins, bacteria, and viruses and is said to provide a protective coating for the intestinal mucosa (Ref. 2). In addition to adsorbing bacteria and various toxins, kaolin may act to increase the resistance of flow by solidifying the colonic contents, although this has not been demonstrated. As with the absorption of some drugs, and with vitamins such as thiamine, thus, prolonged use may not be advisable (Refs. 3 and 4). A kaolin pectin mixture has been reported to interfere with the gastrointestinal absorption of the antibiotic lincomycin (Ref. 5).

A recent unpublished study submitted to the Panel provided data on the effectiveness of kaolin, pectin, the combination of both, and placebo (water) on a variety of diarrheagenic models in the squirrel monkey (Ref. 5). The dose of active ingredient used was comparable to that recommended for adult humans and based on milliliters per square meter of body surface area. Thus, the dose for a 0.9-kilogram squirrel monkey with a body surface of 0.10 square meter was 3.44 milliliters of kaolin and pectin combination given 3 times daily. The experimental models used to induce diarrhea included (a) A diarrheagenic diet, consisting of oranges, carrots, cabbage ad lib and prune juice instead of drinking water; (b) cholera toxin, in 3 doses; a low dose of 500 mg/kg, a medium dose of 2 gm/kg, and a high (lethal in 48 hours) dose of 4 gm/kg; (c) castor oil, 4 ml/kg; (d) phenolphthalein, 100 mg/kg; (e) methyl prostaglandin E_2, 0.4 mg/kg; (f) bile (beef, dehydrated), 2 gm/kg; and (g) lactulose.

In most of the models studied, it was shown that kaolin, pectin, or the combination of both was more effective in reducing the total number of stools or the number of loose and liquid stools than the placebo. The consistency of the stool was determined by simple observation only. In many of the models, the observed effects can probably be explained by the absorption of the diarrheagenic agent by the kaolin and pectin. In the diarrheagenic diet model, there was no change in the total number of stools but the number of loose and liquid stools was reduced by kaolin and pectin. In some of the models studied, the diarrheagenic agent did not increase the total number of stools as compared to control periods but the number of loose and liquid stools was increased.

The Panel accepts the results of these studies but questions the relevance of the experimental models to human disease states.

DATA PERTINENT FOR EFFECTIVENESS EVALUATION

The claim that kaolin acts as an adsorbent and protectant should be tested in man using kaolin alone and compared to other known adsorbents. Clinical effectiveness in treatment of diarrhea should be documented by well-designed and controlled clinical trials to test the effectiveness of kaolin alone and comparisons made with placebo and/or a known effective antidiarrheal. Additional information is needed regarding the interaction of kaolin with other drugs such as cardiac glycosides, antibiotics, alkaloids and vitamins. (See paragraph I below for data pertinent for effectiveness evaluation.)

REFERENCES

(1) The National Formulary, 13th Ed., American Pharmaceutical Association, Washington, DC, p. 388, 1970.

(2) AMA Drug Evaluations, 1st Ed., "Antidiarrheals," American Medical Association, Chicago, p. 579, 1971.

(3) Mann, G. V. and F. J. Stare, "Nutritional Needs in Illness and Disease," Journal of the American Medical Association, 142: 409–419, 1950.

(4) Messerli, N., "The Influence of the Addition of Adsorbents to the One-Sided Diet in the Production of Avitaminosis," Archives et Internationales Physiologie de Biochemie, 19:103–114, 1922.

(5) Hansten, P. D., Drug Interactions, 2nd Ed., Lea and Febiger, Philadelphia, p. 131, 1973.

(6) OTC Volume 000121.[1]

(4) *Pectin.* The Panel concludes pectin is safe in amounts taken orally (e.g. 300 milligrams, 3 to 4 times per day), but there is insufficient evidence to establish its effectiveness, nor are there data to establish a dose response relationship.

Pectin is a purified carbohydrate product obtained from the dilute acid extract of the inner portion of the rind of citrus fruits or from apple pomace. It consists chiefly of partially methoxylated polygalacturonic acids. Pectin yields not less than 6.7 percent of methoxy groups and not less than 74 percent of galacturonic acid calculated on a dried basis. Pectin dissolves in 20 parts of water; the resulting colloidal solution is viscous and opalescent, and acid in reaction (Refs. 1 and 2). The mechanism of action of pectin in diarrhea is unknown (Ref. 3). It has been claimed that pectin produces beneficial results because it is an adsorbent and protective agent (Ref. 4). It has also been claimed the beneficial effects are due to lowering the pH by galacturonic acid (Refs. 5 and 6). When fed to healthy human subjects, only a small amount is recovered in the feces because pectin is decomposed in the colon by bacterial action (Ref. 7). In patients with diarrhea, much larger amounts may be eliminated unchanged.

The effectiveness of pectin in various diarrheagenic models in squirrel monkeys has been discussed in the section on kaolin.

DATA PERTINENT FOR EFFECTIVENESS

The Panel finds insufficient evidence to establish the claimed mechanism of action of pectin as an antidiarrheal agent, i.e. an adsorbent and protective agent. This claim should be tested in man. The effect of pectin on intraluminal pH also has not been well documented. There are no controlled clinical trials substantiating the effectiveness of pectin alone in the treatment of diarrhea in man. Pectin is usually given in combination with

kaolin or other antidiarrheal agents. Effectiveness of pectin should be tested against a placebo in well-controlled clinical trials. A comparison should also be made with a known effective antidiarrheal. If pectin acts by physically altering the suspension of kaolin or otherwise enhancing the effect of other antidiarrheals, this should be documented and the dose-ratio established. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) The National Formulary, 13th Ed., American Pharmaceutical Association, Washington, D.C., p. 525–526, 1970.

(2) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, MacMillan Co., New York, p. 990, 1970.

(3) Howard, P. J. and C. A. Tompkins, "Pectin-Agar for Diarrhea in Infants and the Newborn: A Rational, Simple and Effective Treatment," Journal of the American Medical Association, 114:2355–2358, 1940.

(4) Olsen, A. G., "Pectin Therapy and Pectin Types," American Journal of Digestive Diseases, 7:515–519, 1940.

(5) Haynes, E., C. A. Tompkins, G. Washburn and M. Winters, "Bactericidal Action of Pectin," Proceedings of the Society of Experimental Biology and Medicine, 36:839–840, 1937.

(6) Steinhaus, J. E. and C. E. Georgi, "The Effect of Pectin, Galacturonic Acid and Alpha Methyl Galaturonate Upon the Growth of Enterobacteriaceae," Journal of Infectious Diseases, 69:1–6, 1941.

(7) Werch, S. C. and A. C. Ivy, "A Study of the Metabolism of Ingested Pectin," American Journal of Diseases of Children, 62:499–511, 1941.

(b) *Claimed active ingredients classified as anticholinergics.* The Panel concludes that some anticholinergic drugs are effective in reducing gastrointestinal motility when given in doses which are equivalent to 0.6 to 1.0 milligram of atropine sulfate. However, neither atropine sulfate nor any other anticholinergic drug is safe when given in such doses. Further, the effectiveness of such a small dosage (e.g., 1/100 of the effective atropine dose) of these anticholinergic drugs as contained in present combination of OTC antidiarrheal products is not established. Since the safety and effectiveness is not satisfactorily established for OTC use, the Panel recommends that antidiarrheal products containing anticholinergics when given in doses which are equivalent to 0.6 to 1.0 milligram of atropine sulfate be available only by prescription.

(1) *Atropine sulfate.* The Panel concludes there is insufficient evidence to establish the safety and effectiveness of atropine sulfate.

Atropine sulfate and related belladonna alkaloids significantly reduce the tone and motility of the gastrointestinal tract by producing parasympathetic blockade (Ref. 1). This effect is especially prominent since sympathetic nerve impulses play little or no part in the regulation of intestinal motility and muscle tone. Normal subjects and some patients with gastrointestinal disease exhibit reduced motor activity in the stomach, small and large intestine following full therapeutic doses (0.6–1.0 milligram) subcutaneously or orally (Refs. 1, 2 and 3). However, there is insufficient evidence that the small quantities of anticholinergic agents in antidiarrheal products contribute in any way to effectiveness. Atropine toxicity is well established; children are particularly susceptible. Although doses of 500 milligrams have been survived, as little as 10 milligrams have been fatal (Ref. 1).

(2) *Homatropine methylbromide.* The Panel concludes that there is insufficient evidence to establish the safety and effectiveness of homatropine methylbromide at this time.

Homatropine methylbromide is a quaternary ammonium derivative of belladonna alkaloid which possesses most of the pharmacologic and toxic properties of atropine (Refs. 1, 4, and 5). It is approximately ½ as potent as atropine, and it is claimed to be only 1/50 as toxic as atropine (Ref. 1), although this claim is not well documented (Ref. 1).

(3) *Hyoscyamine sulfate.* The Panel concludes there is insufficient evidence to establish the safety and efficacy of hyoscyamine sulfate.

Atropine is a racemic mixture of equal parts of *d*- and *l*-hyoscyamine. The *l*-form is more potent than *d*-hyoscyamine. Hyoscyamine sulfate is entirely in the *l*-form and is, therefore, nearly twice as potent as atropine sulfate in its antimuscarinic effects (Ref. 1).

LABELING

The Panel concurs with the required warning statements for belladonna preparations in the regulations (21 CFR 369.20) which states in part:

WARNING.—Not to be used by persons having glaucoma or excessive pressure within the eye, or by elderly persons (when undiagnosed glaucoma or excessive pressure within the eye occurs most frequently), or by children under 6 years of age, unless directed by a physician. Discontinue use if blurring of vision, rapid pulse, or dizziness occurs. Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. If eye pain occurs, discontinue use and see your physician immediately as this may indicate undiagnosed glaucoma.

Because of occurrence of severe antropine poisoning in young children, belladonna preparations for OTC use should not contain more than 0.5 milligram antropine equivalent per 15 milliliters or per 15 grams of final preparation.

DATA PERTINENT FOR SAFETY AND EFFECTIVENESS

The Panel concurs that anticholinergic drugs can be effective in the treatment of diarrhea when administered under the supervision of a physician. The Panel's primary concern is that of safety when anticholinergic drugs are included in OTC antidiarrheal products in quantities that contribute to the antidiarrheal effect of the product. Accordingly, if the safety and effectiveness is not satisfactorily established for OTC use, the Panel recommends that antidiarrheal products containing anticholinergics be available only by prescription. It must be demonstrated by carefully controlled clinical trials that anticholinergic drugs used in OTC antidiarrheals are safe and contribute to the effectiveness of the combination products. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) Innes, I. R. and M. Nickerson, "Drugs Inhibiting the Action of Acetylcholine on Structures Innervated by Postganglionic Parasympathetic Nerves (Antimuscarinic or Atropinic Drugs)," The Pharmacological Basis of Therapeutics, 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Co., New York, p. 524–548, 1970.

(2) Bachrach, W. H., "Anticholinergic Drugs: Survey of the Literature and Some Experimental Observation," American Journal of Digestive Diseases, 3:743–799, 1958.

(3) Ingelfinger, F. J., "The Modification of Intestinal Motility by Drugs," New England Journal of Medicine, 229:114–122, 1943.

(4) Hadfield, W. A., Jr., "The Effect of Homatropine Methylbromide on Human Gastrointestinal Motor Activity," Gastroenterology, 28:642–655, 1955.

(5) Cahen, R. L. and K. Tvede, "Homatropine Methylbromide: A Pharmacological Revaluation," Journal of Pharmacology and Experimental Therapeutics, 105:166–177, 1952.

(c) *Claimed active ingredients classified as astringents.* Astringents are locally acting drugs that precipitate protein. They are thought to act by reducing cell membrane permeability without cell destruction. A number of organic chemicals and certain metallic ions such as those of zinc and aluminum are said to have astringent properties in high dilution. Many antidiarrheal drugs are claimed to have an astringent action. The Panel was unable to find evidence to support this claim or to demonstrate that astringent properties confer effectiveness in diarrhea.

(1) *Alumina powder, hydrated.* The Panel agrees with the OTC antacid Panel that hydrated alumina powder is safe in the amounts usually taken orally for antacid therapy (Ref. 1). Doses used for antacid therapy sometimes cause constipation (Ref. 2).

The fact that hydrated alumina powder sometimes causes constipation when used in adequate doses in antacid therapy does not constitute a rational basis for the claim that the agent is also an effective antidiarrheal.

The Panel is unable to find any studies that evaluate aluminum compounds as a single agent for the treatment of acute diarrhea. Nor could any dose-response data relative to the constipating effect be located.

The inclusion of alumina gel in antidiarrheal preparations to maintain kaolin or attapulgite in suspension and allow greater surface area for absorption may be a reasonable formulation or pharmaceutical necessity but does not

justify the claim that it is an active ingredient.

DATA PERTINENT FOR EFFECTIVENESS

It must be demonstrated in man that alumina powder is an effective antidiarrheal by well-controlled clinical comparisons made with a known effective antidiarrheal and a placebo. If found effective, dose-response data should be obtained. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation).

REFERENCES

(1) "Proposal Establishing a Monograph for OTC Antacid Products," published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714).

(2) AMA Drug Evaluations, 1st Ed., American Medical Association, Chicago, p. 575, 1971.

(2) *Bismuth salts (Bismuth subnitrate, bismuth subsalicylate).* The Panel concludes that the bismuth subsalicylate is safe in amounts taken orally (0.6 to 2.0 grams of bismuth subsalicylate, 3 to 4 times per day) but there is insufficient evidence to establish effectiveness at this time. There is some question of the safety of bismuth subnitrate. The manufacturer's maximum recommended dose would provide about 5.6 grams for adults and 0.475 gram for children (3 to 6 years old) in 4 hours. Methemoglobinemia in infants has been reported in the literature due to the absorption of nitrates from bismuth subnitrate (Refs. 1 and 2) contraindicating its use in children under 2 years.

Bismuth salts appear to be poorly absorbed from the gastrointestinal tract; several studies report the absence of detectable bismuth in the urine of human subjects given high doses or used over long periods of time. The ingestion of 30 to 45 milliliters of a liquid bismuth subsalicylate preparation (equivalent to ingesting 5.5 to 8.25 grains (349 to 523.5 mg) of salicylic acid) yielded blood salicylate levels that ranged from barely detectable to 6.2 mg/100 ml.

Data supporting the effectiveness of bismuth in diarrhea are questionable. A ligated calf intestine model was used to study the effect of one bismuth compound on fluid formation by *E. coli*. Fluid production in the intestinal segment with *E. coli* and drug was less than with *E. coli* alone, but the relationship of this model to common diarrhea in humans is unclear. When the drug was administered in vivo to calves with diarrhea, the results indicated that the drug was not effective.

The products are said to provide a coating action. However, two unpublished studies using animals and two using a "gastro-camera" on human subjects failed to demonstrate any clear evidence of a coating action on the mucosa. Reports attempting to document a coating action for bismuth utilizing a technique of pretreatment with bismuth probably are not applicable, as it can be postulated that the majority of consumers do not use bismuth compounds "prophylactically."

Several clinical trials attempted to document effectiveness of the bismuth compounds in diarrhea. One clinical trial utilized a double-blind technique with a control drug in patients suffering from diarrhea secondary to foreign travel. However, the outcome measurements were based on the patient's subjective opinions of relief (good, excellent, poor, none) with no attempt to standardize the criteria for these responses. Interpretation of the results was difficult. Objective parameters as stool frequency and consistency before and after treatment were not carefully measured (Ref. 3).

LABELING

Special labeling should indicate that stools may become dark with use of any bismuth compound.

Bismuth subnitrate is contarindicated for use in infants under the age of 2 because of the known risk of methemoglobinemia.

DATA PERTINENT FOR EFFECTIVENESS

Data to date suggest bismuth salts may be effective in mild diarrhea, but the claim needs confirmation by testing in a well-controlled clinical trial using objective parameters to indicate response (e.g. number of stools, water content). Bismuth salts should be compared to nonsalicylate containing bismuth salts in order to determine the contribution of salicylate to effectiveness. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) "Accumulation of Nitrate," National Academy of Sciences, Washington, DC, p. 46-75, 1972.

(2) Gleason, M. N., et. al., Clinical Toxicology of Commercial Products: Acute Poisoning, 3rd Ed., Williams and Wilkins, Baltimore, MD, p. 24, 1969.

(3) OTC Volume 090120.

(3) *Calcium hydroxide.* The Panel concludes that calcium hydroxide is safe in the amounts taken orally in antidiarrheal products, but there is no evidence of its effectiveness as an antidiarrheal agent.

Calcium hydroxide solution, commonly known as lime water, is claimed useful for its antacid properties and for buffering purposes (Ref. 1). The constipating effects of calcium when used as an antacid in moderate doses are well known. However, there is no evidence of effectiveness in the treatment of diarrhea. Calcium hydroxide has been included in multiple ingredient antidiarrheal preparations to provide "temporary relief of gastric discomfort due to overeating and other dietary indiscretions." The Panel is of the opinion that it is not rational concurrent therapy for a significant portion of the population for the label to claim both antacid and antidiarrheal activity if the antidiarrheal claim is supported by a nonantidiarrheal antacid ingredient. (See antidiarrheals discussion above for Category II claims.)

DATA PERTINENT FOR EFFECTIVENESS

Data are needed on mechanism(s) of action and a dose-response relationship. Effectiveness should be tested in well-controlled clinical trials comparing calcium hydroxide with placebo. Comparison should also be made with a known effective antidiarrheal. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) *The Pharmacopeia of the United States of America*, 18th Revision, The United States Pharmacopeial Convention, Inc., Washington, DC, pp. 93-94, 1970.

(4) *Phenyl salicylate (salol).* The Panel concludes that phenyl salicylate is safe in the small amounts taken orally in antidiarrheal preparations, but there is no evidence that it is an effective antidiarrheal.

Phenyl salicylate is no longer listed in the United States Pharmacopeia or National Formulary. The antiseptic utility of salol depended largely on its hydrolysis to phenol and salicylic acid (Ref. 1). However, the decomposition is uncertain or very slow and the absorption of phenol is so rapid that effective concentration of the drug in the alimentary tract is questionable (Ref. 2). The amount of phenol available in salol antidiarrheal preparations is considerably below the 1 to 2 percent phenol solution accepted as bacteriostatic. Giving larger doses of salol could possibly result in phenol poisoning (Ref. 3).

DATA PERTINENT FOR EFFECTIVENESS

Data are needed on mechanism(s) of action and a dose-response relationship. Effectiveness should be tested in well-controlled, double-blind clinical trials of the antidiarrheal effect of phenyl salicylate (salol) alone and, if desired, in combination as compared with placebo. Comparison should also be with a known effective antidiarrheal. Additionally, measurement of blood salicylate at one hour after dose administration is needed to document the absorption of salicylate. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) The United States Dispensatory and Physicians' Pharmacology, 26th Ed., Edited by Osol, A., R. Pratt and M. D. Altshule, J. B. Lippincott Co., Philadelphia, PA, p. 899, 1967.

(2) OTC Volume 090053.

(3) Gleason, M. N., et al., Clinical Toxicology of Commercial Products: Acute Poisoning, 3rd Ed., The Williams and Wilkins Co., Baltimore, p. 113, 1969.

(5) *Zinc phenolsulfonate.* The Panel concludes that zinc phenolsulfonate is safe in the small amounts usually taken in antidiarrheal preparations, but no evidence exists to establish effectiveness.

The maximal daily adult dose of zinc phenolsulfonate in antidiarrheal products is approximately 400 milligrams. If all of the phenol from zinc phenolsulfonate in antidiarrheal products were absorbed, the amount would be approximately 136 milligrams in a maximum daily adult dose. This figure is well below the reported fatal dose of 1.5 grams (Ref. 1). Therefore, the ingredient seems safe in the small amounts used in antidiarrheal products.

There is no evidence in the scientific literature or modern standard reference texts to establish the effectiveness of zinc phenolsulfonate in the treatment of diarrhea. The sparse information about zinc phenolsulfonate in older editions of textbooks describes the compound as an astringent for topical application to indolent ulcers and subacute inflammation of the nasopharynx or vagina (Ref. 2).

DATA PERTINENT FOR EFFECTIVENESS

The Panel finds zinc phenolsulfonate safe in the amounts usually taken orally. Effectiveness should be tested in well-controlled, double-blind clinical trails of the antidiarrheal effect of zinc phenolsulfonate alone and, if desired, in combination as compared with placebo. Comparison should also be made with a known effective antidiarrheal. In addition, data are needed on mechanism(s) of action and dose-response relationship. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) Gleason, M. N., et al., Clinical Toxicology of Commercial Products: Acute Poisoning, 3rd Ed., Williams and Wilkins, Baltimore, MD, p. 153, 1969.

(2) The Dispensatory of the United States of America, 25th Ed., Edited by Osol, A. and G. E. Farrar, J. B. Lippincott Co., Philadelphia, p. 1519, 1955.

(d) *Other claimed active ingredients*—(1) *Calcium carbonate.* The Panel concludes that calcium carbonate is safe in the amounts taken orally for antacid therapy, but can find no evidence that it is an effective antidiarrheal.

The OTC antacid Panel concluded calcium carbonate to be an effective antacid, with the recommendation that not more than 8 grams be taken per day (Ref. 1). The recommendation was based on the knowledge that calcium ingestion can lead to hypercalcuria in some instances. In some individuals, this dose of calcium carbonate can case constipation (Ref. 2).

The claimed effectiveness of calcium carbonate in acute, self-limiting diarrhea rests on its known constipating effects when used as an antacid in doses of 2 to 4 grams 4 times daily. The Panel could find no dose-response data relative to the constipating effect that could be used to establish dosage as an antidiarrheal. The Panel concludes the constipating effect sometimes observed with effective antacid therapy is not a rational basis for claimed efficacy as an antidiarrheal.

DATA PERTINENT FOR EFFECTIVENESS

Data are needed on mechanism(s) of action and a dose-response relationship. Effectiveness should be tested in well-controlled clinical trials comparing calcium carbonate with placebo. Comparison should also be with a known effective antidiarrheal. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) "Proposal Establishing a Monograph for OTC Antacid Products," published in the FEDERAL REGISTER of April 5, 1973, (38 FR 8714).

(2) AMA Drug Evaluations, 2nd Ed., American Medical Association, Chicago, p. 787, 1973.

(3) *Lactobacillus acidophilus and bulgaricus.* The Panel concludes that lactobacillus acidophilus and lactobacillus bulgaricus are safe in the amounts taken orally in antidiarrheal preparations, but finds inadequate evidence to support their effectiveness as antidiarrheal agents.

In the past 60 years well over 200 papers have reported on the use of *lactobacillus acidophilus* and *lactobacillus bulgaricus* in the treatment of diarrhea. Despite the proliferation of studies the very few controlled studies more often show lack of effectiveness than any antidiarrheal effect. The many clinical trials reported are not only uncontrolled but usually ignore the well-defined evidence that establishment of lactobacillus as the dominant fecal flora requires the administration of large amounts (240 to 400 gm) per day of an appropriate carbohydrate such as lactose or dextrin. Dominant colonization, in fact, can be induced by such carbohydrate alone without supplemental lactobacilli (Refs. 1, 2 and 3). Colonization is virtually impossible in the presence of antibiotic therapy; this fact is theoretically inconsistent with the use of lactobacilli to attempt control of antibiotic diarrhea.

The Panel has been informed that additional clinical studies are in progress. In view of this, the Panel finds it appropriate to place lactobacillus in Category III.

DATA PERTINENT FOR EFFECTIVENESS

The clinical efficacy of lactobacillus should be established in a well-controlled, double-blind study in diarrhea of two or more types. The stool frequency, weight, volume, pH and dominant flora should be included in the evaluation of response of well-matched groups receiving lactobacilli, lactobacilli plus carbohydrate, carbohydrate alone and placebo. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) Cheplin, H. A. and L. F. Rettger, "Studies on Intestinal Implantation of Bacillus acidophilus," Proceedings of the Society of Experimental Biology and Medicine, 17:192-195, 1920.

(2) Conn, H. O. and M. H. Floch, "Effect of Lactulose and Lactobacillus acidophilus on the Fecal Flora," American Journal of Clinical Nutrition, 23:1588-1594, 1970.

(3) Macbeth, W. A. A. G., E. H. Kass and W. V. McDermott, Jr, "Treatment of Hepatic Encephalopathy by Alteration of Intestinal Flora with Lactobacillus acidophilus," Lancet, 1:399-403, 1965.

(3) *Sodium carboxymethylcellulose.* The Panel concludes that sodium carboxymethylcellulose is safe in the small amounts usually taken orally in antidiarrheal products (200 milligrams 2 to 4 times per day) but that there is insufficient evidence to establish effectiveness as an antidiarrheal agent.

Sodium carboxymethylcellulose is a semisynthetic cellulose derivative which was previously evaluated as a bulk laxative. It is categorized in several texts as a thickening agent to increase the viscosity of various solutions (Refs. 1 and 2). The Panel surmises that increase in the viscosity of the diarrheal fluid and the possible adsorptive qualities might be the rationale for inclusion in an antidiarrheal product. However, the Panel was unable to locate any studies substantiating the effectiveness of carboxymethylcellulose in the treatment of diarrhea at any dose.

DATA PERTINENT FOR EFFECTIVENESS

The Panel finds sodium carboxymethylcellulose safe in the amounts usually taken orally and would encourage studies to determine effectiveness of a potentially useful antidiarrheal preparation. Effectiveness should be tested in well-controlled clinical trials comparing sodium carboxymethylcellulose with placebo. Comparison should also be made with a known effective antidiarrheal. In addition, data are needed on mechanism(s) of action and dose-response relationship. (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

REFERENCES

(1) The Pharmacopeia of the United States of America, 18th Rev., The United States Pharmacopeial Convention, Inc., Washington, D.C., p. 593-594, 1970.

(2) Wilson, C. O., O. Gisvold and R. F. Doerge, Textbook of Organic Medicinal and Pharmaceutical Chemistry, 5th Ed., J. B. Lippincott, Co., Philadelphia, pp. 783, 1966.

(e) *Labeling claims for specific ingredient—Bismuth subsalicylate.* The Panel concludes that claims that bismuth produces a protective coating that corrects the symptoms of upset stomach, indigestion and nausea are unfounded. The use of a single ingredient for dual or multiple symptoms must be appropriate and rational therapy for a significant proportion of the population. In the case of bismuth subsalicylate, claims of effectiveness for the treatment of a number of symptoms such as nausea, indigestion, upset stomach, etc., in addition to the primary claim as an antidiarrheal, may be rational provided the medication is proven to be effective against each symptom, and there is a significant target population having such concurrent symptoms to justify its use, as for example, individuals suffering from travel related symptoms such as those commonly occurring in the "Turista" syndrome.

DATA PERTINENT FOR EFFECTIVENESS EVALUATION

The Panel concurs with the conclusions of the OTC Antacid Panel in a proposal published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714) that such claims (nausea, indigestion, upset stomach, etc.) "* * * provide evidence of

effectiveness consisting of statistically valid clinical trials in relieving each of these symptoms for which a claim is made." (See paragraph I below for data pertinent for antidiarrheal ingredient evaluation.)

G. PRODUCTS CONTAINING MULTIPLE ANTIDIARRHEAL INGREDIENTS

1. *General Statements* a. The Panel has followed the regulation (21 CFR 330.10(a)(4)(iv)) which states:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and when the combination, when used under adequate direction for use, and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

b. The Panel concludes that, in general, the fewer the ingredients, the safer and more rational the therapy. The Panel believes that the interests of the consumer are best served by exposing the user of OTC drugs to the fewest ingredients possible at the lowest possible dosage regimen consistent with a satisfactory level of effectiveness.

c. The Panel concludes that OTC drugs should contain only such inactive ingredients as are necessary for pharmaceutical formulation.

2. *Requirement of significant contribution.* The Panel has determined that each claimed active ingredient in the combination must make a significant contribution to the claimed effect. In the absence of data showing the minimum dose necessary to achieve the intended antidiarrheal effect, the amount of ingredient present in antidiarrheal products must be at least equal to the currently accepted minimum dose level for such active ingredients as set forth elsewhere in this document.

The Panel found it impossible to develop a formula for establishing a level below the minimum effective dose level for an ingredient as a single entity at which it could reliably be stated that each antidiarrheal ingredient would make a contribution to a combination drug product. This may be possible with other agents as antacid combination products where the contribution of each antacid can be determined by chemical titration. Antidiarrheals are believed to have a minimum effective dose below which there are few measurable responses. The Panel recognizes that it is possible that some ingredients may be proved to contribute to the effectiveness of a combination product in amounts below the generally recognized minimum effective daily dose. However, because of the numerous variables involved (e.g., differing modes of action, etc.), the Panel could not select one lower level of an active ingredient which may be assumed to be effective in a combination product.

Moreover, the Panel could not establish the percentage of contribution that an active ingredient must make to the effectiveness of the product in order for that contribution to be considered "significant."

The Panel concluded that where a combination product is permitted, as discussed below, it is sufficient to demonstrate in well-controlled clinical trials (Section I below—Data Required for Antidiarrheal Ingredient Evaluation) that each of the ingredients makes a statistically significant contribution to the claimed effect. As long as "statistical significance" is shown, the Panel concludes that a contribution toward antidiarrheal effect will also have been shown to be clinically "significant."

3. *Safety and effectiveness.* In its consideration of active ingredients the Panel reviewed the safety and effectiveness of all the combinations submitted. However, the Panel could not place any combination reviewed in Category I because of a lack of sufficient information concerning the safety and/or effectiveness of such ingredients as contained in the submitted combinations.

The Panel considers it important that the minimum effective dose be established for each ingredient in a combination product.

4. *Single active ingredients.* OTC drugs containing safe and effective single ingredients are preferred to those having multiple active ingredients because of the reduced risks of toxic effects, synergistic effects, allergic and/or idiosyncratic reactions, and possible unrecognized and undesirable drug interaction(s).

It is an established medical principle to give only those medications, preferably as single entities, necessary for the safe and effective treatment of the patient. This principle applies equally to self-medication. To add needlessly to the patient's medication increases the risk of adverse reactions.

5. *Limitation of ingredients in antidiarrheal combination products.* Given the paucity of effective antidiarrheal agents and the multiplicity of pathologic mechanisms causing common diarrhea, the Panel finds it difficult to define or restrict the total number of ingredients. However, in keeping with its conclusion that the fewer the ingredients the safer the combination, Category I combinations will be limited to 2 ingredients.

6. *Active ingredients not reviewed by the Panel.* Each claimed active ingredient must be an ingredient that has been reviewed by the Panel. If a product contains an active ingredient that has not been reviewed by the Panel and consequently not found in this document, such ingredient is automatically classified as a Category II ingredient, i.e., it is not generally recognized as safe and/or effective. Appropriate animal and human testing and prior approval by the Food and Drug Administration is required before a product containing such an ingredient may be marketed.

7. *Review of submitted combination products.* The Panel considered only those combination products submitted pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) and included above in paragraph A. The Panel recognizes that other combination products may be in the market place but it has either no knowledge of such products, or insufficient data with respect to such products to make a reasonable judgment of safety and/or effectiveness.

Accordingly, the Panel recommends that any new combination, or any presently marketed combination not submitted to this Panel be evaluated through the new drug procedures, or be the subject of an appropriate petition to the Commissioner to review or amend the OTC antidiarrheal monograph.

8. *Combinations containing nonantidiarrheal ingredients.* Products combining antidiarrheal ingredient(s) with other ingredients having nonantidiarrheal pharmacologic effects are considered irrational, unless it can be shown that there is a significant target population requiring concurrent treatment of symptoms that require antidiarrheal(s) and nonantidiarrheal(s) in combination. The common symptoms of gastroenteritis would support the rationale of combining an antidiarrheal with an antiemetic or an agent for the treatment of gastritis but no such effective combination has been found.

Nonantidiarrheal ingredient(s) may be present as inactive ingredients in antidiarrheal products as an aid to formulation or to palatability. However, the presence of such ingredient(s) must not be emphasized or identified as active ingredients in the labeling or in the advertisement of such product(s).

9. *Classification of submitted combinations.* Within the categories defined by the Panel the combinations submitted for review are classified as follows:

ORAL DOSAGE FORMS

Category I combinations

None yet designated.

Category II combinations

a. Bismuth subsalicylate, phenyl salicylate (salol), and zinc phenolsulfonate.

b. Bismuth subsalicylate, precipitated calcium carbonate, and aminoacetic acid (glycine, glycocol).

c. Kaolin, pectin, hyoscyamine sulfate, atropine sulfate, scopolamine (hyoscine) hydrobromide, and powdered opium.

d. Kaolin, pectin, hyoscyamine sulfate, atropine sulfate, and scopolamine (hyoscine) hydrobromide.

e. Bismuth subnitrate, rhubarb fluidextract, potassium carbonate, and calcium hydroxide.

f. Activated attapulgite, pectin, and hydrated alumina powder.

g. Paregoric, pectin, and kaolin.

h. Kaolin, hydrated alumina powder, and pectin.

i. Tincture of opium, homatropine methylbromide, and pectin.

Category III combinations

a. Lactobacillus acidophilus and sodium carboxymethylcellulose.

b. Lactobacillus acidophilus and lactobacillus bulgaricus.

c. Activiated attapulgite and pectin.

d. Kaolin and pectin.

e. Tincture of opium and pectin.

f. Kaolin and hydrated alumina powder.

RECTAL DOSAGE FORMS

None yet designated.

10. *Ingredients included in Category I combinations.* Since there are presently no acceptable Category I combinations the Panel is setting forth guidelines whereby present and future Category I ingredients may reasonably be considered for a Category I combination. The Panel recommends:

a. The combination be limited to 2 Category I active antidiarrheal ingredients.

b. Each ingredient in the subject combination must be present within the dosage range for a Category I antidiarrheal ingredient, as set forth elsewhere in this document. The Panel recommends that the Food and Drug Administration designate additional Category I antidiarrheal agents as appropriate safety and efficacy data become available.

c. The specific combination of ingredients must be an approved Category I combination. Since there are no Category I combinations presently designated, the Panel recommends that the Food and Drug Administration designate such combinations as appropriate safety and efficacy data become available.

11. *Criteria for Category II combination products.* A combination is classified by the Panel as a Category II product, i.e., one that is not generally recognized as safe and effective, if any of the following apply:

a. The combination contains 3 or more active antidiarrheal ingredients.

b. The combination contains any ingredient that is above the maximum dosage set for such agent as listed elsewhere in this document or in the future designated by the Food and Drug Administration for an antidiarrheal agent.

c. The combination contains any active antidiarrheal ingredient that has not been reviewed by the Panel and accordingly not listed in this document or in the future designated by the Food and Drug Administration.

12. *Criteria for Category III combination products.* A combination is classified as a Category II combination if any of the following apply:

a. If any Category I ingredient is below the minmum dosage range set by the Panel elsewhere in this document for such respective ingredient.

b. If 1 or more ingredient(s) are Category III ingredients, as set forth elsewhere in this document for single active antidiarrheal ingredients.

13. *Reclassification requirements for Category III combinations to Category I combinations.* a. For any Category III combination found in paragraph 9 where one or both ingredients fall below the minimum effective level as set forth elsewhere in this document for such individual ingredient(s), tests must be performed to substantiate the effectiveness of any such ingredient. The Panel recommends that such testing be pursued under the NDA procedures or petition to the Agency for appropriate modification of the monograph to permit such lower dosages.

b. (1) Any combination that contains one or both ingredients in Category III, as set forth elsewhere in this document, must be tested to satisfy Category I requirements for each such ingredient.

(2) Two Category I ingredients in a combination not found in paragraph 9 must be petitioned to the Agency for an appropriate amendment to the monograph or proceed through the NDA procedures.

14. *Combinations containing nonantidiarrheal ingredients.* Products combining antidiarrheal ingredient(s) with other ingredients having nonantidiarrheal pharmacologic effects are considered irrational, unless it can be shown that there is a significant target population requiring concurrent treatment of symptoms that require antidiarrheal(s) and nonantidiarrheal(s) in combination.

Nonantidiarrheal ingredient(s) may be present as inactive ingredients in antidiarrheal product as an aid to formulation or to palatability. However, the presence of such ingredient(s) must not be emphasized or identified as active ingredients in the labeling or in the advertisement of such product(s).

H. INACTIVE INGREDIENTS

When antidiarrheal products contain inactive ingredients, the Panel recommends that the inactive ingredients be listed on the label with or without the amounts contained in a recommended dose. The availability of sodium, potassium, and magnesium in the maximum recommended daily dose should be stated on the label. (See labeling discussion above for antidiarrheal products.) If significant amounts are present, special warnings on the label should be provided (as indicated previously in this document) for patients with heart disease and renal disease or those on a low salt diet.

I. DATA PERTINENT FOR ANTIDIARRHEAL INGREDIENT EVALUATION

The Panel has given considerable thought to the problem of demonstrating that an antidiarrheal is safe and effective. When a drug is available for widespread use, as in OTC products, its safety and effectiveness must be well documented by toxicological data, data on the absorption, distribution, fate and excretion of the drug, the pharmacological effects of the drug, and the mechanism of action. The drug should also meet certain effectiveness standards.

The Panel recommends that information such as the following be obtained in the categories of data when relevant and pertinent to the drug under study: Toxicological data, absorption, distribution, fate, and excretion (ADFE) data, mechanism of action. The drug should standards.

1. *Toxicological data.* A variety of toxicological data can be obtained to demonstrate that an antidiarrheal is safe. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the safety of their products. The Panel recommends that data such as the following be obtained in animal studies and in clinical studies in man. Certain data on human subjects, such as lethal doses and chronic toxicity, will be available only from poison control centers, hospitals, medical centers, or medical examiners. However, the Panel considers such data important and attempts should be made to obtain them.

(a) *Preclinical animal studies.* (1) The oral LD_{50} established in no less than two animal species.

(2) Determinations of histologic and biochemical alterations in animals given lethal doses acutely or low doses chronically.

(3) Studies of teratogenicity and embryolethality. Studies of effects on fertility, delivery, and nursing offspring may also be indicated.

(b) *Clinical studies.* (1) Biochemical tests of liver and renal function and measurement of serum electrolytes after a therapeutic dose.

(2) Chronic toxicity studies in man, especially in relation to altered function and cytological changes of the mucosa of the intestinal tract of man.

(3) Adverse drug reactions should be well documented. Substantial effort should be made to have physicians document side effects, especially those of a serious nature as indicated.

(4) Minimal lethal dose by single oral ingestion and in divided doses when such data are available from accidental or deliberate overdosing.

(5) Maximal tolerated dose from single oral ingestion, or divided multiple oral ingestions, when such data are available from accidental or deliberate overdosing.

2. *Absorption, distribution, fate, and excretion (ADFE) as determined by currently accepted methods.* Since ADFE bears directly on the safety of drugs and occasionally on the mechanism of action of antidiarrheals, appropriate data should be provided for all active ingredients and their active metabolic products. The methods for obtaining these data are established and are not different from those used in the study of ADFE of other drugs. Data such as the following would provide sufficient information regarding ADFE. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding ADFE of their products:

a. The percentages of various oral doses of the drug which are absorbed in man.

b. The percentages of various oral doses of the drug which are excreted in the urine in man.

c. The percentages of various oral doses of the drug which are excreted in breast milk.

d. The metabolic fate in man of absorbed but unexcreted drug.

e. The fate of unabsorbed drug in man.

f. The net bioavailability of the drug in man.

g. The ingredients and metabolic products associated with fecally excreted drug and/or its unabsorbed intraluminal biotransformation products.

h. The ingredients and metabolic products associated with renally excreted drug and/or its renally excreted biotransformation product.

3. *Effects.* The Panel recognizes that the mechanism of action of many safe and effective drugs is unknown. Nevertheless, data should be provided which serve to elucidate the pharmacologic effects of antidiarrheals. For example, if they are claimed to be adsorptive agents, adsorption must be documented. If the claim is based upon the effects of an anticholinergic action on motility, appropriate methods should be used that will demonstrate the effects of the agent on intestinal or colonic motility. In addition, it is recommended that data such as the following be obtained. Manufacturers are not expected to obtain all of these data, but are expected to obtain those data relevant to the unanswered questions regarding the mode of action of their products:

a. Effects of oral drug on jejunal secretion and the flux of ions and water at the levels of jejunum, ileum, proximal and distal colon.

b. Effects of the oral drug on the absorption of actively transported ions, sugars, and amino acids.

c. Effects of the oral drug on the absorption of carbohydrate, protein, lipids and fat-soluble vitamins.

d. Effects of the oral drug on the absorption of other drugs.

e. Effects of the oral drug on secretion of gastrointestinal enzymes and hormones.

f. Effects on intestinal smooth muscle such as contractility and electromyographic changes.

4. *Effectiveness standards.* The effectiveness of antidiarrheal agents can be tested using patients with diarrheal disorders as occur in travel and commonly referred to as "Turista", or in institutionalized patients where periodic epidemic mild diarrhea may occur, or in outpatient clinics and pharmacies where pediatric and adult patients are frequently seen with diarrheal problems and in specific situations such as radiation diarrhea. Although antidiarrheal agents can be tested in both human and animal models where diarrhea has been induced, i.e., cholera model, the Panel questions the relevance of these to human disease states as related to nonspecific common diarrhea. Antidiarrheals may be of a number of different types. When the antidiarrheal product contains more than one active ingredient, the double-blind, Latin square, design is particularly suited for testing the effectiveness of individual ingredients as well as comparing their effect against that of placebo. When it is impossible or impractical to devise an acceptable placebo, the antidiarrheal ingredient may be compared with another acceptable agent and studied in parallel groups. When experimental models of induced diarrhea are used, each subject can serve as his own control, but the period of study should be sufficiently long to clearly demonstrate differences.

Specific parameters that can be measured quantitatively to determine the effectiveness of an antidiarrheal agent include many of those used for determining the effectivenes of a laxative agent. For an antidiarrheal agent, the following parameters would be considered appropriate for assessing the effectiveness of the agent. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the effectiveness of their products:

a. *Frequency.* The Panel recognizes that frequency of stool evacuation is quite variable among normal, healthy individuals and may range from three bowel movements per day to three per week. Frequency should be expressed in number of evacuations per unit time such as 24 hours or per week, etc.

b. *Volume.* The volume of stool evacuated during a unit time period is easy to determine and is usually expressed in milliliters or cubic centimeters per 24 hours or other time period. Average normal is 150 ml/24 hours.

c. *Weight.* Weight of stool is expressed in grams per 24 hours or other unit time period. Weight is independent of consistency and important in determining the effectiveness of antidiarrheals. Average normal is 110 to 130 grams per 24 hours.

d. *Water content.* Water content of the feces is usually expressed as percent water. Excess water excretion is the hallmark of diarrhea and important in evaluating the effectiveness of antidiarrheals. Average normal is 60 to 85 percent. Since hydrophilic agents may decrease stool frequency and percent water content but actually increase the daily excretion of water and electrolytes, the combined information is particularly relevant to the effect of antidiarrheal in young children.

Because of the large variation in the water content of normal stools, measurement on stool water content for each subject before, during and after treatment become very important.

e. *Consistency.* Consistency should be evaluated in some objective manner in addition to the subject's sensation of ease of passage or the observer's description of the stool as liquid, soft, hard, etc. Since major changes in the consistency of stool (and other materials) may occur with little change in either percent water or total stool weight, the Panel recommends a quantitative determination of consistency. There are few rheologic studies of colonic content (Refs. 1 and 2) but instrumentation used to quantitate the consistency of compounds, such as bread doughs, various pastes, and soils might be appropriate. If a tube viscometer is used, consistency is expressed in terms of shear rate and if a penetrometer is used, consistency is expressed in terms of kilogram per square centimeter.

f. *Fecal solids.* Fecal solids are usually expressed in grams per 24 hours. Average normal is 25 grams/24 hours.

g. *Bulk density.* Bulk density is expressed as unit weight per unit volume, usually grams per cubic centimeter, and is determined by drying a known volume to a constant weight at 105° C. Bulk density is an important parameter in determining the effectiveness of bulk-forming laxatives. Average normal is 0.15 to 0.18 gm/cc.

h. *Transit time.* Transit time may be expressed by either the "time method" or the "distance method" by use of nonabsorbable markers such as polyethylene glycol, nonabsorbable color dyes such as carmine, and nonabsorbable radioactive materials such as chromium. In addition, inert colored plastic beads have been used as a marker to determine transit time. The use of some markers, such as carmine dye, is associated with considerable "streaming" and should be taken into account when markers are used to separate treatment periods. Average normal is 40 to 60 hours for complete transit of the digestive tract.

i. *Fecal excretion rate.* Fecal excretion rate is expressed in weight per unit time, usually grams per hour. Average normal fecal excretion rate is 6 grams per hour.

j. *Stool electrolytes, bile salts, etc.* Feces contain a number of substances that might be appropriate to measure in evaluating antidiarrheal agents. Stool electrolytes, particularly sodium, potassium and chloride, may be markedly altered by diarrhea and losses may be actually increased by antidiarrheals such as hydrophilic agents.

REFERENCES

(1) Picologlou, B. F., P. D. Patel, and P. S. Lykoudis, "Biorheological Aspects of Colonic Activity: Part I. Theoretical Considerations," Biorheology, 10:431–440, 1973.

(2) Picologlou, B. C., P. D. Patel and P. S. Lykoudis, "Biorheological Aspects of Colonic Activity: Part II. Experimental Investigation of Rheological Behavior of Human Feces." Biorhology, 10:441–446, 1973.

III. ANTIEMETICS

Pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) requesting the submission of data and information on OTC antiemetic drugs, the following firms made submissions relating to the indicated products:

A. DATA AND INFORMATION SUBMISSIONS

FIRM	MARKETED PRODUCTS
Pfizer Pharmaceuticals, New York, NY 10017	Bonine.
William H. Rorer, Inc., Fort Washington, PA 19034.	Emetrol.
Searle Laboratories, Chicago, IL 60680	Dramamine, Dramamine Liquid.
Norwich Pharmaceutical Co., Norwich, NY 13815.	Pepto-Bismol Liquid, Pepto-Bismol Tablets.

B. THE LABELED INGREDIENTS CONTAINED IN SUBMITTED PRODUCTS

Aminoacetic acid (glycine, glycocol)
Bismuth subsalicylate
Dimenhydrinate
Meclizine hydrochloride
Orthophosphoric acid
Phenylsalicylate (salol)
Sugar (invert)
Zinc phenolsulfonate

The Panel also undertook a review of the following: Cyclizine hydrochloride.

C. EMESIS AND THE USE OF OTC ANTIEMETICS

Severe nausea, and the realization that one is about to vomit, is one of the more dreadful conditions suffered by man. Motion sickness accompanied by nausea and vomiting is not unusual and may be prevented effectively by a number of antihistamine-like drugs available in OTC antiemetic products. Motion sickness occurs when visual and vestibular stimuli are not in accord, particularly when the head rotates in two axes simultaneously. Some individuals are more resistant to motion sickness than others, but none is immune. Travel aboard ship, in airplanes, or even in automobiles may induce motion sickness. OTC antiemetics are also needed for other causes of nausea and vomiting as in patients undergoing chemotherapy or radiation therapy for malignancy, and episodic vomiting of childhood.

D. CLASSIFICATION OF ACTIVE INGREDIENTS

The Panel reviewed all active ingredients which were the subject of submissions made to the Panel pursuant to the standards for safety, effectiveness, and truthful labeling.

In accordance with the regulation (21 CFR 330.10), the Panel's findings with respect to these ingredients are set forth in three categories:

I. Conditions under which antiemetic products are generally recognized as safe and effective and are not misbranded.

II. Conditions under which antiemetic products are not generally recognized as safe and effective or are misbranded.

III. Conditions for which the available data are insufficient to permit final classification at this time.

The Panel recommends for each class of drugs:

1. That the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the FEDERAL REGISTER.

2. That the conditions excluded from the monograph on the basis of the Panel's determination that they would result in the drug not being generally recognized as safe and effective or would result in misbranding (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the FEDERAL REGISTER, regardless whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph on the basis of the Panel's determination that the available data are insufficient to classify such conditions either as generally recognized as safe and effective and not misbranded or as not being generally recognized as safe and effective or would result in misbranding (Category III) be permitted to remain in use for 2 years after the date of publication of the final monograph in the FEDERAL REGISTER, if the manufacturer or distributor of any such drug utilizing such conditions in the interim conducts tests and studies adequate and appropriate to satisfy the questions raised with respect to the particular condition by the Panel.

E. REVIEW OF ACTIVE INGREDIENTS

All active ingredients which were the subject of submissions made to the Panel were carefully reviewed. The Panel considered all pertinent data and information available to the Panel in arriving at its conclusions and recommendations.

1. *Conditions under which antiemetic products are generally recognized as safe and effective and are not misbranded.* The following antiemetic ingredients were classified as safe and effective and not misbranded:

BENZHYDRYL PIPERAZINE ANTIHISTAMINES

Cyclizine
Meclizine

DIMENHYDRINATE

(a) *Benzhydryl piperazine antihistamines*—(1) *Cyclizine and Meclizine.* The Panel concludes that cyclizine and meclizine are safe and effective in the amounts taken orally (meclizine, for adults 25 to 50 milligrams once daily; and cyclizine, 50 milligrams up to 4 times daily and for children 6 to 12 years 25 mg up to 3 times daily) in antiemetic products for the treatment of nausea and vomiting of motion sickness.

Meclizine is a member of the benzhydryl piperazine group of antihistamine compounds which also includes cyclizine. Chemically, these compounds differ from other antihistamines in that the alkylamino group exists as a ring structure.

An extensive literature is available to support the conclusion that meclizine is effective and safe in the management of motion sickness (Refs. 1 through 5). The drug has a relatively long duration of action and is reported to afford 24-hour protection against the symptoms of motion sickness (Refs. 3 and 4).

Meclizine is relatively free of side effects when administered in therapeutic doses, although sedation (drowsiness) sometimes occurs and may be troublesome in those persons who drive automobiles or operate other machinery. Containers of OTC meclizine tablets are labeled to warn of this potential hazard.

In 1966, the Food and Drug Administration acting on the recommendation of an Ad Hoc Advisory Committee, required relabeling of the OTC products containing meclizine and cyclizine to include the following warning:

Not for use by women who are pregnant or who may become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.

This labeling warning was prompted by concern that the drug may have teratogenic or embryolethal potential. The Panel has carefully reviewed more recent epidemiological data, the previous report of the FDA Ad Hoc Advisory Committee, and the position of the American Teratology Society regarding the limitations of extrapolating animal data to man (Ref. 6). The Panel concluded that the scientific data do not warrant a need to restrict the use of meclizine or cyclizine or require the labeling to include a pregnancy warning, but reevaluation may be needed as additional data become available.

The Panel reviewed data on 50,282 pregnant women of which 1,014 had used meclizine during the early stages of pregnancy. Data showed that the incidence of malformation of the offspring of the 1,014 women was not statistically increased over that of the other 49,268 pregnant women not using meclizine, but who had used other drugs during pregnancy. Further, the Panel had indirect evidence that meclizine is not embryocidal and that the incidence of specific teratogenicity (e.g., cleft palate) was actually less in the data compiled from the use of meclizine in human pregnancies than that which might have been expected from the previous underlying animal studies which had led to the pregnancy warning (Ref. 7).

LABELING

A claim should be made only for the effectiveness of benzydryl piperazine group in the treatment of nausea and vomiting due to motion sickness. Claims for effectiveness for the treatment of nausea and vomiting of other causes have not been proven. The label should carry the warning that this drug can produce drowsiness and persons taking it should be cautioned regarding driving automobiles or operating heavy machinery or equipment. Specific warnings should also cite its anticholinergic action and patients with glaucoma or enlargement of the prostrate gland should be cautioned regarding taking this OTC product other than under the direction of a physician. For cyclizines the label should also contain the following warning:

Do not give to children under 6 years of age except under the advice and supervision of a physician.

For meclizine, the label should also contain the following warning:

Do not give to children under 12 years of age except under the advice and supervision of a physician.

REFERENCES

(1) Chinn, H. I., et al., Evaluation of Drugs for Protection Against Motion Sickness Aboard Transport Ships, Journal of the American Medical Association, 160:755–760, 1956.

(2) Arner, O., H. Diamant, L. Goldberg and G. Wrange, "Antihistamines in Sea Sickness," Archives Internationales de Pharmacodynamie et de Therapie, 117:404–418, 1958.

(3) Handford, S. W., T. E. Cone, H. I. Chinn and P. K. Smith, "Drugs Preventing Motion Sickness at Sea," Journal of Pharmacology and Experimental Therapeutics, 111: 447–453, 1954.

(4) Chinn, H. I., S. W. Handford, P. K. Smith, T. E. Cone, Jr., R. F. Redmond, J. V. Maloney and C. M. Smythe, "Evaluation of

Some Drugs in Seasickness," Journal of Pharmacology and Experimental Therapeutics, 108:69–79, 1953.

(5) Franks, J. J., L. J. Milch and E. V. Dahl, "Prevention of Airsickness with Meprobamate," Journal of the American Medical Association, 181:263–264, 1962.

(6) Staples, R. E., "Teratogens and the Delaney Clause," Science, 185:813–814, 1974.

(7) Shapiro, S., Boston Children's Medical Center, Testimony Before OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Panel, October 11, 1974.

(b) *Other active ingredient—Dimenhydrinate.* The Panel concludes that 50 to 100 milligrams dimenhydrinate is safe and effective in the amounts usually taken orally in antiemetic products (200 mg to 400 mg daily in 4 divided doses) for the treatment of nausea and vomiting associated with motion sickness. The dosage for children 2 to 5 years of age is 12.5 to 25 mg up to 3 times daily and for children 6 years and over 25 to 50 mg up to 3 times daily.

Dimenhydrinate is the 8-chlorotheophyllin salt of the antihistamine diphenhydramine. Since introduction in 1949, the effectiveness of dimenhydrinate against seasickness and airsickness has been repeatedly demonstrated. Dimenhydrinate is relatively free of side effects when administered in recommended doses, although drowsiness sometimes occurs and may prove troublesome in individuals driving an automobile or operating other types of machinery.

LABELING

A claim should be made only for the effectiveness of dimenhydrinate in the treatment of nausea and vomiting due to motion sickness. The Panel is unaware of the existence of acceptable scientific data relating to claims for effectiveness in the treatment of nausea and vomiting from other causes. Such additional claims have not been proven.

The label should carry the warning that this drug can produce drowsiness and persons taking it should be cautioned regarding driving automobiles or operating heavy machinery or equipment. Specific warnings should also cite its anticholinergic action and patients with glaucoma or enlargement of the prostate gland should be cautioned regarding taking this OTC product other than under the direction of a physician.

REFERENCES

(1) Gay, L. N. and P. E. Carliner, "The Prevention and Treatment of Motion Sickness. I. Seasickness," Science, 109:359, 1949.

(2) Chinn, H. I. and P. K. Smith, "Motion Sickness," Pharmacological Reviews, 7:33–82, 1955.

2. *Conditions under which antiemetic products are not generally recognized as safe and effective or are misbranded.* The Panel found that there was no scientific or even sound theoretical basis for claimed effectiveness of a number of ingredients used in OTC antiemetic products. The Panel concludes that it is misleading to make claims regarding multiple indications for use of single ingredients when no evidence exists to support such claims.

The Panel further concludes that the following ingredient should be removed from the market as an antiemetic agent unless and until further scientific testing supports its use:

INDIVIDUAL ACTIVE INGREDIENT

Aminoacetic acid (glycine, glycocol)

(a) *Individual active ingredient*—(1) *Aminoacetic acid (glycine, glycocol).* The Panel concludes that aminoacetic acid is safe in the amounts usually taken orally in antidiarrheal products, but there is no evidence to support its effectiveness as an antiemetic agent.

The Panel can find no evidence to support the claim that glycine (identified in the Antacid Monograph) alone or in combination is an effective antiemetic or antinauseant. The claim that glycine is effective for the relief of "nausea," "indigestion," "gas," "fullness," "bloating," "pressure," and "upset stomach" is not supported by any carefully controlled clinical studies. Since hyperacidity is not a known cause of vomiting there is no sound theoretical or scientific basis to indicate that the addition of glycine to antiemetics would offer relief of the indicated symptoms.

3. *Conditions for which the available data are insufficient to permit final classification at this time.* The Panel concludes that adequate and reliable scientific evidence is not available at this time to permit final classification of the active ingredients listed below:

Bismuth subsalicylate
Phenyl salicylate (salol)
Phosphorated carbohydrate
Zinc phenolsulfonate

The Panel believes it reasonable to allow 2 years for the development and review of such evidence. Marketing need not cease during this time if adequate testing is undertaken. If data regarding adequate effectiveness and safety are not obtained within 2 years, however, the ingredients listed in this category should no longer be marketed as active ingredients in over-the-counter products but may be permitted as inactive ingredients if the amount employed is necessary for the pharmaceutical formulation of the product. Some ingredients may be present in products in quantities which are pharmacologically inactive by virtue of being subclinical doses. In these cases the ingredients may be included for pharmaceutical necessity such as improving the stability or palatability of the product. However, it is the opinion of the Panel that if an ingredient was originally claimed by the sponsor to be active, it cannot then also be claimed inactive and included for formulation purposes unless the following are documented: The absolute necessity for inclusion in the pharmaceutical formulation, the safety of the quantity in the finished product, and the inactivity of the quantity in the finished product.

The Panel has given careful consideration to the types of studies and types of data to be required for removing a claimed active antiemetic ingredient from Category III and placing it in Category I. See data required below for antiemetic ingredient evaluation. In general, to demonstrate effectiveness, the design of the study should have a sound scientific basis (e.g., a randomized, double-blind, cross-over study comparing claimed active ingredients to placebo), the clinical trial should be carefully controlled (e.g., consideration given to selection of subjects representative of general population as well as diet, activity, travel, etc. of subjects being studied), and quantitative measurement of various parameters appropriate for the claimed effects of the ingredient. To demonstrate safety, appropriate toxicological studies in experimental animals (preferably primate) and man are required as outlined elsewhere.

(a) *Bismuth subsalicylate.* The Panel concludes that bismuth subsalicylate is safe in the amounts usually taken (1 to 4 grams) orally. However, the Panel concludes that there is insufficient evidence to establish effectiveness of bismuth subsalicylate as an antiemetic.

Evidence available to the Panel indicates that emesis in dogs induced by 15 ml of ipecac syrup can be controlled effectively by pretreatment with 0.35 gm/kg of bismuth subsalicylate in a liquid preparation (Ref. 1). In human subjects, 1 ounce of a bismuth preparation was no better than 1 ounce of water in preventing emesis which had been induced by a dose of 15 ml of ipecac syrup.

Studies evaluating the effectiveness of bismuth compounds for "upset stomach" or "nausea" suffer from the vague definitions of these complaints. Bismuth compounds appear to control the uncomfortable feelings accompanying low doses of ipecac syrup, but whether pretreatment with bismuth (subsalicylate) followed by ipecac is an appropriate model for the consumer's "upset stomach" is debatable. It is difficult to postulate any effect of any drug on distention symptoms induced by overeating, unless it affects gastric emptying time, the tone of the stomach wall or intragastric pressure. However, bismuth subsalicylate has been promoted for use to treat symptoms such as "indigestion", "gas", "full stomach", etc. The Panel concurs with the Commissioner of Food and Drugs when he noted in the tentative final order establishing the Antacid monograph published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260), that some of these symptoms are vague, and most are poorly understood (Ref. 2).

LABELING

Special labeling should indicate that stools may become dark with use of any bismuth compound.

DATA PERTINENT FOR EFFECTIVENESS

Bismuth is not promoted as an antimotion sickness agent, thus, motion sickness models would not be appropriate for this agent.

Vomiting induced by the oral administration of ipecac, pepper sauce, mustard, or potassium chloride are suggested models for the claim of antiemesis. The investigator using these models should ensure that patients not be pretreated with bismuth.

A model must be developed that approximates the upper gastrointestinal symptoms produced by food intolerance, and it must produce these sensations with some reliability and measure of objectivity. The Panel is unable to define such claims as "upset stomach," and "distention". Accordingly, the Panel cannot appropriately suggest a model to test the effectiveness of bismuth for such claims.

The Panel concurs with the conclusions of the OTC antacid Panel set forth in the proposal published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714) that such claims provide evidence of effectiveness. The evidence should consist of statistically valid clinical trials to support each of the respective claims. (See paragraph G below for data pertinent for antiemetic ingredient evaluation.)

REFERENCES

(1) OTC Volume 090123.[1]

(2) "Tentative Final Order for Antacid Products," published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260).

(b) *Phenyl salicylate (salol).* The Panel concludes that salol is safe in the amounts usually taken orally in OTC products, but there is no evidence to support its effectiveness as an antiemetic agent.

The Panel can find no evidence to support the claim that salol alone or in combination is an effective antiemetic or antinauseant. The claim that phenyl salicylate is effective for the relief of "nausea," "indigestion," "gas," "fullness," "bloating," "pressure," and "upset stomach" is not supported by any carefully controlled clinical studies.

DATA PERTINENT FOR EFFECTIVENESS

Well-controlled, double-blind clinical trials are needed to compare the antiemetic effect of phenylsalicylate, alone and if desired in combination, as compared with placebo and with an effective antiemetic. Documentation is needed of the blood salicylate levels 1 hour after ingestion. The response should be evaluated by objective changes in frequency of vomiting. Careful experimental design, definition of terms and matching of subjects is needed to assess the effect on subject complaints of malaise and nausea. (See paragraph G below for data pertinent for antiemetic ingredient evaluation.)

(c) *Phosphorated carbohydrate (levulose-dextrose-ortho-phosphoric acid).* The Panel concludes that phosphorated carbohydrate is safe in the amounts usually taken (8 to 18 grams) orally. However, the Panel concludes that there is insufficient evidence to establish effectiveness of phosphorated carbohydrate as an antinauseant-antiemetic.

Phosphorated carbohydrate preparation consists of a solution containing invert sugar (a mixture of equimolar amounts of levulose and dextrose obtained by hydrolysis of sucrose) and phosphoric acid which is used to adjust the pH of the solution to a range of 1.5 to 1.6.

A mechanism that has been cited in support of the belief that a carbohydrate-phosphoric acid mixture relieves nausea and vomiting is its potential to inhibit gastric emptying as a consequence of inhibition of gastric peristalsis and a reduction in gastric tone. It has been reported that the high osmotic pressure exerted by concentrated solutions of simple sugars (monosaccharides) inhibits gastric emptying through an action on duodenal osmoreceptors which are sensitive to high osmotic pressures (Ref. 1). However, a positive correlation between an increase in gastric emptying time and relief of nausea and vomiting has not been established.

Only a few clinical studies have been reported on the use of a carbohydrate-phosphoric acid preparation for the management of nausea and vomiting. Most of these were either uncontrolled or partially controlled investigations (Refs. 2 through 4). In the only double-blind clinical investigation, the study was poorly designed (Ref. 5).

DATA PERTINENT FOR EFFECTIVENESS

The Panel concludes that well-controlled, properly designed clinical studies are needed to establish the effectiveness of the carbohydrate-phosphoric acid solution for the control of nausea or vomiting. (See paragraph G below for data pertinent for anti-emetic ingredient evaluation.)

REFERENCES

(1) Van Liere, E. J., D. W. Northrup and J. C. Stickney, "The Effect of Glucose on the Mobility of the Stomach and Small Intestine," Gastroenterology, 7:218-223, 1946.

(2) Bradley, J. E., L. Proutt, E. R. Shipley and R. H. Oster, "An Evaluation of Carbohydrate-Phosphoric Acid Solution in the Management of Vomiting", Journal of Pediatrics, 38:41-44, 1951.

(3) Crunden, A. B., Jr. and W. A. Davis, "The Oral Use of a Phosphorated Carbohydrate Solution in Nausea and Vomiting of Pregnancy," American Journal of Obstetrics and Gynecology, 65:311-313, 1953.

(4) Tebrock, H. E. and M. M. Fisher, "Nausea and Vomiting: Evaluation of an Orally Administered Phosphorated Carbohydrate Solution," Medical Times, 82: 271-275, 1954.

(5) Agerty, H. A., "A Phosphorated Carbohydrate Solution for the Prevention of Motion Sickness," Adult and Child, 1:66, 1969.

(d) *Zinc phenolsulfonate.* The Panel concludes that zinc phenolsulfonate is safe in amounts usually taken orally in OTC products, but there is no evidence to support its effectiveness as an antiemetic agent.

The Panel can find no evidence to support the claim that zinc phenolsulfonate alone or in combination in OTC products is an effective antiemetic or antinauseant. The claim that zinc phenolsulfonate is effective for the relief of "nausea," "indigestion," "gas," "fullness," "bloating," "pressure," and "upset stomach" is not supported by any carefully controlled clinical studies.

DATA PERTINENT FOR EFFECTIVENESS

Well-controlled, double-blind clinical trials are needed to compare the antiemetic effect of zinc phenolsulfonate, alone and if desired in combination, as compared with placebo and with an effective antiemetic. The response should be evaluated by objective changes in frequency of vomiting. Careful experimental design, definition of terms, and matching of subjects is needed to assess the effect on subject complaints of malaise and nausea. (See paragraph G below for data pertinent for antiemetic ingredient evaluation.)

F. PRODUCTS CONTAINING MULTIPLE ANTIEMETIC INGREDIENTS

1. *General statements.* a. The Panel noted the regulation (21 CFR 330.10(a)(4)(iv)) which states: "An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and when the combination, when used under adequate direction for use, and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population."

b. The Panel concludes that, in general, the fewer the ingredients, the safer and more rational the therapy. The Panel believes that the interests of the consumer are best served by exposing the user of OTC drugs to the fewest ingredients possible at the lowest possible dosage regimen consistent with a satisfactory level of effectiveness.

c. The Panel further concludes that OTC drugs should contain only such inactive ingredients that are necessary for pharmaceutical formulation.

2. *Requirement of significant contribution.* The Panel has further determined that each claimed active ingredient in the combination must make a significant contribution to the claimed effect. In the absence of data showing the minimum dose necessary to achieve the intended antiemetic effect, the amount of ingredient present in antiemetic products must be at least equal to the currently accepted minimum dose range for such active ingredients as set forth elsewhere in this document.

The Panel found it difficult to quantitate the contribution of each antiemetic ingredient in combinations, as is possible with antacid combination products, for example, where the contribution of each antacid can be determined by chemical titration. Further, the minimum effective dose may vary considerably with the cause of the vomiting. The Panel recognizes that it is possible that some ingredients may be proved to contribute to the effectiveness of a combination product in amounts below the generally recognized minimum effective daily dose.

The Panel concluded that where a combination product is permitted, it is sufficient to demonstrate, in well-controlled clinical trials that each of the ingredients makes a statistically significant contribution to the claimed effect.

As long as "statistical significance" is shown, the Panel concludes that a contribution toward antiemesis will also have been shown.

3. *Single active ingredients.* OTC drugs containing safe and effective single ingredients are preferred to those having multiple active ingredients because of the reduced risks of toxic effects, synergistic effects, allergic and/or idiosyncratic reactions, and possible unrecognized and undesirable drug interaction(s).

It is an established medical principle to give only those medications, preferably as single entities, necessary for the safe and effective treatment of the patient. This principle applies equally to self-medication. To add needlessly to the patient's medication increases the risk of adverse reactions.

4. *Active ingredients not reviewed by the Panel.* Each claimed active ingredient must be an ingredient that has been reviewed by the Panel. If a product contains an active ingredient that has not been reviewed by the Panel and consequently not found in this document, such ingredient is automatically classified as a Category II ingredient, i.e., it is not generally recognized as safe and/or effective. Appropriate animal and human testing and prior approval by the Food and Drug Administration is required before a product containing such an ingredient may be marketed.

5. *Review of submitted combination products.* The Panel considered only those combination products submitted pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) and included above in paragraph —. The Panel recognizes that other combination products may be in the marketplace but it has either no knowledge of such products, or insufficient data with respect to such products to make a reasonable judgment of safety and/or effectiveness.

Accordingly, the Panel recommends that any new combination, or any presently marketed combination not submitted to this Panel be evaluated through the new drug procedures, or be the subject of an appropriate petition to the Commissioner to review or amend the OTC antiemetic monograph.

6. *Category II combination product.* The Panel concludes that combinations of bismuth subsalicylate, aminoacetic acid, phenyl salicylate, and zinc pheniolsulfonate are safe in the amounts usually taken orally in OTC combination products, but there is no evidence that each of these four ingredients makes a significant contribution to the claimed antiemetic action of such combination.

Further, because any combination containing a Category II ingredient is classified as a Category II combination, the above combination is deemed a Category II product.

G. DATA PERTINENT FOR ANTIEMETIC INGREDIENT EVALUATION

When a drug is available for widespread use, as in OTC products, its safety and effectiveness must be well documented by toxicological data, data on the absorption, distribution, fate, and excretion of the drug, the pharmacological effects of the drug, and the mechanism of action. The drug should also meet certain effectiveness standards. The Panel recommends that information such as the following be submitted when relevant and pertinent to the drug under study: Toxicological data, absorption, distribution, fate, and excretion (ADFE) data, pharmacological effects, and effectiveness standards.

1. *Toxicological data.* A variety of toxicological data can be obtained to demonstrate that an antiemetic is safe. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding the safety of their products. The Panel recommends that data such as the following be required in preclinical animal studies and in clinical studies in man. Certain data on humans, such as lethal doses and chronic toxicity, will only be available from poison control centers, hospitals, medical centers, or medical examiners. However, the Panel considers such data important and attempts should be made to obtain them.

(a) *Preclinical animal studies.* (1) The oral LD_{50} should be established in several animal species.

(2) Determinations must be made to detect histologic and biochemical alterations in animals given lethal doses acutely or low doses chronically.

(3) Studies of teratogenicity and embryolethality are necessary. Studies of effects on fertility, delivery, and nursing offspring may also be indicated.

(b) *Clinical studies in man.* (1) Biochemical tests of liver and renal function and measurement of serum electrolytes after a therapeutic dose.

(2) Chronic toxicity studies in man.

(3) A clear record of unwanted drug effects. Substantial effort should be made to have physicians document side effects, especially those of serious nature.

(4) Minimal lethal dose by single oral ingestion and in divided doses when such data are available from accidental or deliberate overdosing.

(5) Maximal tolerated dose from single oral ingestion, or divided multiple oral ingestions, when such data are available from accidental or deliberate overdosing.

2. *Absorption, distribution, fate and excretion (ADFE) as determined by currently accepted methods.* Since ADFE bears directly on the safety of drugs and occasionally on the mechanism of action, appropriate data should be provided for all active ingredients and their metabolic products. The method for obtaining these data are established and are not different from those used in the study of other drugs: Data such as the following would provide sufficient information regarding ADFE. Manufacturers are not expected to obtain all of the following data, but are expected to obtain these data relevant to the unanswered questions regarding ADFE of their products:

a. The percentages of various oral doses of the drug which are absorbed in man.

b. The percentages of various oral doses of the drug which are excreted in the urine in man.

c. The metabolic fate in man of absorbed but unexcreted drug including studies on placental transfer and breast milk excretion.

d. The fate of unabsorbed drug in man.

e. The net bioavailability of the drug in man.

f. The ingredients and metabolic products associated with fecally excreted drug and/or its unabsorbed intraluminal biotransformation products.

g. The ingredients and metabolic products associated with renally excreted drug and/or its renally excreted biotransformation product.

3. *Effects.* The Panel recognizes the lack of physiological data on the gastrointestinal receptors and effectors of emesis and the related difficulty in establishing the mechanism of action of agents acting on either the central or autonomic nervous system or directly affecting gastric motility or tone. However, data should be provided which serve to elucidate the pharmacologic effects of antiemetic agents. The Panel recommends that data such as the following be obtained. Manufacturers are not expected to obtain all of the following data, but are expected to obtain those data relevant to the unanswered questions regarding pharmacologic effects of their products:

a. Effects of oral drug on nausea and vomiting.

b. Effects of oral drug on cardiovascular system (blood pressure and heart rate).

c. Effects of oral drug on autonomic nervous system.

d. Duration of oral drug effects.

e. Effects on drowsiness and the central nervous system.

4. *Effectiveness standards.* Motion sickness, which may occur when visual and vestibular stimuli are not in accord, may be induced by a number of techniques. Unusual motion patterns in which the head is rotated in two axes simultaneously will produce motion sickness in anyone; some individuals are more resistant than others, but none is immune. Motion sickness may also be induced when the body is stationary and the individual looks at a motion picture film as seen from an airplane doing acrobatics or a roller coaster ride (Ref. 1). Thus, a number of experimental models are available to test the effectiveness of antiemetic agents advocated for nausea and vomiting resulting from motion sickness. Both normal individuals and subjects with known susceptibility to motion sickness could be tested.

The threshold of stimulus (duration in time, rotation rate in r.p.m., and acceleration rate) to induce motion sickness should be determined before and after the test drug is administered to determine degree of effectiveness and duration of time of protection from motion sickness. Comparisons should be made

using the double-blind technique, with placebo and a known effective agent such as scopolamine. Manufacturers are not expected to obtain all of the data listed above, but are expected to obtain those data relevant to the unanswered questions regarding the effectiveness of their products. The effectiveness of drugs in vomiting due to causes other than motion sickness requires well-controlled clinical trials in homogenous groups of subjects with vomiting of relatively specific types such as that of radiation sickness, epidemic food or chemical poisoning, post-operative vomiting, epidemic gastroenteris, etc.

The experimental design for testing effectiveness of antiemetic may be of a number of different types. When the antiemetic product contains more than one active ingredient, the double-blind, Latin square, cross-ver design is particularly suited for testing the effectiveness of individual ingredients as well as comparing their effect against that of placebo. When it is impossible or impractical to devise an acceptable placebo, the antiemetic ingredient may be compared with another acceptable agent and studied in parallel groups. When experimental models of induced diarrhea are used, each subject can serve as his own control, but the period of study should be sufficiently long to clearly demonstrate differences.

REFERENCES

(1) Brown, J. L., Best and Taylor 9th Ed., Edited by John R. Brobeck, Chap. 8; p. 60–61, Williams & Wilkins, 1973.

IV. EMETICS

Pursuant to the notice published in the FEDERAL REGISTER of February 8, 1973 (38 FR 3614) requesting the submission of data and information on OTC emetic drugs, no submissions were made. Although the Panel received no submissions from the pharmaceutical industry or other source, it elected to review ipecac syrup as an OTC emetic drug.

A. CLASSIFICATION OF ACTIVE INGREDIENTS INTO CATEGORIES

The Panel reviewed one ingredient pursuant to the standards for safety, effectiveness and truthful labeling. In accordance with the regulation (21 CFR 330.10), the Panel's findings are set forth below:

B. REVIEW OF ACTIVE INGREDIENT

1. *Conditions under which emetic products are generally recognized as safe and effective and not misbranded.* The following ingredient was classified as safe and effective and not misbranded:

IPECAC SYRUP

The Panel concludes that ipecac syrup is safe and effective when used in the recommended dose of 15 milliliters in persons above 1 year of age and 5 to a maximum 10 milliliters in infants under 1 year.

An emetic is often used to induce vomiting in poisoning victims, who ingest systemic poisons, in order to prevent absorption of the chemicals from the gastrointestinal tract. The Panel believes that the most effective and dependable emetic for use in the home is ipecac syrup.

Ipecac syrup is prepared from powered ipecac, which is obtained from the plant Cephaelis ipecacuanha. The syrup contains the emetic alkaloids emetine and cephaeline. These emetic principles probably act both centrally and locally in the gastrointestinal tract to cause vomiting. An overdose of an ipecac preparation may cause serious poisoning.

The recommended effective and safe emetic dose of ipecac syrup for persons over 1 year of age is 15 milliliters. This dose usually induces vomiting within 20 minutes, but in the event emesis does not occur by this time, it is recommended that a similar dose be repeated once. The ipecac should be recovered by gastric lavage if emesis does not occur after the second dose. The OTC product container should not contain more than 30 milliliters of ipecac syrup.

LABELING

Labeling should identify the product as an "emetic to induce emesis (vomiting) in case of poisoning" and state the following:

(1) Before using, call physician, Poison Control Center, or hospital emergency room for advice. (2) Do not use in unconscious persons. (3) *Caution:* If emesis (vomiting) does not occur after a repeated dose or after the first dose if a second dose is not given, the ipecac should be recovered by gastric lavage. (4) Ordinarily, this drug should not be used if strychnine, corrosive [alkalies (lye) and strong acids], or petroleum distillates (kerosene, gasoline, paint thinner, or cleaning fluid) have been ingested.

REFERENCES

(1) Cashman, T. M. and H. C. Shirkey, "Emergency Management of Poisoning," Pediatric Clinics of North America, 17:525–534, 1970.

(2) The Pharmacopeia of the United States of America, 18th Rev., The United States Pharmacopeial Convention, Inc., Washington, D.C., Mack Printing Co., Easton, Pa., p. 345, 1970.

(3) Robertson, W. O., "Syrup of Ipecac—A Slow or Fast Emetic?," American Journal of Diseases of Children. 103:136–139, 1962.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 404)) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes that Subchapter D be amended by adding new Parts 334, 335, 336 and 337 to read as follows:

PART 334—LAXATIVE PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

AUTHORITY: Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1055–56 as amended by 72 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371), and Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 554, 702, 703, 704)).

Subpart A—General Provisions

§ 334.1 Scope.

An over-the-counter laxative product in a form suitable for oral or rectal administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

§ 334.3 Definitions.

As used in this part:

(a) *Adequate liquid intake.* The ingestion of a full glass (8 oz.) of liquid with each dose.

(b) *Age (dosage) range.* Infant (not more than 2 years), child (2 years and over but not more than 12 years), and adult (12 years and over).

(c) *Bulk forming laxative.* An agent that promotes the evacuation of the bowel by increasing bulk volume and water content of the stools.

(d) *Constipation.* Infrequent or difficult bowel movement.

(e) *Hyperosmotic laxative.* An agent that attracts water into the stool.

(f) *Laxative.* Any agent used for the relief of constipation.

(g) *Lubricant laxative.* An agent that lubricates the contents of the intestinal tract, promoting easier bowel movements.

(h) *Oral Dosage.* The dosage range (minimum and maximum amounts) that is generally recognized as safe and effective by mouth.

(i) *Rectal dosage.* The dosage range (minimum and maximum) that is generally recognized as safe and effective by rectum.

(j) *Saline laxative.* An agent that increases water in the intestine thereby promoting bowel movement.

(k) *Short-term use.* Use of a laxative for no longer than a 1 week period.

(l) *Stimulant laxative.* An agent that promotes bowel movement by one or more direct actions on the intestine.

(m) *Stool softener laxative.* An agent that penetrates and softens the stool.

Subpart B—Active Ingredients

§ 334.10 Bulk forming laxatives.

The active ingredients of the product consist of the following when used within the dosage limit established for each ingredient:

(a) *Bran, dietary.* Usual oral dosage is 6 gm to 14 gm daily accompanied by adequate liquid intake; however, no upper dosage limitation is indicated.

(b) *Cellulose derivatives, semi-synthetic (methylcellulose, sodium carboxymethylcellulose).* Adult oral dosage is 4 gm to 6 gm daily accompanied by adequate liquid intake. Children over 6 years oral dosage is 1 gm to 1.5 gm daily accompanied by adequate liquid intake.

(c) *Karaya (sterculia gum).* Oral dosage is 5 gm to 10 gm daily accompanied by adequate liquid intake.

(d) *Malt soup extract.* Adult oral dosage is 12 gm to 64 gm daily accompanied by adequate liquid intake. Infants (not more than 2 years) oral dosage is 6 gm to 32 gm daily accompanied by adequate liquid intake.

(e) *Polycarbophil.* Adult oral dosage is 4 gm to 6 gm daily accompanied by adequate liquid intake. Infants (not more than 2 years) oral dosage is 0.5 gm to 1.0 gm, children (2 to 5 years) oral dosage is 1.0 gm to 1.5 gm, children (6 to 12 years) oral dosage is 1.5 gm to 3.0 gm accompanied by adequate liquid intake.

(f) *Psyllium preparations [Plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophyllic mucilloid (psyllium hydrocolloid), psyllium seed, psyllium seed (blond), psyllium seed husks].* Adult oral dosage is 2.5 gm to 30 gm daily accompanied by adequate liquid intake. Children 6 to 12 years oral dosage is 1.25 gm to 15.0 gm daily accompanied by adequate liquid intake. No pediatric dose for under 6 years.

§ 334.12 Hyperosmotic laxatives.

The active ingredients of the product consists of the following when used within the dosage limit established for each ingredient:

(a) *Glycerin.* Adult rectal dosage is 3 gm suppository or 5 ml to 15 ml enema. Children under 6 years rectal dosage is 1 gm to 1.5 gm suppository or 2 ml to 5 ml enema.

(b) *Sorbitol.* Adult rectal dosage is 120 ml as a 25 to 30 percent weight/volume solution. Children 2 years and older rectal dosage is 30 ml to 60 ml as a 25 to 30 percent weight/volume solution.

§ 334.14 Lubricant laxatives.

The active ingredients of the product consists of the following when used within the dosage limit established for the ingredient:

(a) *Mineral oil, plain.* Adult oral dosage is 15 ml to 45 ml and children over 6 years oral dose is 10 ml to 15 ml taken only at bedtime; adult rectal dosage is 120 ml and children 3 years and older rectal dose is 60 ml.

(b) *Mineral oil, emulsion.* Adult oral dosage is 15 ml to 45 ml of mineral oil component of emulsion administered orally twice daily with the first dose taken on arising and the second dose taken at bedtime and neither dose at mealtimes; and children over 6 years oral dosage is 0.25 ml and 5 ml of mineral oil component of emulsion administered orally twice daily with the first dose taken on arising and the second dose taken at bedtime and neither dosage at mealtimes.

§ 334.16 Saline laxatives.

The active ingredients of the product consists of the following when used within the dosage limit established for each ingredient:

(a) *Magnesium citrate.* (1) Adult oral daily dosage taken in divided doses is 11 gm to 18 gm (77 to 126 mEq magnesium ion). Children 2 to 5 years oral daily dosage is 2.5 gm to 5 gm and children 6 years and older oral daily dosage is 5 gm to 10 gm taken in divided doses.

(2) Magnesium citrate products may be formulated in combinations with sequestering agents, citric acid and anhydrous sodium citrate, to allow magnesium to be held in solution as a complex. Citric acid and anhydrous sodium citrate are not laxative agents and shall not be claimed as active ingredients on the labeling.

(b) *Magnesium hydroxide.* Adult oral daily dosage taken in divided doses is 2.4 gm to 4.8 gm (82 to 164 mEq magnesium ion). Children 2 to 5 years oral daily dosage is 0.4 gm to 1.2 gm and children 6 years and older oral daily dosage is 1.2 gm to 2.4 gm taken in divided doses.

(c) *Magnesium sulfate.* Adult oral daily dosage taken in divided doses is 10 gm to 30 gm (81 to 243 mEq magnesium ion). Children 2 to 5 years oral daily dosage is 2.5 gm to 5 gm and children 6 years and older oral daily dosage is 5 gm to 10 gm taken in divided doses.

(d) *Phosphate salts (combined sodium biphosphate, sodium phosphate, disodium phosphate and monosodium phosphate).* Total adult oral daily combined amount is 9.6 gm to 19.2 gm [210 to 420 mEq (biphosphate ion)] sodium biphosphate, 3.6 gm to 7.2 gm [40 to 80 mEq (phosphate ion)] sodium phosphate, 1.9 gm to 3.8 gm [40 to 80 mEq (phosphate ion)] disodium phosphate, and 8.3 gm to 16.6 gm [208 to 415 mEq (phosphate ion)] monosodium phosphate. Total adult rectal single combined amount is 19.2 gm [420 mEq (biphosphate ion)] sodium biphosphate, 7.2 gm [80 mEq (phosphate ion)] sodium phosphate, 3.8 gm [80 mEq (phosphate ion)] disodium phospate and 16.6 gm [415 mEq (phosphate ion)] monosodium phosphate. The usual oral dosage for children 5 to 10 years of age is ¼ adult dosage of phosphate salts; for children over 10 years usual oral dosage is ½ adult dosage of phosphate salts. The usual rectal dosage for children over 2 years is ½ adult dosage of phosphate salts.

§ 334.18 Stimulant laxatives.

The active ingredients of the product consists of the following when used within the dosage limit established for each ingredient:

(a) *Aloe.* Adult oral dosage is 120 mg to 250 mg daily. Children 6 to 8 years oral dosage is 40 mg to 80 mg daily. Adolescent 8 to 15 years oral dosage is 80 mg to 120 mg daily. No pediatric dosage under 6 years.

(b) *Bisacodyl.* Adult oral dosage is 5 mg to 15 mg and children over 3 years oral dose is 5 mg at bedtime in enteric coated dosage form. Adult rectal suppository dosage is 10 mg and children under 2 years 5 mg.

(c) *Cascara sagrada preparations (aromatic cascara fluidextract, cascara sagrada bark, cascara sagrada fluidextract, cascara sagrada extract, casanthranol).* (1) Adult oral daily dosage of aromatic cascara fluidextract is 2 ml to 6 ml. Infants (not more than 2 years) oral daily dose is 1 ml to 2 ml.

(2) Adult oral daily dosage of cascara sagrada bark is 300 mg to 1.0 gm.

(3) Adult oral daily dosage of cascara sagrada fluidextract is 0.5 ml to 1.5 ml.

(4) Adult oral daily dosage of cascara sagrada extract is 200 mg to 400 mg.

(5) Adult oral daily dosage of casanthranol is 30 mg to 90 mg.

(6) For all Cascara sagrada preparations the usual infant dose is ¼ adult dose; usual childhood dose is ½ adult dose.

(d) *Castor oil.* Adult oral dosage is 15 ml to 60 ml in a single dose. Infants not more than 2 years oral dosage is 1 ml to 5 ml in a single dose. Children 2 years and over but not more than 12 years oral dosage is 5 ml to 15 ml in a single dose.

(e) *Danthron.* Adult oral dosage is 75 mg to 150 mg daily. No pediatric dosage for children under 12 years.

(f) *Dehydrocholic acid.* Adult oral dosage is 750 mg to 900 mg daily in divided doses. No pediatric dosage for children under 12 years.

(g) *Phenolphthalein (white phenolphthalein, yellow phenolphthalein).* Adult oral dosage is 30 mg to 270 mg daily in single or divided dose. Children 2 to 5 years oral dosage is 15 mg to 30 mg in single or divided dose. Children 6 years to 12 years oral dosage is 30 mg to 60 mg in single or divided dose.

(h) *Senna preparations (senna leaf powder, senna fluidextract, senna fruit extract, senna syrup, sennosides A & B crystalline, senna pod concentrate).* (1) Adult oral daily dosage of senna leaf powder is 2 gm in a single dose.

(2) Adult oral daily dosage of senna fluidextract is 2 ml in a single dose.

(3) Adult oral daily dosage of senna fruit extract is 3.4 gm to 4 gm in a single dose.

(4) Adult oral daily dosage of senna syrup is 8 ml in a single dose.

(5) Adult oral daily dosage of sennosides A and B is 12 mg to 36 mg in a single dose.

(6) Adult oral dosage of senna pod concentrate is 0.6 gm to 1.0 gm per dose 1 to 4 times daily.

(7) The usual childhood dose of senna preparations is ⅛ adult dose for infants (not more than 2 years), ¼ adult dose for children 1 to 5 years, and ½ adult dose for children 6 to 12 years.

§ 334.20 Stool softener laxatives.

The active ingredients of the product consist of the following when used within the dosage limit established for each ingredient:

(a) *Dioctyl calcium sulfosuccinate.* Adult oral dosage is 50 mg to 360 mg daily. Infants (not more than 2 years) oral dosage is 25 mg daily. Children 2 years and over but not more than 12 years oral dosage is 50 to 150 mg daily.

(b) *Dioctyl pitassium sulfosuccinate.* Adult rectal dosage is 50 mg to 250 mg daily. Children 2 years and over but not more than 12 years rectal dosage is 100 mg daily.

(c) *Dioctyl sodium sulfosuccinate.* Adult oral dosage is 50 mg to 360 mg daily. Infants (not more than 2 years) oral dosage is 20 to 25 mg daily. Children 2 years and over but not more than 12 years oral dosage is 50 to 125 mg daily.

§ 334.22 Miscellaneous laxative.

The active ingredient of the product consists of the following when used within the dosage limit established: (a) *Released carbon dioxide from combined sodium biphosphate anhydrous, sodium acid pyrophosphate and sodium bicarbonate.* Adult rectal dose is 1.2 gm to 1.5 gm sodium biphosphate anhydrous, 0.04 gm to 0.05 gm sodium acid pyrophosphate and 1.0 gm to 1.5 gm sodium bicarbonate releasing approximately 230 ml carbon dioxide per moistened suppository. No pediatric dosage for childern under 12 years. The suppository is moistened by placing under a water tap for about 30 seconds or by immersing in a cup of water for at least 10 seconds prior to rectal insertion.

§ 334.30 Combinations of active laxative ingredients.

The active laxative ingredients of the product consist of the combination of ingredients permitted in § 334.32 within the dosage range for such active ingredients established in § 334.10, 334.12, 334.14, 334.16, 334.18 or § 334.20 and meet the laxative combination criteria established in § 334.31.

§ 334.31 Laxative combination criteria.

(a) The sum of the percentages of the effective range dosage (EDR) determined in paragraph (b) of this section for each active ingredient in the combinations permitted in § 334.32 shall not exceed 100 percent.

(b) The method used for determining the EDR percentage value of each active ingredient is as follows:

$$\frac{\text{L max d—EDR (min)}}{\text{EDR (max)—EDR (min)}} 100 = \%\ \text{EDR of each ingredient}$$

where:

(1) L max d is the labeled maximum daily dosage for the product,

(2) EDR (min) is the effective range dosage minimum of the monograph, and EDR (max) is the effective range dosage maximum of the monograph for the active ingredient established in this Subpart B of such ingredient established in §§ 334.10, 334.12, 334,14, 334.16, 334.18 or 334.20.

§ 334.32 Permitted active ingredient combinations.

(a) *Oral dosage forms.* (1) Dioctyl calcium sulfosuccinate and danthron.

(2) Dioctyl sodium sulfosuccinate and casanthranol.

(3) Dioctyl sodium sulfosuccinate and danthron.

(4) Dioctyl sodium sulfosuccinate and phenolphthalein.

(5) Cascara sagrada and aloe.

(6) Cascara sagrada and magnesium hydroxide.

(7) Cascara sagrada and phenolphthalein.

(8) Malt soup extract and blond psyllium seed.

(9) Malt soup extract and blond psyllium seed husks.

(10) Mineral oil and casanthranol.

(11) Mineral oil and cascara sagrada.

(12) Mineral oil and cascara sagrada fluidextract.

(13) Mineral oil (emulsified) and magnesium hydroxide.

(14) Mineral oil and phenolphthalein.

(15) Mineral oil and psyllium seed.

(16) Plantago ovata husk and methylcellulose.

(17) Psyllium and senna concentrate.

(18) Senna concentrate and dioctyl sodium sulfosuccinate.

(19) Sodium carboxymethylcellulose and dioctyl sodium sulfosuccinate.

(b) *Rectal dosage forms.* (1) Glycerin and dioctyl potassium sulfosuccinate.

(2) Sorbitol and dioctyl potassium sulfosuccinate.

§ 334.35 Combinations with nonlaxative active ingredients.

(a) The antacid ingredient, sodium bicarbonate, identified in § 331.11(k)(1) of this chapter may be combined with monosodium phosphate identified in § 334.16(c) for purposes of product formulation (effervescence) but is not an active ingredient when used for this purpose.

Subpart C—[Reserved]

Subpart D—Labeling

§ 334.50 Labeling of laxative products.

(a) *Indications.* (1) The labeling shall identify the product as a "laxative" for the "short-term relief of constipation." The appropriate definition(s) describing the action of the active ingredient(s) as set forth in § 334.3 shall appear on the label. Products combining 2 laxative ingredients with differing modes of action shall identify both modes of action in the labeling of the product.

(2) Products containing magnesium hydroxide may be labeled as both an antacid and a laxative. No claims of superior laxation on the basis of the antacid properties shall be made.

(3) Rectal suppository products releasing carbon dioxide shall describe the mode of action as a gentle pressure in the rectum from expanding gas thereby promoting bowel movement.

(b) *Directions for use.* The labeling of the product contains the recommended dosage and appropriate directions identified under §§ 334.10, 334.12, 334.14, 334.16, 334.18, 334.20 or 334.22, under the heading "Directions," per time interval, e.g., every 4 hours, or other time period, e.g., once daily or at bedtime broken down by age groups if appropriate followed by "or as directed by a physician."

(c) *Warnings.* The labeling of the product contains the appropriate warning(s) under §§ 334.52, 334.54, 334.56, 334.58, 334.60, 334.62, or 334.64 and the following general warning(s) under the heading "Warnings", which may be combined with warnings for specific ingredients to eliminate duplicative words or phrases so the resulting warning is clear and understandable:

(1) "Do not use this product when abdominal pain, nausea, or vomiting are present."

(2) "If you have noticed a sudden change in bowel habits that persist over a period of 2 weeks, consult a physician before using a laxative."

(3) "This product should not be used for a period of longer than 1 week except under the advice and supervision of a physician."

(4) For products containing more than 15 mEq (345 mg) sodium in the maximum recommended daily dose:

(i) "Do not use this product except under the advice and supervision of a physician if you are on a low salt diet."

(ii) "Do not use this product except under the advice and supervision of a physician if you have kidney desease."

(5) For products containing more than 25 mEq (975 mg) potassium in the maximum recommended daily dose: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

(6) For products containing more 50 mEq (600 mg) magnesium in the maximum recommended daily dose: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

(d) *Drug interaction precautions.* The labeling of the product, where appropriate under §§ 334.52, 334.56 or 334.62, contains drug interaction precautions, under the heading "*Drug Interaction Precautions.*"

(e) *Statement of sodium content.* A product containing more than 1.0 mEq (23 mg) sodium per maximum daily dose shall be labeled as to the sodium content per dosage unit.

§ 334.52 Bulk forming laxatives.

(a) *Warnings.* The labeling of the product contains the following warnings, under the heading *"Warnings":*

(1) *"Caution:* Drink a full glass (8 oz.) of liquid with each dose."

(2) For products containing karaya (sterculia gum): "Drink a full glass (8 oz.) of liquid immediately with each dose."

(b) *Drug interaction precautions.* For products containing cellulose derivatives: "This product may combine with certain other drugs. Do not take this product if you are presently taking salicylates or a prescription drug."

§ 334.54 Hyperosmotic laxatives.

The labeling of the product contains the following warnings under the heading *"Warnings":*

(a) For products containing glycerin:

(1) "For rectal use only and not for oral use. Large doses of glycerin if taken orally can lead to serious toxic effects."

(2) *"Caution:* Glycerin administered rectally may produce in some individuals rectal discomfort or a burning sensation."

(b) For products containing sorbitol: "For rectal use only."

§ 334.56 Lubricant laxatives.

The labeling of the product contains the following warnings under the heading *"Warnings":*

(a) For products containing mineral oil (plain) to be used orally:

(1) *"Caution:* To be taken only at bedtime. Do not administer orally to infants or to children under 6 years of age, to pregnant women, to bedridden or aged patients, to persons with difficulty in swallowing, to persons having recent episode of vomiting or regurgitation, or to persons having abdominal pain."

(2) *Drug Interaction precaution.* "Do not take this product if you are presently taking a stool softener laxative."

(b) For products containing mineral oil (emulsion) to be used orally:

(1) *"Caution:* Do not administer orally to infants or to children under 6 years of age, to pregnant women, to bedridden or aged patients, to persons with difficulty in swallowing, to persons having recent episodes of vomiting or regurgitation, or to persons having abdominal pain."

(2) *Drug interaction precaution.* "Do not take this product if you are presently taking a stool softener laxative."

§ 334.58 Saline laxatives.

The labeling of the product contains the following warnings under the heading *"Warning":*

(a) "For occasional use only. Serious side effects from prolonged use or overdosage may occur."

(b) For products containing magnesium citrate solution: "Store this product in a cold place (refrigerator temperature) to retard decomposition."

(c) For products containing phosphates:

(1) "Do not take this product except under the advice and supervision of a physician if you have kidney disease."

(2) For oral preparations: "Do not give to children under 6 years of age except under the advice and supervision of a physician."

(3) For rectal preparations: "Do not give to children under 2 years of age except under the advice and supervision of a physician."

§ 334.60 Stimulant laxatives.

The labeling of the product contains the following warnings, under the heading *"Warnings":*

(a) For all products containing stimulant laxatives:

(1) *"Caution:* Prolonged or continued use of this product can lead to laxative dependency and loss of normal bowel function."

(2) "Serious side effects from prolonged use or overdose can occur."

(3) "This product should be used only occasionally, but in any event no longer than daily for 1 week, except on the advice of a physician."

(b) For products contains bisacodyl:

(1) "Do not chew."

(2) "Do not give to children under 3 years of age or to persons who cannot swallow without chewing."

(3) *"Caution*—Do not take this product within 1 hour after taking an antacid and/or milk."

(4) "This product may cause abdominal discomfort, faintness, rectal burning and mild cramps."

(5) "Store in a cool place at temperatures not above 86° F (30° C)."

(c) For products containing castor oil:

(1) "For the treatment of isolated episodes of constipation."

(2) "Do not take this product on a daily basis except under the advice and supervision of a physician."

(3) *"Caution:* Castor oil affects the small intestine and regular use may cause excessive loss of water, and body salts, which can have debilitating effects".

(d) For products containing phenolphthalein: *"Caution:* If a skin rash appears, do not use this product or any other preparation containing phenolphthalein."

§ 334.62 Stool softener laxatives.

(a) For all products containing stool softener laxatives the labeling of the product contains the following warnings, under the heading *"Warnings": "Caution:* This product should be used only occasionally but in any event no longer than daily for 1 week."

(b) Drug interaction precaution: "Do not take this product if you are presently taking a prescription drug or mineral oil."

§ 334.64 Miscellaneous laxative.

For products providing for release of carbon dioxide from a rectal suppository dosage form the labeling of the product contains the following warnings, under the heading *"Warnings":*

(a) "For rectal use only."

(b) "Do not lubricate with mineral oil or petrolatum jelly prior to rectal insertion."

(c) "Rectal bleeding or failure to evacuate may indicate a serious condition and a physician should be consulted."

§ 334.80 Professional labeling.

The labeling of the product provided to health professionals (but not to the general public):

(a) For products containing phosphates:

(1) "Do not use in patients with megacolon, as hypernatremic dehydration may occur. Use with caution in patients with impaired renal functions as hyperphosphatemia and hypocalcemia may occur."

(2) Shall provide the total dose of sodium in mEq (mg) per standard dose.

(b) For products containing mineral oil:

(1) May contain as an additional indication, "For the preparation of the colon for x-ray and endoscopic examination."

(2) Shall contain the following: "Side effects with the proper use of mineral oil are few. However, with chronic use and particularly with excess dosage, laxation, anal leakage and dermatologic reactions may occur. Owing to its property as a lipid solvent, liquid paraffin (mineral oil) may interfere with the absorption of provitamin A, vitamin A, and vitamin D leading to impairment of calcium and phosphorus metabolism. This occurs only under conditions of chronic usage. Administration of mineral oil may lower prothrombin levels, probably secondary to impaired vitamin K absorption, and regular use in pregnancy may predispose to hemorrhagic disease of the newborn. Because of possible interference with nutrition, mineral oil should not be ingested in close proximity to meals. These side effects occur very rarely and then only with chronic and abusive use."

(c) For products containing castor oil: May contain as an additional indication, "For the preparation of the colon for x-ray and endoscopic examination."

(d) For products containing karaya (sterculia gum):

(1) "Warnings: Rare cases of allergic reactions and urticaria caused by karaya have been reported."

(2) "Inadequate fluid intake may cause large bowel obstructions."

(e) For products containing senna: may contain as additional indication, "For the preparation of the colon for x-ray and endoscopic examination."

(f) For products containing bisacodyl: May contain additional indications, "For use in preparation of the patient for surgery or for preparation of the colon for x-ray and endoscopic examination."

PART 335—ANTIDIARRHEAL PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—[Reserved]

Subpart D—Labeling

335.50 Labeling for antidiarrheal products.

AUTHORITY: Federal Food, Drug and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1055–56 as amended by 72 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371), and Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243, as amended; (5 U.S.C. 553, 554, 702, 703, 704))).

Subpart A—General Provisions

§ 335.1 Scope.

An over-the-counter antidiarrheal product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

§ 335.3 Definitions.

As used in this part:

(a) *Diarrhea.* The abnormally frequent passage of watery stools, self limiting (24–48 hours) usually with no identifiable cause.

(b) *Antidiarrheal.* An agent that is effective for the treatment of diarrhea.

Subpart B—Active Ingredients

§ 335.10 Antidiarrheal active ingredients.

The active ingredient of the product consists of the following when used within the dosage limit established for each ingredient:

(a) *Opiates—opium powder, tincture of opium, paregoric (camphorated tincture of opium).* (1) Adult oral dosage equivalent to 15 mg to 20 mg opium per unit dose or 1.5 mg to 2.0 mg of morphine per unit dose 1 to 4 times a day not to exceed 2 days use. Children 6 to 12 years oral dosage equivalent to 5 mg to 10 mg opium per unit dose or 0.5 mg to 1.0 mg morphine per unit dose 1 to 4 times a day not to exceed 2 days use.

(2) Shall apply to antidiarrheal products pursuant to the requirements identified in § 329.20(a) of this chapter.

(b) *Polycarbophil:* Adult oral dosage is 4 gm to 6 gm daily. Infants (not more than 2 years) oral dosage is 0.5 gm to 1.0 gm daily. Children 2 to 5 years oral dosage is 1 gm to 1.5 gm daily and over 5 years oral dosage is 1.5 gm to 3.0 gm daily.

Subpart C—[Reserved]

Subpart D—Labeling

§ 335.50 Labeling of antidiarrheal products.

(a) *Indications.* The labeling shall identify the product as an "antidiarrheal" for the treatment of diarrhea.

(b) *Directions for use.* The labeling of the product contains the recommended dosage and appropriate directions identified under § 335.10, under the heading "Directions", per time interval, e.g., every 4 hours or other time period, e.g., twice daily, broken down by age groups if appropriate, followed by "except under the advice or supervision of a physician."

(c) *Warnings.* The labeling of the product contains the following warning(s) under the heading "Warnings":

(1) "Do not use for more than 2 days or in the presence of high fever, or in infants or children under 3 years unless directed by a physician."

(2) Products containing opiates (opium powder, tincture of opium, paregoric (camphorated tincture of opium)) shall contain the labeling requirements identified in § 329.10 of this chapter.

(3) For products containing more than 15 mEq (345 mg) sodium in the maximum recommended daily dose:

(i) "Do not use this product except under the advice and supervision of a physician if you are on a low salt diet."

(ii) "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

(4) For products containing more than 25 mEq (975 mg) potassium in the maximum recommended daily dose: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

(5) For products containing more than 50 mEq. (600 mg) magnesium in the maximum recommended daily dose: "Do not use this product except under the advice and supervision of a physician if you have kidney disease."

(d) *Statement of sodium content.* A product containing more than 1.0 mEq (23 mg) sodium per maximum daily dose shall be labeled as to the sodium content per dosage unit.

PART 336—ANTIEMETIC PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

336.1 Scope.

Subpart B—Active Ingredients

336.10 Antiemetic active ingredients.

Subpart C—[Reserved]

Subpart D—Labeling

336.50 Labeling for antiemetic products.

AUTHORITY: Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1055–56 as amended by 72 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371), and Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 554, 702, 703, 704))).

Subpart A—General Provisions

§ 336.1 Scope.

An over-the-counter antiemetic product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

Subpart B—Active Ingredients

§ 336.10 Antiemetic active ingredients.

The active ingredients of the product consists of the following when used within the dosage limit established for each ingredient.

(a) *Cyclizine.* Adult oral dosage is 50 mg to 200 mg daily. Children 6 to 12 years oral dosage is 25 mg up to 3 times daily.

(b) *Dimenhydrinate.* Adult oral dosage is 200 mg to 400 mg daily in 4 divided doses. Children 2 to 6 years oral dosage is 12.5 mg to 25 mg up to 3 times daily and children over 6 years oral dosage is 25 mg up to 3 times daily.

(c) *Meclizine.* Adult oral dosage is 25 mg to 50 mg once daily.

Subpart C—[Reserved]

Subpart D—Labeling

§ 336.50 Labeling of antiemetic products.

(a) *Indications.* The labeling shall identify the product as a "antiemetic" for the "treatment of nausea and vomiting associated with motion sickness."

(b) *Directions for Use.* The labeling of the product contains the recommended dosage and appropriate directions identified under § 336.10, under the heading "Directions", per time interval or other time period, (e.g., 4 times daily), broken down by age groups if appropriate, followed by "except under the advice or supervision of a physician."

(c) *Warnings.* The labeling of the product contains the following warning(s) under the heading "Warnings":

(1) "Drowsiness sometimes occurs while taking this product." "Do not operate motor vehicles or other machinery while taking this product."

(2) "Do not take this product in the presence of glaucoma or enlargement of the prostate gland, except under the advice and supervision of a physician."

(3) For products containing cyclizine: "Do not give to children under 6 years of age except under the advice and supervision of a physician."

(4) For products containing meclizine: "Do not give to children under 12 years of age except under the advice and supervision of a physician."

PART 337—EMETIC PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

337.1 Scope.

Subpart B—Active Ingredient

337.10 Emetic active ingredient.

Subpart C—[Revised]

Subpart D—Labeling

337.50 Labeling for emetic products.

AUTHORITY: Federal Food, Drug and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–42 as amended, 1055–56 as amended by 72 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371), and Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243, as amended; (5 U.S.C. 553, 554, 702, 703, 704))).

Subpart A—General Provisions

§ 337.1 Scope.

An over-the-counter emetic product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.

Subpart B—Active Ingredients

§ 337.10 Emetic active ingredient.

The active ingredient of the product consists of the following when used within the dosage limit established:

(a) *Ipecac syrup.* (1) Oral dosage is 15 ml above 1 year of age. Infants under 1 year of age oral dosage is 5 ml to maximum 10 ml. If emesis (vomiting) does not occur within 20 minutes, a similar dose is repeated once.

(2) The OTC product container shall not contain more than 30 ml of ipecac syrup.

Subpart C—[Reserved]

Subpart D—Labeling

§ 337.50 Labeling of emetic products.

(a) *Indications.* The labeling shall identify the product as an "emetic" to "induce vomiting (emesis) in case of poisoning."

(b) *Directions for use.* The labeling of the product contains the recommended dosage and appropriate directions identified under § 336.10, under the heading "Directions", followed by "except under the advice or supervision of a physician".

(c) *Warnings.* The labeling of the product contains the following warnings, under the heading *"Warnings"*:

(1) "Before using, call physician, Poison Control Center, or hospital emergency room for advice."

(2) "Do not use in unconscious persons."

(3) *"Caution:* If vomiting (emesis) does not occur after a repeated dose or after the first dose if a second dose is not given the ipecac should be recovered by gastric lavage."

(4) "Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, paint thinner, or cleaning fluid have been ingested."

Interested persons are invited to submit their comments in writing (preferably in quintuplicate) regarding this proposal on or before June 19, 1975. Such comments should be addressed to the Office of the Hearing Clerk, Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20852, and may be accompanied by a memorandum or brief in support thereof. Additional comments replying to any comments so filed may also be submitted on or before Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: March 11, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc. 75-6855 Filed 3-20-75;8:45 am]

federal register

FRIDAY, MARCH 21, 1975

WASHINGTON, D.C.

Volume 40 ■ Number 56

PART III

DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended (40 U.S.C. 276a)) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determinations by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138), and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR, Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and supersedeas decisions to General Wage Determination Decisions.. Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended (40 U.S.C. 276a)), and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138), and of Secretary of Labor's Orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR, Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

NEW GENERAL WAGE DETERMINATION DECISIONS

Pennsylvania	PA75-3021
South Carolina	SC75-1038

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

Alaska:	
AK75-5033	Mar. 7, 1975
Florida:	
FL75-1009; FL75-1010; FL 75-1011	Jan. 24, 1975
FL75-1016	Jan. 31, 1975
FL75-1024	Feb. 21, 1975
Hawaii:	
HI75-5002	Jan. 24, 1975
Idaho:	
ID75-5024	Feb. 21, 1975
Indiana:	
IN75-2039	Do.
Iowa:	
IA75-4034; IA75-4036; IA 75-4037; IA75-4042	Jan. 31, 1975
Louisiana:	
LA75-4033	Jan. 24, 1975
Maryland:	
MD75-3003	Jan. 3, 1975
Nevada:	
AR-1058; AR-1059	Dec. 20, 1975
New York:	
AR-2063	Oct. 11, 1974
Pennsylvania:	
AQ-2081	Mar. 29, 1974
Texas:	
TX75-4007	Jan. 17, 1975
TX75-4020; TX75-4022; TX 75-4025; TX75-4029	Jan. 24, 1975
TX75-4047	Feb. 7, 1975
TX75-4056	Feb. 28, 1975
Washington:	
WA75-5025	Feb. 21, 1975

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State.

Supersedeas Decision numbers are in parentheses following the numbers of the decision being superseded.

Alabama:	
AL75-1028 (AL75-1032)	Feb. 28, 1975
Arizona:	
AR-1009 (AZ75-5035); AR-1010 (AZ75-5036)	Aug. 9, 1975
Florida:	
AQ-4100 (FL75-1034)	Apr. 12, 1974
AQ-4121 (FL75-1035)	June 7, 1974
AR-4026 (FL75-1037)	Aug. 30, 1974
Illinois:	
AR-3175 (IL75-2051)	Dec. 13, 1974
Iowa:	
AR-74 (IA75-4066)	Nov. 1, 1975
Pennsylvania:	
PA75-3018 (PA75-3025)	Feb. 21, 1975

Signed at Washington, D.C., this 14th day of March 1975.

RAY J. DOLAN,
Assistant Administrator,
Wage and Hour Division.

STATE: Pennsylvania COUNTIES: Cameron, Clarion, Clearfield, Jefferson
DECISION NO.: 75-PA-3021
DESCRIPTION OF WORK: Building Construction DATE: Date of Publication
(excluding single family homes and garden type apartments up to and including 4 stories)

12-CA-16-CL-17-CLEAR-33-JE- PA-1-A

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ASBESTOS WORKERS	$ 9.92	.35	.70		
BOILERMAKERS	9.07	7%	7%		.01
BRICKLAYERS & STONEMASONS:					
Cameron County	9.755	.45	.70		a
Remaining Counties	9.15	.45	.20		
CARPENTERS & SOFT FLOOR LAYERS	8.26	5%	7%	6%	.4 of1%
CEMENT MASONS	9.00	6%	16%		
ELECTRICIANS:					
Cameron County	8.75	.45	1%+.25		1%
Remaining Counties	10.10	.35	.20+1%	.60	.05
ELEVATOR CONSTRUCTORS	9.54	.445	.29	3%+b+c	.02
ELEVATOR CONSTRUCTORS HELPERS	6.68	.445	.29	3%+b+c	.02
ELEVATOR CONSTRUCTORS HELPERS (PROB.)	4.77				
IRONWORKERS:					
Clarion County	8.775	.765	.775		.03
Remaining Counties	9.08	.70	.81		.04
LABORERS:					
Clearfield County:					
Building Laborer	6.38	.40	.40		
Plasterer tender	6.43	.40	.40		
Remaining Counties:					
Laborers, carryable pumps, west brick buggy or similar, vibrator operators, walk behind forklift or similar (non self-propelled), stripper & mover of forms, cement masons, footers, window cleaner, tool room man, all material conveyor (regardless of power used, incl. starting & stopping)	7.05	.40	.40		
West brick buggy or similar (self-propelled), power wheelbarrows & buggies, walk behind forklift or similar (self-propelled), wagon drill helper, drill runner, drill runner's drill runner's helper, (incl. drill mounted on truck, track or similar), Blaster's helpers, all operators of compacting equipment, pipe layer, burner, jackhammerman, concrete buster	7.175	.40	.40		
LABORERS (CONT'D)					
Hod carrier, scaffold builder, bell & bottom man on furnaces & stacks, mortar mixer, mortar mixing machine (regardless of power used, inc. starting & stopping), grout machine feeder & pump operator	$ 7.35	.40	.40		
Concrete saw operators	7.35	.40	.40		
Gunnite nozzleman	7.55	.40	.40		
Blaster & wagon drill operators	7.60	.40	.40		
LEAD BURNERS	9.25	.35		d	.01
LINE CONSTRUCTION:					
Cameron County					
Lineman, dynamite man, heavy equipment operator	9.50	.20	1%		
Groundman-Truck Driver	6.74	.20	1%		
Remaining Counties:					
Linemen	10.82	.30	1%		3/8%
Winch truck operator	7.57	.30	1%		3/8%
Groundman	6.49	.30	1%		3/8%
MILLWRIGHTS	7.995	5%	3%+.25	26%	1%
PAINTERS:					
Jefferson County					
Brockway					
Brush	6.75			e	
Spray	7.25			e	
Beaver Ringgold, and Porter Twp					
Commercial Brush	7.59	.60	.40		.12
Commercial Spray	8.09	.60	.40		.12
Industrial Brush	8.44	.60	.40		.12
Industrial Spray	9.65	.60	.40		.12
Remaining of Counties plus Remaining Twps in Jefferson County					
Commercial Brush	7.70	.40	.50		.01
Commercial Spray	8.70	.40	.50		.01
Industrial Brush	8.40	.40	.50		.01
Industrial Spray	9.40	.40	.50		.01
PILEDRIVERMEN	9.58	5%	8%		.50of1%
PLASTERERS:					
Clarion County	9.15	.45	.20		
Clearfield and Jefferson Co	7.58	.37	.50		

PA-42-FEO-1-H

BUILDING CONSTRUCTION POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
CLASS 1	$9.925	.50	.50		.09
CLASS 1-A	10.175	.50	.50		.09
CLASS 1-B	10.425	.50	.50		.09
CLASS 1-C	10.675	.50	.50		.09
CLASS 2	9.775	.50	.50		.09
CLASS 2-A	9.30	.50	.50		.09
CLASS 3	8.80	.50	.50		.09
CLASS 4	8.40	.50	.50		.09
CLASS 5	7.50	.50	.50		.09
CLASS 6	7.65	.50	.50		.09
CLASS 6-A	7.75	.50	.50		.09
CLASS 6-B	7.90	.50	.50		.09

CLASS 1: Austin-Western or similar type up to 25 ton, auto grader (CMI or similar), backhoe, batch plant, cableway, caisson drill, central mix plant, cranes (excluding overhead), cranes tower (mobile), crane tower (stationary), crane tower (climbing type), derrick traveler (self-propelled), derrick (all types), derrick boats, dragline, dredge, engineer-maintenance franki or similar type pile driver, gradall (remote control or otherwise), helicopter & helicopter hoist when used for erection purposes), hi-lift 4 yds. or over, hoist-hod (2 cages up to 10 floors), hoist-single cage with Chicago boom attached, hoist (50 ft. or over), hoist (slipform jobs), hop-to or similar type with 180 swing, hop-to or similar type with 360 swing, kocal, koehring scooper, metro chip harvester or similar type, mix mobile or similar type (with self-loading attachment), mix mobile or similar type, mucking machine (tunnel), mutiple bowl machines, pile driver (sonic or similar type), post driver-guard rail (truck mounted), post driver-guard rail (skid type), pumpkrete-mobile or similar type, Quad Nine, shovels (all type), slip form paver (CMI or similar), tractors-boom mounted (all types), tractors (all types with hydraulic backhole attached), tug boat, Whirley

CLASS 1A: Austin-Western or similar type up to 25 ton with jib, Austin-Western or similar type 25 tons or over with jib, cranes (boom or mast 100 ft. or over up to & including 150 ft.), cranes-mobile (any type 15 ton or over placed on any building structure

CLASS 1B: Cranes (boom or mast over 150 ft. up to & including 200 ft.) engineer-lead

CLASS 1C: Cranes (boom or mast over 200 ft.)

CLASS 2: Asphalt plant op., athoy loader, auger-truck, truck or tractor mounted, back-filling machine, boat-material or personnel carrying (powered), boat-job work (inboard or outboard), bulldozer, cable layer, comapctor with blade, compressors-2, compressor and air pump, compressor and air tugger, compressor & gunnite machine (combination), compressor & sandblasting machine (combination), concrete bolt placer, crane-overhead, crushing and scrooning plants, drillcore (truck or skid mounted) drill-Davey or similar type, drill-well & core (truck mounted), elevator euclid loader, excavating equipment (all other), grader, grader-elevating, greaser-equipment (hoad), hi-liftless than 4 yds., hoist-one drum (4 floors or over), hoist-hod (bldgs., 4 floors or more), hoist (2 drums or more in one unit), jumbo op., locomotive, lift slab machine (hydraulic), mixer-paving musking machine, pipe cleaning machine, refrigeration plant, ross carrier (or similar type), scoop (single bowl) self-powered & tractor drawn), spreader-concrete, asphalt and stone, tower mobile (hoisting or lowering material, trencher, welding machines (up to two small machines, grout pump (10 H.P. or over) paver op., asphalt spreader), pumpkrete machine op., (stationary), tire repairman, welder (repairman)

CLASS 2A: Conveyors 4 units or more

CLASS 3: Oiler, compactor (ridden or silf-propelled) concrete finishing machine & spreader, crane, carry, curb builder (self-propelled), drill well and horizontal (self-propelled and self-contained. elevator. forklifts (ridden or self-propelled. hoist one drum (regardless of power used), pavement breaker (self propelled or ridden), pipe dream, roller saw concrete. soil stabilizer (pump type). stone crusher. stone spreader self-propelled tractors (when used for snaking and hauling), tube finisher C.M.I. or similar type. tugger. truck winch truck or hydraulic boom (when hoisting and placing), all other equipment

CLASS 4: Ballast regulator. boring machines, broom power (except push type), compressor-single (regardless of power used), conveyor-over 1 and up to 3 units (regardless of power used), form line machine, generator (over 5KW) hoists monorail (regardless of power used), hoist roof (regardless of power used) hunk machine or similar type, mixer concrete (regardless of power used), mixer mortar-over 10 c.f. (regardless of power used) pump (over 1-½" discharge, regardless of power (used) spray cure machine (power driven) steam Jenny (or similar type) syphon (steam or air) welding machine single (300 Amp or over) plant, private or industrial air or stream valve.

CLASS 5: Compressor - 65 c.f. or under (regardless of power used) conveyor 1 unit (regardless of power used) heat-up to & including 6, jack motor, hydraulic (single type) power driven, ladavator, mixer mortar (10 c.f. or under, mulching machine. pin puller (powered), pulverizer. pump-1½" discharge or less, seeding machine, spreader side delivery shoulder (attachment tie tamper (multiple heads), tractor farm (when used on landscaping) water blaster, oilertruck crane 50 ton or over

CLASS 6: Brake man, deck hand, helicopter, signalman, oiler, mechanical helper

CLASS 6A: Crane truck oiler and fireman

CLASS 6B: Oiler - truck crane 50 ton or over

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
PLUMBERS & STEAMFITTERS:					
Clarion County	$9.47	.30	.25		.04
Remaining Counties	$ 9.32	.65	.65		
ROOFERS COMPOSITION	9.41	.57	1.30		.06
SHEET METAL WORKERS:					
Cameron and Clearfield Cos.	8.425	.65	.85		.02
Remaining Counties	9.18	.70	.90		.03
SPRINKLER FITTERS	9.60	.50	.70		.08
TRUCK COUNTY:					
Clarion County:					
Warehousemen, service trucks (pick-up, jeep, station wagon, panel truck)	5.855	.30	.30	f	
Dumps and flat tops	5.905	.30	.30	f	
Transit-,ix, single axle	5.93	.30	.30	f	
Transit-mix, tandem	5.93	.30	.30	f	
Distributed truck over 3300 lbs gross weight	5.905	.30	.30	f	
Distributed truck up to 33,00 lbs. gross weights	6.055	.30	.30	f	
Heavy duty trailers with high bed, 4 wheels	5.955	.30	.30	f	
Heavy duty trailers with low bed, 6 to 16 wheels	6.255	.30	.30	f	
Trucks with dolly	6.055	.30	.30	f	
Euclids or equivalent	6.055	.30	.30	f	
Truck with dump trailers or tandems	6.055	.30	.30	f	
Winch trucks	6.23	.30	.30	f	
Towing equipment off job site	6.055	.30	.30	f	
Cameron County:					
Trucks up to 30,000 lbs. (includes pickups, fuel and water trucks), warehousemen	7.20	.20	.20		
Trucks over 30,000 lbs. (includes fuel and water trucks)	7.30	.20	.20		
Tri-Axle Trucks over 30,000 lbs. (includes fuel and water tri trucks	7.40	.20	.20		
Low Boy	7.50	.20	.20		
Concrete Mixer Trucks	7.35	.20	.20		
Concrete Mixer Trucks (Tri-Axle)	7.45	.20	.20		
Semi-Trailer	7.40	.20	.20		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Earth Moving Equipment up to 35 Ton (Belly Dump, Side Dump, End Dump, etc.)	$ 7.70	.20	.20		
Earth Moving Equipment over 35 Ton (Belly Dump, Side Dump, End Dump, etc.	7.80	.20	.20		
A-Frame and Winch Trucks (when used for hauling material on bed of truck)	7.45	.20	.20		
Distributor Truck (Oil, Tar, Asphalt, etc.)	7.70	.20	.20		
Clearfield and Jefferson:					
Service, dump, flat top, jeep, fuel and water	5.46	g	h		
Transit mix, dump trailer, winch truck	5.54	g	h		
Euclids, & tractor trailer	5.61	g	h		
Helper	5.36	g	h		
Welders - receive rate prescribed for craft performing operation to which welding is incidental.					

PAID HOLIDAYS:(Where Applicable)
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving F-Christmas Day.

FOOTNOTES:
a. Employer contributes $45.00 per year.
b. Employer contributes 4% of basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
c. Paid holidays: A through F.
d. Nine paid holidays: A through F and Washington's Birthday; Good Friday and Christmas Eve provided the employee has worked 45 full days for the employer during the 120 days prior to the holiday and is available for work the days preceding and following the holidays.
e. Paid holiday Labor Day provided the employee has worked six calendar months and appears on the payroll during the pay period in which the Holiday occurs.
f. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day,

FOOTNOTE (CONT'D):

Thanksgiving Day, Christmas Day and Veterans Day & Good Friday, provide the employee is available for work the day before and the day after the holiday and has been employed by the employer a minimum of 40 hours each calendar month for two consecutive months.
g. $37.61 per month.
h. $8.00 per week.

NEW DECISION

STATE: South Carolina COUNTY: Greenville
DECISION NUMBER: SC75-1038 DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction (excluding single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Air conditioning mechanic	4.50				
Bricklayers	5.75				
Carpenters	4.75				
Cement masons	3.91				
Drywall mechanic	4.00				
Electricians	4.73				
Glaziers	4.38				
Ironworkers, structural & ornamental	5.95				
Ironworkers, reinforcing	5.95				
Laborers:					
Laborers	2.95				
Mason tenders	3.00				
Pipelayers	3.63				
Painters:					
Painters, brush	4.00				
Painters, spray	4.65				
Plumbers & pipefitters	5.50				
Roofers	3.91				
Sheet metal workers	4.35				
Sprinkler fitters	7.92	.50	.70		.08
Soft floor layers	3.50				
Tile setters	4.75				
Truck drivers	3.26				
Welders - rate for craft.					
POWER EQUIPMENT OPERATORS:					
Asphalt paving machine	4.00				
Backhoe	4.03				
Front end loader	4.25				
Motor grader	3.42				
Pan	3.25				
Roller	3.75				
Bulldozer	3.92				

MODIFICATIONS P. 1

DECISION #AK75-5033 - Mod. #1
(40 FR 10885 - March 7, 1975)
Statewide, Alaska

Change:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Boilermakers	$12.06	.65	1.00	.50	.02
Bricklayers, Blocklayers, Stonemasons	13.03	.55	1.75		.09
Culinary Workers:					
Baker of combination cook-baker; Head cook; Working camp manager	9.88	.50	1.00		
Cook	9.52	.50	1.00		
Butcher	9.46	.50	1.00		
Head waiter or head wairtess	8.97	.50	1.00		
Head bullcook	8.87	.50	1.00		
Camp worker (waiter, waitress, bullcook, general helper, miscellaneous worker); Bartender	8.81	.50	1.00		
Lathers	13.16	.60		1.08	.04
Marble Setters, Terrazzo Workers	13.03	.55	1.75		.09

MODIFICATIONS P. 2

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #FL75-1009 - Mod. #1 (40 FR 3882 - January 24, 1975) Orange County, Florida					
Change:					
Asbestos workers	$8.91	.35	.35		.06
Boilermakers	8.20	60	.90		.01
Bricklayers:					
Bricklayers & Stonemasons	8.05	.35	.30		.02
Marblemason & Plasterers	8.05	.35	.30		.02
Cement masons	8.00	.35	.30		.02
Roofers	7.00	.35	.20		
Kettlemen	5.55	.35	.20		
Helpers	4.90	.35	.20		
Sheet metal workers	8.44	.30	.30	.50	.04
Terrazzo workers	8.05		.25		.02
Tile setters	8.05		.25		.02
DECISION # FL75-1010 - Mod. #1 (40 FR-3884 - January 24, 1975) Hillsborough County, Florida					
Change:					
Boilermakers	8:20	.60	.90		.02
Lathers	8.355	.30	.20		.01
Line Construction:					
Linemen	8.80	.35	1%		1%
Cable splicers	9.19	.35	1%		1%
Winch truck driver operator	6.86	.35	1%		1%
Groundmen	5.13	.35	1%		1%
Roofers	7.25	.25	.20		.02
Helpers	4.20	.25	.20		.02
Kettlemen	5.10	.25	.20		.02

MODIFICATIONS P. 3

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION # FL75-1011 - Mod. #2 (40 FR-3886 - January 24, 1975) Broward County, Florida					
Change:					
Asbestos workers	9.90	.35	.40		.04
Boilermakers	8.20	.60	.90		.02
Elevator Constructors	9.34	.395	.26	2½%+a+b	.015
Elevator Constructors helpers	70%JR	.395	.26	2½%+a+b	.015
Elevator Constructors helpers (prob.)	50%JR	.395	.26	2½%+a+b	.015
Line Construction:					
Linemen	9.09	5%	1%		3/8of 1%
Cable splicer	9.34	5%	1%		3/8of 1%
Groundman	5.45	5%	1%		3/8of 1%
A class operators	9.09	5%	1%		3/8of 1%
DECISION #FL75-1016 - Mod. #1 (40 FR 4807 - January 31, 1975) Duval County, Florida					
Change:					
Asbestos workers	$8.81	.30	.30		.04
Boilermakers-blacksmith	8.20	.60	.90		.02
Carpenters and soft floor layers	7.42	.39	.30	.30	.03
Electricians	8.50	.30	1%+.43	.43	.04
Piledrivermen and acoustical workers	7.42	.39	.30	.30	.03
Plumbers and steamfitters	9.25	.40	.45		.06

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #FL75-1024 - Mod. #1 (40 FR-7801 - February 21,1975) Escambia, Okaloosa, Santa Rosa & Walton Counties, Florida					
Change:					
Boilermakers	8.20	.60	.90		.02
Bricklayers & stonemasons	7.80				
Marble masons, terrazzo workers & tile setters	7.80				
Carpenters & soft floor layers	7.15	.40			.01
Piledrivermen	7.40	.40			.01
Glaziers	5.70		.15	e	
Lathers	6.00				.01
Linemen	7.85	.30	1%		½ of 1%
Plumbers & Steamfitters: Remaining Counties & Walton Co., W. of Hwy. 331 incl. DeFuniak Springs	10.10	.45	.55	E	.05
Sheet metal workers	9.00	.40	.50		.03
DECISION #HI75-5002 - Mod. #2 (40 FR 3888 - January 24, 1975) Statewide, Hawaii					
Change:					
Plasterers	$8.10	.55	.60		.16

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #ID75-5024 - Mod. #1 (40 FR 7803 - February 21, 1975) Statewide, Idaho					
Change:					
Cement Masons: Remainder of Counties and Idaho County (South of 46th Parallel) Cement Masons	$7.40	.40	.35	.25	.10
Elevator Constructors: Remainder of Counties and Idaho County (South of 46th Parallel) Elevator Constructors	8.04	.445	.29	2%+a	
Elevator Constructors' Helpers	70%JR	.445	.29	2%+a	
Elevator Constructors' Helpers (Prob.)	50%JR				
Marble Setters: Clearwater, Idaho, Latah, Lewis, Nez Perce Counties	9.16		.50		
Sheet Metal Workers: Bannock, Bear Lake, Bingham, Blaine, Bonneville, Butte, Caribou, Clark, Franklin, Fremont, Jefferson, Madison, Oneida, Power, Teton Cos.	8.03	.32	.24		.02
DECISION #IN75-2039 - Mod. #1 (40 FR 7824 - February 21, 1975) Blackford, Delaware, Fayette, Grant, Hamilton, Hancock, Henry, Jay, Johnson, Madison, Marion, Randolph, Rush, Shelby, Union, & Wayne Counties, Indiana					
CHANGE:					
Ironworkers: Marion County	$9.50	.55	.80		.05

DECISION #IA75-4036--MOD. #2
(40-FR-4828--January 31, 1975)
Clinton County (City of Clinton & abutting municipalities),Iowa

CHANGE:
Heavy & Highway Construction:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Power Equipment Operators:					
Group 1	$6.60	.40	.40		.03
Group 2	6.55	.40	.40		.03
Group 3	6.20	.40	.40		.03
Group 4	6.10	.40	.40		.03
Group 5	5.80	.40	.40		.03
Group 6	5.45	.40	.40		.03

CLASSIFICATIONS DEFINITIONS

POWER EQUIPMENT OPERATORS

GROUP 1-Power shovel,crane,backhoe,&dragline;Central mix plant op.;Dredge engineer; Dredge leverman;Paver or spreader op.;Hoisting engineer(steel erection);Motor Patrol; Piledriver machine op.;Concrete mixer;Tow or push boat op.;Master Mechanic.
GROUP 2-C.M.I. paver;C.M.I. subgrader(or equivalent);Asphalt plant op.;Front endloader op.;Scraper op.;Bulldozer;Push Cat;Tractor pulling scraper;Sideboom tractor;Churn or rotary drill;Trenching Machine(Cleveland 80 or similar capacity);Asphalt laydown op.; Asphalt Screed op.;Asphalt Heater-planer unit;Asphalt roller op.;Self-propelled elevating grader or similar machine;Spreader op.(concrete);Horizontal boring machine op.;Mechanics-Welders;Group equipment greaser;Concrete pump.
GROUP 3-Concrete curb breaking machine;Concrete widening machine op.;Paving breaker op.; Barber-Green,Hais. loader or similar machine;Tractor pulling ripper,disc,sheepsfoot or flat roller;Self-propelled sheepsfoot roller.
GROUP 4-Self-propelled roller op. (other than asphalt);Distributor op;Screening & washing plant op;Self-Proposed vibrating compactor;Trenching machine op. (other than above);Steel placing machine op.;Conveyor op.;Finishing machine op.(on concrete); Flexplane op.;Bull Float op.;Form Gracer op.
GROUP 5-Boiler op.;Mechanical broom op.;Oiler or mechanics helper or group greaser helper;Farm-type tractor (pulling disc,harrow or roller);Welding machine op;Pump op(other than dredge);Boom & winch truck op.;Compressor op.;Tank car heater (combination boiler & booster);Pumps on wellpoints & deep wells for dewatering;Truck crane combination driver-oiler;Concrete curing machine op.;Safety boat op.
GROUP 6-Batch plant op.-dry.

DECISION #IA75-4037--MOD. #2
(40-FR-4831--January 31, 1975)
Des Moines County (City of Burlington & abutting municipalities & Burlington Ordnance Plant),Iowa

CHANGE:
Heavy & Highway Construction:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Power Equipment Operators:					
Group 1	$6.60	.40	.40		.03
Group 2	6.55	.40	.40		.03
Group 3	6.20	.40	.40		.03
Group 4	6.10	.40	.40		.03
Group 5	5.80	.40	.40		.03
Group 6	5.45	.40	.40		.03

CLASSIFICATIONS DEFINITIONS

POWER EQUIPMENT OPERATORS

GROUP 1-Power shovel,crane,backhoe,&dragline;Central mix plant op.;Dredge engineer; Dredge leverman;Paver or spreader op.;Hoisting engineer(steel erection);Motor Patrol; Piledriver machine op.;Concrete mixer;Tow or push boat op.;Master Mechanic.
GROUP 2-C.M.I. paver;C.M.I. subgrader(or equivalent);Asphalt plant op.;Front endloader op.;Scraper op.;Bulldozer;Push Cat;Tractor pulling scraper;Sideboom tractor;Churn or rotary drill;Trenching Machine(Cleveland 80 or similar capacity);Asphalt laydown op.; Asphalt Screed op.;Asphalt Heater-planer unit;Asphalt roller op.;Self-propelled elevating grader or similar machine;Spreader op.(concrete);Horizontal boring machine op.;Mechanics-Welders;Group equipment greaser;Concrete pump.
GROUP 3-Concrete curb breaking machine;Concrete widening machine op.;Paving breaker op.; Barber-Green,Hais. loader or similar machine;Tractor pulling ripper,disc,sheepsfoot or flat roller;Self-propelled sheepsfoot roller.
GROUP 4-Self-propelled roller op. (other than asphalt);Distributor op;Screening & washing plant op;Self-Proposed vibrating compactor;Trenching machine op. (other than above);Steel placing machine op.;Conveyor op.;Finishing machine op.(on concrete); Flexplane op.;Bull Float op.;Form Gracer op.
GROUP 5-Boiler op.;Mechanical broom op.;Oiler or mechanics helper or group greaser helper;Farm-type tractor (pulling disc,harrow or roller);Welding machine op;Pump op(other than dredge);Boom & winch truck op.;Compressor op.;Tank car heater (combination boiler & booster);Pumps on wellpoints & deep wells for dewatering;Truck crane combination driver-oiler;Concrete curing machine op.;Safety boat op.
GROUP 6-Batch plant op.-dry.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #IA75-4042--MOD. #2 (40-FR-4843--January 31, 1975) Pottawattamie County (City of Council Bluffs & the area within 3 miles from the city limits), Iowa					
CHANGE: Building Construction:					
Asbestos Workers	$10.00	.40	.51		.03
DECISION #IA75-4034--MOD. #2 (40-FR-4823--January 31, 1975) Black Hawk County (City of Waterloo & abutting municipalities), Iowa					
CHANGE: Building Construction:					
Carpenters	$6.97	.31	.73		.01
Sheet Metal Workers	8.41	.35	.20		
DECISION #LA75-4033 - Mod. #4 (40 FR 3898 - January 24, 1975) Statewide Louisiana					
Change: DESCRIPTION OF WORK: Building (including Residential in Bossier, Caddo, & Calcasieu Parishes only) Construction and Construction of Highways, Roads, Streets and Parking Areas (except in St. Mary Parish and those let with a building contract)					
Also Change: Lathers: Zone 2	$8.275				.01
Painters: Zone 8 Group 1	6.05				
Group 2	7.05				
Group 3	6.55				
Sheet Metal Workers Zone 2	8.56	3%+.35	.50		.14

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #AR-1058 - Mod. #1 (39 FR 44168 - December 20, 1974) Clark County, Nevada (Excluding the Nevada Test Site)					
Change: Carpenters: Carpenters	$8.56	.45	.60	.80	.10
Hardwood Floorlayers; Patent Scaffold Erectors; Power Saw Operators	8.71	.45	.60	.80	.10
Piledrivermen	8.76	.45	.60	.80	.10
Millwrights	9.06	.45	.60	.80	.10
Power Equipment Operators: (Except Piledriving and Steel Erection)					
Group 1	8.13	.95	1.50	.30	.04
Group 2	8.39	.95	1.50	.30	.04
Group 3	8.64	.95	1.50	.30	.04
Group 4	8.76	.95	1.50	.30	.04
Group 5	8.96	.95	1.50	.30	.04
Group 6	9.06	.95	1.50	.30	.04
Group 7	9.17	.95	1.50	.30	.04
Group 8	9.32	.95	1.50	.30	.04
Group 9	9.43	.95	1.50	.30	.04
DECISION #AR-1059 - Mod. #1 (39 FR 44172 - December 20, 1974) Washoe County, Nevada					
Change: Carpenters: Carpenters	$8.35	.50	.96	1.00	.04
Floorlayers; Patent Scaffold Erectors; Power Saw Operators	8.50	.50	.96	1.00	.04
Piledrivermen	8.55	.50	.96	1.00	.04
Millwrights	8.95	.50	.96	1.00	.04
Drywall Installers	8.60	.50	.96	1.00	.04
DECISION NO AR-2063 - Mod. #1 (39 FR 36792 - October 11, 1974 Orange County, New York					
Change: Electricians: Remainder of County	$9.70	.45	1%+.69	.60	1%

Decision #AQ-2081 - Mod. #6
(39 FR 11805 - March 29, 1974)
Cambria County, Pennsylvania

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Change:					
Electricians	$10.10	.35	1%+.20	.60	.05
Line Construction:					
Linemen	10.82	.30	1%		3/8%
Winch truck operator	7.57	.30	1%		3/8%
Groundman	6.49	.30	1%		3/8%
Plasterers	8.50				.01

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #TX75-4007 - Mod. #2					
(40 FR 3165 - January 17, 1975)					
Cameron, Hidalgo, Starr & Willacy Counties, Texas					
Change:					
Line Construction:					
Linemen	$6.41	.28	1%		1/2%
Groundmen	3.92	.28	1%		1/2%
Groundmen, 1st 6 mos.	2.70	.28	1%		1/2%
DECISION #TX75-4020 - Mod. #4					
(40 FR 3922 - January 24, 1975)					
Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher & Wheeler Counties, Texas					
Change:					
Lathers	7.75				.01
DECISION #TX75-4022 - Mod. #2					
(40 FR 3927 - January 24, 1975)					
Bell, Bosque, Coryell, Falls, Hill & McLennan Counties, Texas					
Change:					
Building Construction:					
Glaziers	5.90				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
DECISION #TX75-4025 - Mod. #4 (40 FR 3933 - January 24, 1975) Galveston & Harris Counties, Texas					
Change: Bricklayers & stonemasons	$8.69	.325	.40		.05
DECISION #TX75-4029 - Mod. #3 (40 FR 3940 - January 24, 1975) Lubbock County, Texas					
Change: Cement masons	6.25				
DECISION #TX75-4047 - Mod. #2 (40 FR 5969 - February 7, 1975) Brazos County, Texas					
Change: Bricklayers	8.69	.325	.40		.05
DECISION #TX75-4056 - Mod. #2 (40 FR 8755 - February 28, 1975) Wichita County, Texas					
Change: Plumbers-Pipefitters:					
Zone 1	8.05	.25	.55		.02
Zone 2	8.55	.25	.55		.02
Zone 3	8.05	.25	.55		.02
Zone 4	9.15	.25	.55		.02
Zone 5	9.45	.25	.55		.02

DECISION NO. MD75-3003 - Mod. #1 (40 FR 937 - January 3, 1975) Montgomery and Prince Georges Counties, Maryland; Arlington and Fairfax Counties, the city of Alexandria and Dulles International Airport, Virginia.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
CHANGE:					
Ironworkers:					
Structural, Ornamental and Chain Link Fence	$9.55	.50	.60		.05
Reinforcing	9.35	.35	.60		.03
Line Construction:					
Linemen, Cable Splicers, Equipment Operators	10.11	.35	1%		1%
Truck With Winch, Truck Pole or Steel Handling	7.13	.35	1%		1%
Groundmen (0 to 1 year)	5.71	.35	1%		1%
Groundmen (1 to 2 years)	6.62	.35	1%		1%
Groundmen (over 2 years)	6.87	.35	1%		1%
Terrazzo and Mosaic Workers	9.33	.40	.30		
Terrazzo Workers' Helpers	8.05	.40	.40		
Tile Setters	9.33	.40	.30		
Tile Setters' Helpers	8.05	.40	.40		

DECISION #WA75-5025 - Mod. #1
(40 FR 7868 - February 21, 1975)
Statewide, Washington

Change:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Cement Masons:					
Adams, Asotin, Benton, Chelan, Columbia, Douglas, Ferry, Franklin, Garfield, Grant, Kittitas (except western portion lying one mile west of City of Easton), Lincoln, Okanogan, Pend Oreille, Spokane, Stevens, Walla Walla, Whitman, and Yakima Counties	$8.23	.45	.60		.04
Lewis, Pierce, Thurston Cos., and the City of Auburn in King County	8.25	.50	.65		.02
Electricians:					
Chelan, Douglas, Grant, and Okanogan Counties					
Electricians	8.95	.35	1%+.40		.02
Cable Splicers	9.85	.35	1%+.40		.02
Laborers (Area 1):					
(All counties and portions of counties East of the 120th Meridian)					
Group 1	6.85	.45	.65		.02
Group 2	7.00	.45	.65		.02
Group 3	7.10	.45	.65		.02
Group 4	7.15	.45	.65		.02
Group 5	7.20	.45	.65		.02
Group 6	7.25	.45	.65		.02
Group 7	7.30	.45	.65		.02
Group 8	7.50	.45	.65		.02
Group 9					
Class A	6.90	.45	.65		.02
Class B	6.95	.45	.65		.02
Class C	7.35	.45	.65		.02
Class D	7.40	.45	.65		.02

SUPERSEDEAS DECISION

STATE: Alabama COUNTY: Madison
DECISION NO.: AL75-1032 DATE: Date of Publication
Supersedes Decision No. AL75-1028 dated February 28, 1975 in 40 FR-8703
DESCRIPTION OF WORK: Building construction (excluding single family homes and garden type apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos workers	8.61	.30	.30		.05
Boilermakers	7.50	.40	.90		.02
Bricklayers	8.20				
Carpenters	7.49				.03
Cement Masons	6.75				
Electricians; Linemen	8.35	30	1%		.5%
Glaziers	6.00				
Ironworkers:					
Reinforcing	7.605	.40	.25		.03
Structural	7.605	.40	.25		.03
Laborers:					
Laborers; Mason tenders	4.38	.15	.25		
Air tool op. (jackhammer, vibrator); Mortar mixers	4.63	.15	.25		
Millwrights	7.88				.03
Painters:					
Commercial	6.50		.20		.05
Industrial	7.25		.20		.05
Plumbers: Pipefitters	8.20	.40	.35		.10
Roofers	4.85				
Sheet metal workers	9.00	.45	.40		.05
Truck Drivers	3.67				
POWER EQUIPMENT OPERATORS:					
Mechanic	8.43	.25	.25		
Hoist	8.43	.25	.25		
Bulldozers	8.43	.25	.25		
Motor Patrol	8.43	.25	.25		
Crane	8.43	.25	.25		
Scraper	8.43	.25	.25		
Tractor	7.16	.25	.25		
Front End Loader	8.43	.25	.25		
Oiler	6.48	.25	.25		
Air Compressor	6.48	.25	.25		

SUPERSEDEAS DECISION

STATE: Arizona
COUNTY: Maricopa
DECISION NUMBER: AZ75-5035
DATE: Date of Publication
Supersedes Decision No. AR-1009 dated August 9, 1974, in 39 FR 28781.
DESCRIPTION OF WORK: Residential Construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ASBESTOS WORKERS	$ 9.89	.50	.82		.01
BOILERMAKERS	9.95	.65	1.00	.50	.02
BRICKLAYERS; Stonemasons:					
Zone A (0-25 miles from City Hall of Phoenix; Flagstaff and Yuma)	9.07	.50	.45		.03
Zone B (25-40 miles from City Hall of Phoenix; and Williams AFB)	9.52	.50	.45		.03
Zone C (40-70 miles from City Hall of Phoenix)	10.43	.50	.45		.03
Zone D (70-100 miles from City Hall of Phoenix)	10.88	.50	.45		.03
Zone E (100-200 miles from City Hall of Phoenix)	11.34	.50	.45		.03
Zone F (200 miles and over from City Hall of Phoenix)	11.79	.50	.45		.03
CARPENTERS:					
Carpenters; Drywall Applicator Piledrivermen; Floorlayers (finish)	8.535	.65	.885		.025
	8.805	.65	.885		.025
Millwrights	8.93	.65	.885		.025
CEMENT MASONS	7.985	.50	.60		.025
DRYWALL:					
(From Court House in Phoenix, Mesa, including Williams AFB and Luke AFB).					
Tapers:					
Zone A (0-40 miles)	8.90	.49		.50	.07
Zone B (41-60 miles)	10.40	.49		.50	.07
Zone C (61 miles and over)	11.15	.49		.50	.07
Texture Spraymen:					
Zone A (0-40 miles)	9.00	.49		.50	.07
Zone B (41-60 miles)	10.50	.49		.50	.07
Zone C (61 miles and over)	11.25	.49		.50	.07

DECISION NO. AZ75-5035

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ELECTRICIANS:					
Zone A (Beginning at the northeast corner, a line extending southward on Bush Highway to McKellips Road; a line extending east on McKellips Road to a point one mile east of the intersection of State Highway 88 and U. S. 60 and 70 near Apache Junction; southward to Baseline Road; West on Baseline Road to the intersection Baseline Road and Ellsworth Road; south on Ellsworth Road to Hunt Highway; west on Hunt Highway to Powers Road; a line extending south on Powers Road five miles, then extending straight west to a point five miles west of Interstate 10, then northwest on a line parallel with Interstate 10 to intersect with Pecos Road, west on Pecos Road to intersect with Cotton Lane. North on Cotton Lane to Beloat Road. West on Beloat Road to Airport Road. North on Airport Road in a straight line to intersect Waddell Road. East on Waddell Road to intersect with Cotton Lane. North on Cotton Lane to Deer Valley Drive and east on Deer Valley Drive to intersection with Bush Highway and including Luke and Williams Air Force Bases.)					
Electricians	$ 10.45	.60	1% + .70		3/4%
Cable Splicers	10.97	.60	1% + .70		3/4%

DECISION NO. AZ75-5035

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ELECTRICIANS: (Cont'd)					
Zone B (Area outside of Zone A and bounded by a line formed by measuring sixteen (16) road miles from the outer boundaries of an area enclosed by the following boundaries: Powers Road on the east from Hunt Highway on the south to one mile south of Pinnacle Peak Road on the north. One mile south of Pinnacle Peak Road to Cotton Lane on the west. Cotton Lane to Pecos Road on the south. Pecos Road to Price Road and from Price Road to Hunt Highway on the south. Hunt Highway to Powers Road on the east.)					
Electricians	$ 12.28	.60	1% + .70		3/4%
Cable Splicers	12.89	.60	1% + .70		3/4%
Zone C (Outside edge of Zone B and extend to the outside limits of the Union's Jurisdiction.)					
Electricians	13.22	.60	1% + .70		3/4%
Cable Splicers	13.88	.60	1% + .70		3/4%
ELEVATOR CONSTRUCTORS	9.255	.395	.26	3% + a	.02
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	.395	.26	3% + a	.02
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	50%JR				
GLAZIERS	8.15	.35	.30	.56	.01
IRONWORKERS	8.58	.58	.625		.04

DECISION NO. AZ75-5035

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
PAINTERS:					
Zone A (0-40 miles from Court House in Phoenix, Mesa and including Luke and Williams Air Force Bases):					
Brush; Tapers	$ 8.10	.57	.38	.50	.05
Spray; Paperhangers	8.35	.57	.38	.50	.05
Zone B (41-60 miles from Court House in Phoenix):					
Brush; Tapers	9.10	.57	.38	.50	.05
Spray; Paperhangers	9.35	.57	.38	.50	.05
Zone C (61 miles and over from Court House in Phoenix):					
Brush; Tapers	9.60	.57	.38	.50	.05
Spray; Paperhangers	9.85	.57	.38	.50	.05
PLASTERERS (Northern 3/4 of Co.):					
Zone A (0-30 miles from Phoenix)	8.495	.35	.65		.035
Zone B (30-40 miles from Phoenix)	8.995	.35	.65		.035
Zone C (40-50 miles from Phoenix)	9.245	.35	.65		.035
Zone D (50 miles and over from Phoenix)	10.12	.35	.65		.035
PLASTERERS (Southern 1/4 of Co.):					
Zone A (0-30 miles from Tucson)	8.57	.35	.60		
Zone B (30-40 miles from Tucson)	9.07	.35	.60		
Zone C (40-50 miles from Tucson)	9.32	.35	.60		
Zone D (Over 50 miles from Tucson)	10.07	.35	.60		
PLUMBERS; Steamfitters:					
FREE ZONE 0-15 miles					
The "Free Zone" (Zone I shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas. The "Free Zone" from Phoenix shall be 15 miles radius from the stated base point. In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones. Any work contracted for outside of these Zones will be determined from the Phoenix and Tucson basing points.	9.39	.65	1.24	1.25	.10

DECISION NO. AZ75-5035

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
PLUMBERS; Steamfitters (Cont'd)					
Zone II (15-30 miles)	$ 9.74	.65	1.24	1.25	.10
Zone III (30-40 miles)	10.16	.65	1.24	1.25	.10
Zone IV (40 miles and over)	10.46	.65	1.24	1.25	.10
Plumbers:					
(Phoenix Area)					
Utility Mechanics (For installation of metallic or non-metallic piping or conduits used in water mains, storm sewers, sanitary sewers, invasion piping and culvert piping) (Installation of gas distribution piping for Public Utility Companies); Lawn Sprinkler Mechanics (Pipe layers fountain and equipment installation, service and maintenance landscaping and nurseryman); Swimming Pool Mechanics (Swimming pool piping of any mode or method or material service and repair, pipe excavation, installation of equipment); Residential Plumbing Service Work including repair and service of the plumbing in single family dwellings and multiple single family dwellings; Refrigeration and Air Conditioning Mechanics (Installation, service, maintenance and repair of air conditioning, refrigeration of 5 ton and under on single-family dwellings and multiple single family dwellings and heating systems)	6.73	.65			.02

DECISION NO. AZ75-5035

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ROOFERS	$ 7.35	.40	.20		.02
SHEET METAL WORKERS:					
Zone I (0-25 miles from Phoenix)	9.02	.40	.56		.02
Zone II (25-50 miles from Phoenix)	9.67	.40	.56		.02
Zone III (50 miles and over from Phoenix)	11.52	.40	.56		.02
SOFT FLOOR LAYERS:					
Zone A (0-40 miles from Court House in Phoenix, and including Luke and Williams Air Force Bases)	7.85	.49	.12		.12
Zone B (41-60 miles from Court House in Phoenix)	8.85	.49	.12		.12
Zone C (61 miles and over)	9.85	.49	.12		.12
SPRINKLER FITTERS	9.85	.50	.70		.08

FOOTNOTE:

a. Employer contributes 4% of basic hourly rate for 5 years' service and 2% of basic hourly rate for 6 months to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

	Basic Hourly Rates	Basic Hourly Rates	Fringe Benefits Payments			
			H & W	Pensions	Vacation	Apprentice
LABORERS,	C&S AREA	N AREA				
GROUP 1:	$ 6.48	$8.105	.60	.65		.07
GROUP 2:	6.60	8.225	.60	.65		.07
GROUP 3:	6.73	8.355	.60	.65		.07
GROUP 4:	6.83	8.455	.60	.65		.07
GROUP 5:	6.99	8.615	.60	.65		.07
GROUP 6:	7.335	8.96	.60	.65		.07
GROUP 7:	7.925	9.55	.60	.65		.07
GROUP 8:	7.175		.60	.65		.07
GROUP 8-A:	7.55		.60	.65		.07
POWER EQUIPMENT OPERATORS (Except Piledriving & Steel Erection)						
GROUP 1:	7.17	8.795	.65	.70		.04
GROUP 2:	7.52	9.145	.65	.70		.04
GROUP 3:	7.96	9.585	.65	.70		.04
GROUP 4:	8.46	10.085	.65	.70		.04
GROUP 5:	8.96	10.585	.65	.70		.04
GROUP 5-A:	9.25	10.875	.65	.70		.04
GROUP 6:	9.56	11.185	.65	.70		.04
GROUP 7:	10.13	11.755	.65	.70		.04
TRUCK DRIVERS						
GROUP 1:	6.64	8.265	.60	.65		.04
GROUP 2:	6.76	8.385	.60	.65		.04
GROUP 3:	6.96	8.585	.60	.65		.04
GROUP 4:	7.29	8.915	.60	.65		.04
GROUP 5:	7.44	9.065	.60	.65		.04
GROUP 5-A:	7.60	9.225	.60	.65		.04
GROUP 6:	7.73	9.355	.60	.65		.04
GROUP 7:	8.12	9.745	.60	.65		.04
GROUP 8:	8.595	10.22	.60	.65		.04
GROUP 8-A:	9.35	10.975	.60	.65		.04
GROUP 8-B:	9.06	10.685	.60	.65		.04
GROUP 8-C:	7.27	8.895	.60	165		.04

LABORERS

Group 1: All Helpers Not Herein Separately Classified; Cesspool diggers and installers; Chat box man; Checker, tool dispatcher; Concrete dump manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence builder, guard rail builder highway; Form strippers; Labor, general or construction; Landscape gardener and nurseryman; Packing rod steel and pans; Rip rap stoneman; Astro turf layer

Group 2: Cement Finisher Tender; Concrete curer (impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy; Lazer beam operator

Group 3: Bander; Chucktender (except tunnel); Creosote tieman; Guinea chaser; Powderman helper; Rip-rap stone paver; Sandblaster (pot tender); Spikers and wrenchers

Group 4: Cement Dumpers (Skip-type mixer or handling bulk cement); Chain saw machines (on clearing and grubbing); Concrete vibrating machines; Cribber and shorer (except tunnel); Floor sanders - concrete; Hydraulic jacks, and similar mechanical tools not separately herein classified; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

Group 5: Air and Water Wash-Out Nozzleman; Asphalt rakers and ironers; Driller; Grade setter (pipeline); Hand guided trencher and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock slinger; Scaler (using Bos'ns chair or safety belt); Tampers (mechanical-all types); Precast manhole erector

Group 6: Concrete Cutting Torch; Concrete saw (hand guided); Driller (core, diamond, wagon or air track); Drill doctor and/or air tool repairman; Gunman and mixerman (gunite); Sandblaster (nozzleman)

Group 7: Concrete Road Form Setter; Gunite nozzleman or rodman; Drillers, Joy Mustang, PR 143, 2200 Gardner-Denver, Hydrasonic; Powderman; Scaler (drillers); Welders and/or pipelayers installing process piping

Group 8: Mason Tenders

Group 8A: Plaster Tenders

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Air compressor operator; Field equipment servicemen helper; Heavy duty repair helper; Heavy duty welder helper; Oiler; Pump operator

Group 2: Conveyor operator; Generator operator - portable; Power grizzly operator; Self-propelled chip spreading machine - conveyor operator; Watch fireman; Welding machine operator - gasoline and diesel power

Group 3: Concrete mixer operator - skip type; Dinky operator - (under 20 tons wt.); Driver-moto paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power sweeper operator - self-propelled; Ross carrier or fork lift operator; Skip loader operator - all types with rated capacity 1-1/2 cu. yds. or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fresno, push blade, post hole auger, mower, etc., excluding compacting equipment

Group 4: A-Frame boom truck or winch truck operator; Asphalt plant firemen; Elevator hoist operator (including Tuskey hoist or similar types); Grade checker (excluding civil engineer); Multiple power concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator - all types - except as otherwise classified; Screed operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator) Stationary pipewrapping and cleaning machine operator: Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Beltcrete machine; Boring machine operator; Concrete mechanical tamping, spreading or finishing machine (incl. Clary, Johnson, or similar types); Concrete pump operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classified); Field equipment serviceman; Highline cableway signalman; Kolman belt loader operator or similar, w/belt width 48" or over; Locomotive engineer (incl. Dinky-20 tons wt. and over); Moto-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu. yds.; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Road Oil mixing machine operator; Roller operator-on all types asphalt pavement; Self-propelled compactor, with blade; Skip loader operator-all types with rated capacity over 1-1/2 but less than 4 cu. yds.; Slip form operator (power driven lifting device for concrete forms); Soil cement road mixing machine operator - single pass type; Stationary Central generating plant operator-rated 300 k.w. or more; Surface heater and planer operator; Traveling pipewrapping machine operator

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu. yds. up to and incl. 45 cu. yds. MRC (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment); Tractor operator (Pusher,

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-Grade Machine (CMI and similar equipment); Boring machine operator (including Mole, Badger and similar type); Concrete mixer operator-paving type, and mobile mixer; Concrete pump operator with boom attachment (Truck mounted); Crane operator-crawler and pneumatic type, under 100 ton capacity MRC; Crawler type tractor operator - with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Mass excavator operator (150 Bucyrus Erie and similar types); Mechanical hoist operator (two or more drums); Motor grade operator - any type power blade; Motor grade operator with elevating grader attachment; Mucking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Turnapull, Euclid, Cat, D-W, Hancock & similar equipment over 45 cu. yds., MRC); Power driven ditch lining or ditch trimming machine operator; Skip loader operator - all types with rated capacity 4 cu. yds., but less than 8 cu. yds.; Slip form paving machine operator (including Gunnert, Zimmerman & similar types); Specialized power digger operator- attached to wheel-type tractor; Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over; Tugger operator (two or more); Universal equipment operator-Shovel, Backhoe, Dragline, Clamshell, etc., up to 8 cu. yds.

Group 7: Crane operator - pneumatic or crawler (100 ton hoisting capacity and over MRC rating); Helicopter pilot - FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator - all types with rate capacity of 8 cu. yds. or more; Universal equipment - Shovel, backhoe, dragline, clamshell, etc., 8 cu. yds. and over

TRUCK DRIVERS

Group 1: Pickup; Station wagon; Teamsters; Man Haul Driver

Group 2: Buggymobile, 1 C.Y. or less; Bulk cement spreader (2 or 3 axle); Bus driver; Dump (2 or 3 axle); Flatrack (2 or 3 axle); Water (under 2500 gal.); Warehouseman

Group 3: Bulk cement spreader (4 axle); Dump (4 axle); Dumptor or dumpster, less than 7 c.y.; Flatrack (4 axle); Water (2500 gal. but less than 4000 gal.)

Group 4: Bulk Cement Spreader (5 axle); Dump (5 axle); Dumptor or dumpster, 7 c.y. but less than 16 c.y.; Flaherty spreader or similar type equipment or leverman; Flatrack (5 axle); Slurry type equipment or leverman; Transit mix, 8 c.y. or less mixer capacity

Group 5: Bulk Cement Spreader (6 axle); Dump (6 axle); Flatrack (6 axle); Rock truck (Dart, Euclid and other similar type end dumps, single unit) less than 16 c.y.

Group 5-A: Oil Tanker or Spreader Truck Driver and/or bootman, retortman or leverman

Group 6: Bulk Cement Spreader (7 axle); Concrete pump truck driver, (when integral part of transit mix truck); Dump (7 axle); Flatrack (7 axle); Hydro lift, Swedish crane, Iowa 300 and similar types; Ross carrier fork lift or lift truck; Transit mix, over 10.5 c.y. but less than 14 c.y. mixer

Group 7: Bulk Cement Spreader (8 axle); Dump (8 axle); Flatrack (8 axle)

Group 8: Off-Highway Equipment Driver (2 or 4 wheel power unit, i.e. Cat DW series, Euclid, International, and similar type equipment, transporting material when top loaded or by external means, incl. pulling water tanks, fuel tank, or other teamsters classifications; Bulk Cement spreader (9 axle); Dumptor or dumpster, 16 c.y. and over; Eject-alls; Flatrack (9 axle); Rock truck (dart, euclid, or other similar end dump types) 16 c.y. and over

Group 8-A: Heavy Duty Mechanic/Welder; Body and Fender man

Group 8-B: Field Equipment Serviceman or Fuel Truck Driver

Group 8-C: Heavy Duty Mechanic/Welder Helper

SUPERSEDEAS DECISION

STATE: Arizona COUNTY: Pima
DECISION NUMBER: AZ75-5036 DATE: Date of Publication
Supersedes Decision No. AR-1010 dated August 9, 1974, in 39 FR 28787.
DESCRIPTION OF WORK: Residential Construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ASBESTOS WORKERS	$9.89	.50	.82		.02
BOILERMAKERS	9.95	.65	1.00	.50	.02
BRICKLAYERS; Stonemasons:					
Zone A (0-15 miles from Tucson)	9.395	.60	.60		.06
Zone B (15-30 miles from Tucson)	9.77	.60	.60		.06
Zone C (30-40 miles from Tucson)	10.145	.60	.60		.06
Zone D (Over 40 miles from Tucson)	10.895	.60	.60		.06
CARPENTERS:					
Carpenters; Drywall applicator	8.535	.65	.885		.025
Piledrivermen; Floorlayers (finish)	8.805	.65	.885		.025
Millwrights	8.93	.65	.885		.025
CEMENT MASONS	7.985	.50	.60		.025
ELECTRICIANS:					
Zone A (within 16 miles of City Hall, Tucson)	8.11	.45	1%		1/2%
Zone B (From 16-32 miles from City Hall, Tucson)	8.61	.45	1%		1/2%
Zone C (From 32-48 miles from City Hall, Tucson)	9.11	.45	1%		1/2%
Zone D (Over 48 miles from City Hall, Tucson)	9.61	.45	1%		1/2%
ELEVATOR CONSTRUCTORS	9.255	.395	.26	3%+a	.02
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	.395	.26	3%+a	.02
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	50%JR				
GLAZIERS	8.15	.35	.30	.56	.01
IRONWORKERS	8.58	.58	.625		.04
MARBLE SETTERS; Terrazzo Workers; Tile Setters	8.43	.60	.60		
PAINTERS, Brush:					
Zone A (1-30 miles from Tucson P. O.)	7.43	.47	.35		.04
Zone B (31-40 miles from Tucson P. O.)	8.18	.47	.35		.04
Zone C (41-50 miles from Tucson P. O.)	8.93	.47	.35		.04
Zone D (51 miles and over)	9.43	.47	.35		.04

DECISION NO. AZ75-5036

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
PAINTERS, Structural steel, brush:					
Zone A (1-30 miles from Tucson P. O.)	$8.43	.47	.35		.04
Zone B (31-40 miles from Tucson P. O.)	9.18	.47	.35		.04
Zone C (41-50 miles from Tucson P. O.)	9.93	.47	.35		.04
Zone D (51 miles and over)	10.43	.47	.35		.04
PLASTERERS:					
Zone A (0-30 miles from Tucson P. O.)	8.57	.35	.60		
Zone B (30-40 miles from Tucson P. O.)	9.07	.35	.60		
Zone C (40-50 miles from Tucson P. O.)	9.32	.35	.60		
Zone D (Over 50 miles from Tucson P. O.)	10.07	.35	.60		
PLUMBERS; Steamfitters					
FREE ZONE 0-15 miles					
The "Free Zone" (Zone I shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas. The "Free Zone" from Phoenix shall be 15 miles radius from the stated base point. In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones.) Any work contracted from outside of these zones will be determined from the Phoenix and Tucson basing points.	9.39	.65	1.24	1.25	.10
Zone II (15-30 miles)	9.74	.65	1.24	1.25	.10
Zone III (30-40 miles)	10.16	.65	1.24	1.25	.10
Zone IV (40 miles and over)	10.46	.65	1.24	1.25	.10

DECISION NO. AZ75-5036

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ROOFERS:					
Zone A (0-44 miles from Tucson)	$7.47	.65	.20		.03
Zone B (Over 44 miles from Tucson)	9.22	.65	.20		.03
SHEET METAL WORKERS:					
Zone A (1-17 miles from Tucson)	9.04	.63	1.30		.01
Zone B (18-28 miles from Tucson)	9.54	.63	1.30		.01
Zone C (29-40 miles from Tucson)	10.54	.63	1.30		.01
Zone D (41 miles and over from Tucson)	11.54	.63	1.30		.01
SOFT FLOOR LAYERS	7.25	.38			
SPRINKLER FITTERS	9.85	.50	.70		.08

FOOTNOTE:
a. Employer credits 4% basic hourly rate of employee with over 5 years' service, 2% basic hourly rate from 6 months to 5 years' service to Vacation Fund. 6 Paid Holidays: A through F.

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

DECISION NO. AZ75-5036

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
LABORERS					
GROUP 1:	$6.48	.60	.65		.07
GROUP 2:	6.60	.60	.65		.07
GROUP 3:	6.73	.60	.65		.07
GROUP 4:	6.83	.60	.65		.07
GROUP 5:	6.99	.60	.65		.07
GROUP 6:	7.335	.60	.65		.07
GROUP 7:	7.925	.60	.65		.07
GROUP 8:	7.175	.60	.65		.07
GROUP 8-A:	7.55	.60	.65		.07
POWER EQUIPMENT OPERATORS (Except Piledriving & Steel Erection)					
GROUP 1:	7.17	.65	.70		.04
GROUP 2:	7.52	.65	.70		.04
GROUP 3:	7.96	.65	.70		.04
GROUP 4:	8.46	.65	.70		.04
GROUP 5:	8.96	.65	.70		.04
GROUP 5-A:	9.25	.65	.70		.04
GROUP 6:	9.56	.65	.70		.04
GROUP 7:	10.13	.65	.70		.04
TRUCK DRIVERS					
GROUP 1:	6.64	.60	.65		.04
GROUP 2:	6.76	.60	.65		.04
GROUP 3:	6.96	.60	.65		.04
GROUP 4:	7.29	.60	.65		.04
GROUP 5:	7.44	.60	.65		.04
GROUP 5-A:	7.60	.60	.65		.04
GROUP 6:	7.73	.60	.65		.04
GROUP 7:	8.12	.60	.65		.04
GROUP 8:	8.595	.60	.65		.04
GROUP 8-A:	9.35	.60	.65		.04
GROUP 8-B:	9.06	.60	.65		.04
GROUP 8-C:	7.27	.60	.65		.04

LABORERS

Group 1: All Helpers Not Herein Separately Classified; Cesspool diggers and installers; Chat box man; Checker, tool dispatcher; Concrete dump manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence builder, guard rail builder highway; Form strippers; Labor, general or construction; Landscape gardener and nurseryman; Packing rod steel and pans; Rip rap stoneman; Astro turf layer

Group 2: Cement Finisher Tender; Concrete curer (impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy; Lazer beam operator

Group 3: Bander; Chucktender (except tunnel); Creosote tieman; Guinea chaser; Powderman helper; Rip-rap stone paver; Sandblaster (pot tender); Spikers and wrenchers

Group 4: Cement Dumpers (Skip-type mixer or handling bulk cement); Chain saw machines (on clearing and grubbing); Concrete vibrating machines; Cribber and shorer (except tunnel); Floor sanders - concrete; Hydraulic jacks, and similar mechanical tools not separately herein classified; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

Group 5: Air and Water Wash-Out Nozzleman; Asphalt rakers and ironers; Driller; Grade setter (pipeline); Hand guided trencher and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipe, underground tile and conduit); Rock slinger; Scaler (using Bos'ns chair or safety belt); Tampers (mechanical-all types); Precast manhole erector

Group 6: Concrete Cutting Torch; Concrete saw (hand guided); Driller (core, diamond, wagon or air track); Drill doctor and/or air tool repairman; Gunman and mixerman (gunite); Sandblaster (nozzleman)

Group 7: Concrete Road Form Setter; Gunite nozzleman or rodman; Drillers, Joy Mustang, PR 143, 2200 Gardner-Denver, Hydrasonic; Powderman; Scaler (drillers); Welders and/or pipelayers installing process piping

Group 8: Mason Tenders

Group 8A: Plaster Tenders

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Air compressor operator; Field equipment servicemen helper; Heavy duty repair helper; Heavy duty welder helper; Oiler; Pump operator

Group 2: Conveyor operator; Generator operator - portable; Power grizzly operator; Self-propelled chip spreading machine - conveyor operator; Watch fireman; Welding machine operator - gasoline and diesel power

Group 3: Concrete mixer operator - skip type; Dinky operator - (under 20 tons wt.); Driver-moto paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power sweeper operator - self-propelled; Ross carrier or fork lift operator; Skip loader operator - all types with rated capacity 1-1/2 cu. yds. or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fresno, push blade, post hole auger, mower, etc., excluding compacting equipment

Group 4: A-Frame boom truck or winch truck operator; Asphalt plant firemen; Elevator hoist operator (including Tuskey hoist or similar types); Grade checker (excluding civil engineer); Multiple power concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator - all types - except as otherwise classified; Screed operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator) Stationary pipewrapping and cleaning machine operator; Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Beltcrete machine; Boring machine operator; Concrete mechanical tamping, spreading or finishing machine (incl. Clary, Johnson, or similar types); Concrete pump operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classified); Field equipment serviceman; Highline cableway signalman; Kolman belt loader operator or similar, w/belt width 48" or over; Locomotive engineer (incl. Dinky-20 tons wt. and over); Moto-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu. yds.; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Road Oil mixing machine operator; Roller operator-on all types asphalt pavement; Self-propelled compactor, with blade; Skip loader operator-all types with rated capacity over 1-1/2 but less than 4 cu. yds.; Slip form operator (power driven lifting device for concrete forms); Soil cement road mixing machine operator - single pass type; Stationary Central generating plant operator-rated 300 k.w. or more; Surface heater and planer operator; Traveling pipewrapping machine operator

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu. yds. up to and incl. 45 cu. yds. MRC (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment); Tractor operator (Pusher,

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-Grade Machine (CMI and similar equipment); Boring machine operator (including Mole, Badger and similar type); Concrete mixer operator-paving type, and mobile mixer; Concrete pump operator with boom attachment (Truck mounted); Crane operator-crawler and pneumatic type, under 100 ton capacity MRC; Crawler type tractor operator - with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Mass excavator operator (150 Bucyrus Erie and similar types); Mechanical hoist operator (two or more drums); Motor grade operator - any type power blade; Motor grade operator with elevating grader attachment; Mucking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Tournapull, Euclid, Cat, D-W, Hancock & similar equipment over 45 cu. yds., MRC); Power driven ditch lining or ditch trimming machine operator; Skip loader operator - all types with rated capacity 4 cu. yds., but less than 8 cu. yds.; Slip form paving machine operator (including Gunnert, Zimmerman & similar types); Specialized power digger operator- attached to wheel-type tractor; Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over; Tugger operator (two or more); Universal equipment operator-Shovel, Backhoe, Dragline, Clamshell, etc., up to 8 cu. yds.

Group 7: Crane operator - pneumatic or crawler (100 ton hoisting capacity and over MRC rating); Helicopter pilot - FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator - all types with rate capacity of 8 cu. yds. or more; Universal equipment - Shovel, backhoe, dragline, clamshell, etc., 8 cu. yds. and over

TRUCK DRIVERS

Group 1: Pickup; Station wagon; Teamsters; Man Haul Driver

Group 2: Buggymobile, 1 C.Y. or less; Bulk cement spreader (2 or 3 axle); Bus driver; Dump (2 or 3 axle); Flatrack (2 or 3 axle); Water (under 2500 gal.); Warehousemen

Group 3: Bulk cement spreader (4 axle); Dump (4 axle); Dumptor or dumpster, less than 7 c.y.; Flatrack (4 axle); Water (2500 gal. but less than 4000 gal.)

Group 4: Bulk Cement Spreader (5 axle); Dump (5 axle); Dumptor or dumpster, 7 c.y. but less than 16 c.y.; Flaherty spreader or similar type equipment or leverman; Flatrack (5 axle); Slurry type equipment or leverman; Transit mix, 8 c.y. or less mixer capacity

Group 5: Bulk Cement Spreader (6 axle); Dump (6 axle); Flatrack (6 axle); Rock truck (Dart, Euclid and other similar type end dumps, single unit) less than 16 c.y.

Group 5-A: Oil Tanker or Spreader Truck Driver and/or bootman, retortman or leverman

Group 6: Bulk Cement Spreader (7 axle); Concrete pump truck driver, (when integral part of transit mix truck); Dump (7 axle); Flatrack (7 axle); Hydro lift, Swedish crane, Iowa 300 and similar types; Ross carrier fork lift or lift truck; Transit mix, over 10.5 c.y. but less than 14 c.y. mixer

Group 7: Bulk Cement Spreader (8 axle); Dump (8 axle); Flatrack (8 axle)

Group 8: Off-Highway Equipment Driver (2 or 4 wheel power unit, i.e. Cat DW series, Euclid, International, and similar type equipment, transporting material when top loaded or by external means, incl. pulling water tanks, fuel tank, or other teamsters classifications; Bulk Cement spreader (9 axle); Dumptor or dumpster, 16 c.y. and over; Eject-alls; Flatrack (9 axle); Rock truck (dart, euclid, or other similar end dump types) 16 c.y. and over

Group 8-A: Heavy Duty Mechanic/Welder; Body and Fender man

Group 8-B: Field Equipment Serviceman or Fuel Truck Driver

Group 8-C: Heavy Duty Mechanic/Welder Helper

SUPERSEDEAS DECISION

STATE: Florida COUNTY: Pinellas
DECISION NUMBER: FL75-1034 DATE: Date of Publication
Supersedes Decision No. AQ-4100, dated April 2, 1974 in 39 FR 13425.
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos workers	$8.91	.35	.35		.06
Boilermakers	8.20	.60	.90		.02
Bricklayers	7.55	.30	.50		.05
Carpenters:					
Carpenters & soft floor layers	7.865	.325	.20		.04
Millwrights	7.37	.45	.45		.04
Piledrivermen	8.115	.325	.20		.04
Cement masons	6.80	.30	.50		.05
Electricians:					
Electricians	9.45	.35	1%		3/4 of 1%
Cable splicers	9.95	.35	1%		3/4 of 1%
Elevator constructors	7.79	.395	.26	2%+a+b	.02
Elevator constructors' helpers	70% JR	.395	.26	2%+a+b	.02
Elevator constructors' helpers (probationary)	50% JR				
Ironworkers:					
Structural and ornamental	7.81	.45	.30	.25	.05
Reinforcing	7.81	.45	.30	.25	.05
Laborers:					
Air tool op., (jackhammer vib.)	6.00	.25	.20		
Common laborers	5.85	.25	.20		
Mason tenders and mortar mixers	6.00	.25	.20		
Pipelayers (concrete & clay)	6.00	.25	.20		
Plasterers' tenders	6.00	.25	.20		
Lathers	7.905	.30	.20		.01
Lead burners	9.25	.35		c	.01
Line construction :					
Class A	9.15		1%	d	1/10 of 1%
Class B	7.21		1%	d	1/10 of 1%
Cable splicers	9.55		1%	d	1/10 of 1%
Groundman A	5.46		1%	d	1/10 of 1%
Groundman B	3.69		1%	d	1/10 of 1%
Marble setters	7.30	.30	.50		.05
Painters:					
Brush and roller	6.84	.30	.25		.06
Swing stage and window jacks, spray and sandblasting	7.34	.30	.25		.06
Dry wall tapers	7.69	.30	.25		.06
Structural steel, bridge and Industrial:					
Brush, roller, swing, stage bos'n chair	7.05	.30	.25		.06
Spray and sandblasting	7.30	.30	.25		.06
Paperhangers	6.95	.30	.25		.06

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Plasterers	7.96	.30	.50		.05
Plumbers and steamfitters	7.45	.30	.70		.025
Roofers	7.25	.25	.20		.02
Kettlemen	5.10	.25	.20		.02
Helpers	4.20	.25	.20		.02
Sheet metal workers	7.56	.38	.35	.15	
Sprinkler fitters	9.31	.50	.70		.10
Stonemasons	7.55	.30	.50		.05
Terrazzo workers	7.30	.30	.50		.05
Terrazzo workers' helpers	4.05	.20			
Terrazzo grinders	4.15	.20			
Terrazzo base grinders	4.35	.20			
Tile setters	7.30	.30	.50		.05
Tile setters' helpers	4.05	.20			
Air conditioning or refrigeration mechanic	7.45	.30	.70		.025
Welders - Rate for Craft.					

FOOTNOTES:

a. Six paid holidays, A through F.

b. Employer contributes 1% of regualr hourly rate to vacation pay credit for employee who has worked in business more than 5 years. Employer contributes 2% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years.

c. Nine paid holidays, A through F plus Washington's Birthday, Good Friday, and Christmas Eve, providing employee has worked 45 full days during the 120 calendar days prior to the holiday, and the regular scheduled work days immediately preceding and following the holiday.

d. One-half day paid holiday: National General Election Day.

PAID HOLIDAYS: (WHERE APPLICABLE)
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

Florida 2-PEO-1-V

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Group I	$9.74	.375	.35		.05
Group II	8.755	.375	.35		.05
Group III	8.99	.375	.35		.05
Group IV	8.535	.375	.35		.05
Group V	6.725	.375	.35		.05
Group VI	6.985	.375	.35		.05
Group VII	6.495	.375	.35		.05

GROUP I:
Cat cranes, truck cranes, pile driver crane, derrick, dragline, material hoist with Chicago boom, material hoist with two drums, hydraulic lift form, diesel, electric and steam generators, motor grader, pumpcrete or similar machine, cherry picker, gradall, hypto and wheelabrator and mechanic, tractor backhoe, drill, rig and tack boom tractor

GROUP II:
Trenching machine over 24", winch truck, material hoist (elevator type)

GROUP III:
Tugger hoist

GROUP IV:
Crawler bulldozer, crawler tractor and turnapull, heavy huff-type front end loader, heavy DW-10 to DW-21 type rubber tired tractor, road roller, fireman, forklift, concrete batch plant operator

GROUP V:
Wellpoint system and pumps, material hoist, front end loader other than heavy huff-type rubber tired tractor with attachments other than backhoe

GROUP VI:
Air compressor 125 cu. ft. or over

GROUP VII:
Concrete mixer, rubber tired tractor without attachments, trenching machine under 24", high lift, sandblasting machines, welding machine, air compressor, miscellaneous pumps

150' boom; including jib: scale of top operator classification plus $.25 p.h. Tower crane operators $.25 per hour above top operator classification not including long boom pay.

Florida 29-PEO-1-h 1 of 1

Building Construction

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
POWER EQUIPMENT OPERATORS On building sites and includes roads, parking lots, storm sewer systems, railroads, drain fields, settling basins, pipelines (concrete and/or clay), land clearing, bulk heads and sea walls, and site preparation exclusive of excavation for buildings.						
HEAVY DUTY EQUIPMENT OPERATORS Cranes, shovels, draglines, pile-drivers (all types), concrete paving machines, ditching machines, mechanics, finish, motor grades, front end loaders, hoist (two drums or more), cherry pickers	$5.88	.325	.30		.05	
MEDIUM DUTY EQUIPMENT OPERATORS Motor patrols, bulldozers, rubber tired scrapers (all types), winch trucks, stabilizers, asphalt spreaders, rollers, asphalt rock crushers, concrete mixers (charger pan), light duty hydraulic tractor backhoe, and wellpoint pumps	5.605	.325	.30		.05	
LIGHT DUTY EQUIPMENT OPERATORS Finishing machine, bull floats, spray machines, subgraders, rollers on subgrade, pull cats (all types), form grader, bituminous distributor, hoist (less than two drums) and fireman	5.33	.325	.30		.05	

STATE: Florida COUNTY: See Below
DECISON NUMBER: FL75-1035 DATE: Date of Publication
Supersedes Decision No. AQ-4121 dated June 7, 1974 in 39 FR 20300
DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories) and Heavy and Highway Construction.

5 Florida -1-D

*COUNTIES: Brevard and Volusia (Cape Kennedy, Kennedy Space Flight Center and Patrick Air Force Base only and including Melabar Radar Site), Florida	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos workers	$8.91	.35	.35		.06
Boilermakers	8.20	.60	.90		.02
Bricklayers:					
Bricklayers and blocklayers	6.26	.35	.25		
Cement masons	6.26	.35	.25		
Masonry cutting or grinding machines	6.26	.35	.25		
Plasterers and manhole bricklayers	6.26	.35	.25		
Terrazzo workers	6.26	.35	.25		
Tile setters	6.26	.35	.25		
Carpenters:					
Carpenters, gypsum dry wall hangers	7.31	.35	.25		.05
Millwrights	8.65	.45	.45		.06
Piledrivermen	7.56	.35	.25		.05
Saw operator (radial)	7.56	.35	.25		.05
Soft floor layers	7.31	.35	.25		.05
Electricians:					
Base Zone (within 40 mile of the Union Office, 215 Ridgewood Ave., Daytona Beach):					
Electricians	8.28	.25	1%+.44		1%
Cable splicers	8.73	.25	1%+.44		1%
Zone 1 (beyond 40 miles from the Union Office):					
Electricians	8.73	.25	1%+.44		1%
Cable splicers	9.18	.25	1%+.44		1%
Ironworkers:					
Structural, finishers, burners, rodmen, welders, riggers and machinery movers	7.73	.45	.30	.54	.05
Sheeters	7.73	.45	.30	.54	.05
Laborers:					
Common laborers	4.70	.20	.30		.01
Hod carriers, kettlemen, mason tenders, mortar mixers, pipelayers (conc. & clay), air tool op., vibrator, plasterers tenders, well point dewatering, powdermen, paving form setters, concrete workers	4.85	.20	.30		.01
Nozzlemen (handling the nozzle of cement gun)	5.52	.20	.30		.01
Curb and gutter form setters	4.85	.20	.30		.01
Sidewalk	4.85	.20	.30		.01
Linemen:					
Linemen	7.61	.25	1%		½ of 1%
Cable splicer	7.76	.25	1%		½ of 1%
Class A operators	7.61	.25	1%		½ of 1%
Class B operators	5.38	.25	1%		½ of 1%
Groundman over 1 year	4.01	.25	1%		½ of 1%
Groundman under 1 year	3.39	.25	1%		½ of 1%
Painters:					
Commercial repainting:					
Brush and roller	6.55		.20		.05
Sandblasting	7.05		.20		.05
All other painting:					
Brush and roller	6.95		.20		.05
Sandblasting and spray	7.65		.20		.05
Hand drywall taping and finishing	6.95		.20		.05
Drywall work using Ames Tools or automatic tapers	7.65		.20		.05
Gloves and mittens, paperhanging, steam cleaning or power driven tools, grouting or caulking	7.65		.20		.05
Hot or cold tar materials, bitumatic, martite, flame matic or any similar materials	7.65		.20		.05
Asphalt excluding asphalt base aluminum and varnish	7.65		.20		.05
Plumbers and pipefitters	9.00	.43	.47		.05
Roofers:					
Roofers	4.85	.10	.05		
Helpers and tile tenders	2.75	.10	.05		
Kettlemen	3.40	.10	.05		
Sheet metal workers	8.89	.40	.25		.06
Sprinkler fitters	9.31	.50	.70		.10

Welders - Rate for Craft.

Florida 5-PEO-1-B

POWER EQUIPMENT OPERATORS

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP I	8.00	.40	.35		.05
GROUP II	7.51	.40	.35		.05
GROUP III	7.05	.40	.35		.05
GROUP IV	6.65	.40	.35		.05
GROUP V	5.93	.40	.35		.05

GROUP I: Cranes, hydraulic or derrick on structural or reinforcing iron, cranes or derrick, clam shell dragline. piledriver operator (including auger & boring machine op. for drilling in piling), backhoe (including hydraulic), hydraulic crane. gradeall, shovel. motor patrol, mechanic heavy equipment, side boom cat & multi-drum hoist.

GROUP II: Bulldozer & trenching machine, bridge crane, highlift, straddle buggy, hoist, earth hauling scraper (regardless how powered), pump crete & front end loader

GROUP III: Winch truck, concrete/asphalt paver, fork lift, locomotive engineer, boring machine, well drilling machine & mobile cleaning plant

GROUP IV: Tractor, well point pump & installation man, fireman, lubrication engineer equipment greaser & air compressor

GROUP V: Motor boat, oiler, mechanic helper, pumpman (other than well point), roller (steel & rubber tires) self-powered, conveyor, welding machine (three or more combustion engines & Pulver mixer)

5 - Florida TD (SP) (1-1)

TRUCK DRIVERS

	Basic Hourly Rates	Fringe Benefits Payments				
		H & W	Pensions	Vacation	App. Tr.	Others
GROUP I	$4.40					
GROUP II	$4.50					
GROUP III	$4.60					
GROUP IV	$4.65					
GROUP V	$5.00					
GROUP VI	$5.10					

GROUP I: Buses, jeeps, station wagons, pilot or escort cars, trucks up to 6 cu. yds. or 2-ton capacity, water trucks (single axle), dumpmen & tire repairmen

GROUP II: Dump trucks 6 cu. yds. to 13 cu. yds. capacity, transit mix trucks (single axle), 3 axle trucks

GROUP III: Dump trucks 13 cu. yds. capacity, truck mechanic helper

GROUP IV: Ashpalt distributor trucks, lumber carriers & similar type equipment, lift gate trucks, transit mix trucks (tandem axle), dump trucks 16 cu. yds. or more, fuel & grease trucks, and 4-axle trucks

GROUP V: A-frame trucks, boom trucks, gin pole trucks, winch trucks (when used for hauling material & equipment), trucks with 5-axle or more, fork lift trucks

GROUP VI: Euclids, euclid water truck, caterpillars, or similar off highway earth moving equipment (not self-loaded), truck mechanic

STATE: Florida COUNTY: Alachua
DECISION NUMBER: FL75-1037 DATE: Date of Publication
Supersedes Decision No. AR-4026 dated August 30, 1974 in 39 FR 31791
DESCRIPTION OF WORK: Building and Heavy Construction (excluding single family homes and garden type apartments up to and including 4 stories, and excluding Sewer and Water Line Construction).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos workers	8.81	.30	.30		.02
Boilermakers	8.20	.60	.90		.02
Bricklayers	7.50	.25	.20		.02
Carpenters	7.42	.39	.30	.30	.03
Accoustical workers	7.42	.39	.30	.30	.03
Millwrights	8.10	.39	.20		.03
Piledrivermen	7.42	.39	.30	.30	.03
Cement masons	6.90	.25	.20		.02
Electricians:					
Wiremen	7.40	.25	1%		1%
Cable splicers	8.00	.25	1%		1%
Elevator Constructors	8.16	.445	.29	3%+a+b	.02
Elevator Constructors' helpers	70%JR	.445	.29	3%+a+b	.02
Elevator Constructors helpers (prob.)	50%JR				
Glaziers	8.00		.20		.01
Ironworkers, structural & ornamental	7.75	.47	.60		
Laborers:					
Unskilled	4.25	.15	.05		
Air tool operator	4.35	.15	.05		
Mortar mixers	4.35	.15	.05		
Pipelayers (concrete & clay)	4.35	.15	.05		
Lathers	5.50				.01
Leadburners	6.90	.30		c	.01
Line Construction:					
Linemen	7.39	.25	1%		1%
Cable splicers	7.59	.25	1%		1%
Winch truck operator	5.91	.25	1%		1%
Heavy equipment operator	7.14	.25	1%		1%
Flat bed pick-up driver	5.21	.25	1%		1%
Groundmen, 1st class	4.34	.25	1%		1%
Groundmen, 2nd class	3.43	.25	1%		1%
Marble setters	6.20	.15			
Painters:					
Brush	6.11				
Paperhangers	6.61				
Structural steel	6.71				
Spray	6.61				
Sandblasting	6.61				
Roller	6.61				
Swing stage	6.71				
Boatswain's chair	6.71				
Plasterers	6.85	.18			
Plumbers	9.40	.20	.25		.10
Roofers	6.99	.30	.05		
Roofers' helpers & Kettlemen	3.83	.30	.05		
Sheet metal workers	7.78	.50	.40	.70	.085
Soft floor layers	7.42	.39	.20	.15	.03
Sprinkler fitters	9.31	.50	.70		.10
Steamfitters	9.40	.20	.25		.10
Stone masons	7.10				
Terrazzo workers	6.90	.25	.20		.02
Tile setters	6.90	.25	.20		
Welders - receive rate prescribed for craft performing operation to which welding is incidential.					

FOOTNOTES:

a. Six paid holidays, A through F.

b. Employer contributes 4% of regular hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 2% or regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

c. Nine paid holidays, A through F plus Christmas Eve, Washington's Birthday and Good Friday, providing employee has worked 45 full days during the 120 calendar days prior to the holidays, and the regular schedule work days immediately preceding and following the holidays.

PAID HOLIDAYS (Where Applicable)
A-New Year's Day; B-Memorial Day; C-Indenpendence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

Florida 1-PEO-1-W (1-1)

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Apprn. Tr.
GROUP I	8.03	.40	.35		.05
GROUP II	6.96	.40	.35		.05
GROUP III	6.12	.40	.35		.05
GROUP IV	5.04	.40	.35		.05

GROUP I: Cranes, derricks, clam shells, draglines, piledriver (including auger & boring machine for drilling in piling), backhoes, hydra cranes, grade all, shovels, patrols, cableways, tug boat captain (150 H.P. or more), multi-bowl operator (similar to R.G. LaTourneau Model L-60-2 or 3 twenty cu. yd. scrapers), front end loaders, (over 4 cy cap.), side boom cats, multi-drum hoist (for rigging), mechanic (heavy equip.) tower crane (stationary, climbing & traveling), gantry cranes, locomotive cranes, bridge cranes (over 20 ton cap.), concrete pump with boom (mobile), high lift or fork lift (second floor & higher) Locomotive engineer (jobs not covered by railrdad unions)

GROUP II: Bulldozers, bridge cranes (20 tons & under), highlift or forklift (up to 2nd floor), straddle buggys, hoists (other than rigging) including winch truck not mobile & used as a hoist, front end loader (over 2 cy & up to & incl., 4 cy cap.), trenching machine (ladder & wheel type) over 6' cut & over 24" width, concrete paver & scrapers

GROUP III: Concrete pumps, front end loader (2 cy or less not used as hoist) mobile winch trucks, self-propelled sub-grader, asphalt paving machine concrete mixer, tractors, air compressor plant (2 or more compressors on a common manifold), lubricating engineer (mobile plant), pavement breakers, street sweeping machines

GROUP IV: Tractor operated sweeper, trenching machine (ladder & wheel type maximum cut 6' & maximum width 24"), fireman, self-propelled rollers, wellpoint pump, asphalt distributor, water truck driver, motor boat operator, oiler, mechanics' helpers, pumpman (other than well point up to & incl., 5 pumps within 300 ft. radius), self-propelled sweepers, combination pump, compressor & combustion type welding machine

SUPERSEDEAS DECISION

STATE: Illinois

COUNTIES: Henry, Knox, Mercer & Rock Island

DECISION NUMBER: IL75-2051

DATE: Date of Publication

Supersedes Decision N. AR-3175 dated December 13, 1974, in 39 FR 43469

DESCRIPTION OF WORK: Building Construction, (excluding single family homes and garden type apartments up to and including 4 stories).

DECISION NO. IL75-2051

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
ASBESTOS WORKERS	$8.05	.25	.25		.10
BOILERMAKERS	8.55	.40	.65		.01
BRICKLAYERS & STONEMASONS:					
Rock Island & Mercer Counties:					
Bricklayers & Stonemasons	8.85	.35	.30		.02
Marble, Tile & Terrazzo Workers	8.75		.30		
Henry County:					
Bricklayers, Stonemasons and Plasterers	9.00	.20			
Knox County:					
Bricklayers & Stonemasons	8.92	.45	.40		.05
CARPENTERS:					
Rock Island, Mercer & Henry Cos:					
Carpenters & Soft Floor Layers	8.31	.35	.50		.02
Millwrights	8.45	6%	7%		6%
Piledrivermen	8.56	.35	.50		.02
Knox County:					
Carpenters, Piledrivermen & Soft Floor Layers	7.65	.45	.25		.02
Millwrights	8.62	.45	.25		.02
CEMENT MASONS:					
Rock Island; Mercer & Western ½ of Henry County	8.27	.40	.35		
Remainder of Henry County	8.55	.20			
Knox County	7.60	.15	.25		
ELECTRICIANS:					
Knox County, Mercer (Twps. of Ohio Grove, North Henderson & Suez) County	8.65	.30	1%+.20		.25%
Henry (Twps. of Annawan, Burns, Cambridge, Galva, Kewanee, Weller & Westerfield) County	9.50	.30	1%+.80		.25%
Rock Island County & Remainder of Henry & Mercer Counties	9.25	.32	5.5%		.03
ELEVATOR CONSTRUCTORS:					
Constructors	8.885	.445	.29	3%+a&b	.02
Helpers	70%JR	.445	.29	3%+a&b	.02
Helpers (Prob.)	50%JR				
GLAZIERS	$7.3848	.40	.82		
IRONWORKERS:					
Knox (All Area South & East of Galesburg) County	9.025	.40	.475		
Mercer Co., Knox (All Area West & Southwest of Galesburg) County	8.54	.40	.30		
Rock Island County, Henry County & Knox (Within Galesburg & all Area North of City) County	8.75	.40	.375		.07
LATHERS:					
Knox County	9.00				.01
Remainder of Counties	8.98		.20		
LEADBURNERS	9.25	.35		c	.01
PAINTERS:					
Rock Island, Mercer, Henry Counties & West of line extending from NE Corner to SW Corner of Knox County:					
Brush & Roller	7.22	.40	.40		.09
Spray & Structural Steel	7.47	.40	.40		.09
Remainder of Knox County:					
Brush & Paperhangers	6.38	.25	.15		
Structural Steel	6.63	.25	.15		
PLASTERERS:					
Knox County	7.60	.15	.25		
Rock Island & Mercer Counties	9.18				
ROOFERS:					
Knox County	7.15				
Remainder of Counties	9.75		.20		
SHEET METAL WORKERS:					
Rock Island & Mercer Counties	8.95	.25	.20		.02
Knox & Henry Counties	8.00	.25	.20		.035
SPRINKLER FITTERS	9.40	.50	.70		.08
WELDER - receive rate prescribed for craft performing to which welding is incidential.					

DECISION NO. IL75-2051

PAID HOLIDAYS (WHERE APPLICABLE):
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Six Paid Holidays: A through F.

b. Employer contributes 4% of regular hourly rate to Vacation Pay Credit for employee who has worked in business more than 5 years. Employer contributes 2% of regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

c. Nine paid holidays, A through I plus Washington's Birthday and Good Friday and Christmas Eve, providing employee has worked 45 full days during the 120 calendar days prior to the holiday, and the regular scheduled work days immediately preceding and following the holiday.

DECISION NO. IL75-2051

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
LABORERS:					
ROCK ISLAND & MERCER COUNTIES					
UNSKILLED	$7.12	.30	.50		.035
SEMI-SKILLED	7.37	.30	.50		.035
SKILLED	7.62	.30	.50		.035

LABORERS - ROCK ISLAND & MERCER COUNTIES

UNSKILLED
Common Laborer; Carpenter Tender; Rod & Chain Man; Flagman; Gravel Box Men; Dumpmen & Spotters; Form Handlers; Material Handlers; Fencing Laborers; Cleaning Lumber; Material Checkers; Dispatchers; Landscapers; Unloading Explosives; Laying of Sod; Planting of Trees; Removal of Trees; Asphalt Plant Laborers; Wrecking Laborers; Writers of Scale Tickets, Scaleman (Permanent-Portable or Temporary Plant); Dock Hand.

SEMI-SKILLED
Laying & Jointing of Telephone Conduit; Darco & Jackhammer Operator; Mechanical Tamper and Air Spade; Wagon & Hand Drill; Vibrator Operator; Operator on Power Tools used under the jurisdiction of Laborers; Cement Jumper; Puddler; Form Setter Helper; Power & Hand Saw (when clearing timber); Center Strip; Reinforcing in Concrete; Wire Mesh; Concrete Saw; Mortar Mixer; Prime Mover or any mechanical device taking the place of concrete buggy or wheelbarrow; Sand Point Setter; Asphalt Kettleman; Mastic Asphalt Mixerman or other preparations used on joints; Shooting Hammer Drivers (2-Men) Back up Man or Joint Man with Pipelayer; Laborer in ditch or tunnel on sewer and water main & telephone conduit Gas Distribution Men; Pipe Setter on Laterals, Drain Tiles, Culvert Pipe, & Storm Sewer Connections to Catch Basins, Manholes or Main Line; Handling of Materials treated with oil, creosote, asphalt and/or any foreign material harmful to skin or clothing; Chloride Handlers; the Unloading & Laborers w/Steel Workers and Re-Bars; Tunnel Helpers in Free Air; Batch Dumpers; Tank Cleaners; Cofferdam Workers; Bankmen on Floating Plant.

SKILLED
String on Wireline (1-man); Head Form Setter; Dynamite Man; Asphalt Raker; Tunnel Miner; Pipelayer on Sewer & Water Main; Gunnite Nozzle Man; Welders; Cutters; Burners & Torchman; Screedman on Asphalt Pavers; Lutemen; Curb Asphalt Machine Operator; Laser Beam Operator; Concrete Burning Machine Operator; Coring Machine Operator; Head Grade Man.

DECISION NO. IL75-2051

LABORERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
HENRY COUNTY					
UNSKILLED	$6.97	.30	.20		.035
SEMI-SKILLED	7.17	.30	.20		.035
SKILLED	7.37	.30	.20		.035
KNOX COUNTY					
UNSKILLED	7.29	.30	.20		.035
SEMI-SKILLED	7.49	.30	.20		.035
SKILLED	7.69	.30	.20		.035

LABORERS - HENRY & KNOX COUNTIES

UNSKILLED

Common Laborer; carpenter tenders; tool cribmen; firemen or salamander tenders; flagmen; gravel box men; dumpmen; spotters; form handlers; material handlers; fencing laborers; cleaning lumber; pit men; material checkers; dispatchers; lanscapers; unloading explosives; laying of sod; planting of trees; asphalt plant laborers; wrecking laborers; writer of scale tickets; fire shop laborers; fireproofing laborers; janitors; wrecking - dismantling buildings; wallmen & housemovers; driving of stakes; stringlines for all machinery.

SEMI-SKILLED

Handling of materials treated with oil, creosote, asphalt or any foreign material, track laborers; cement handlers; chloride handlers; the unloading and laborers w/steel workers & rebars; concrete workers (wet); tunnel helpers in free air; batch dumpers; mason & plasterer tenders & material wheelers; kettlemen & tarmen; tank cleaners; plastic installers; scaffold workers; motorized buggies or motorized unit used for wet concrete or handling of building materials; laborers w/dewatering systems; all sewer workers plus depth; rod & chainmen with land surveyors; vibrator operators; mortar mixer operator; cement silica, clay, fly ash, lime & plasters; handlers (bulk or bag); cofferdam workers plus depth; (on concrete paving) placing, cutting & trying or reinforcing; deck hand; dredge hand & shore laborers; bankmen on floating plant; asphalt workers w/machine; asphalt raker; grade checker.

SKILLED

Dynamite man or blasters; caisson workers plus depth; gunnite nozzle men; leadman on sewer work; welders; cutters; burners; torchmen; chain saw operator; jackhammer & drill operators; layout man; steel form setters (street or highway); air tamping hammerman; signal man on crane, concrete saw operator; screenman on asphalt pavers; laborers tending masons w/hot materials are used; multiple concrete duct-leadmen; lutemen; curb asphalt machine operator; ready-mix scalemen; portable or temporary plant; laborers handling masterplate or similar materials; laser beam operator; coring machine operator.

DECISION NO IL75-2051

POWER EQUIPMENT OPERATORS: ROCK ISLAND; MERCER COUNTIES; & WESTERN ½ OF HENRY COUNTY	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
CLASS I	$9.10	.40	.50		.08
CLASS II	9.00	.40	.50		.08
CLASS III	8.90	.40	.50		.08
CLASS IV	7.75	.40	.50		.08
CLASS V	6.65	.40	.50		.08
CLASS VI	7.50	.40	.50		.08

POWER EQUIPMENT OPERATORS - ROCK ISLAND; MERCER COUNTIES; & WESTERN ½ OF HEAVY COUNTY

CLASS I:

All hoists or steel erecting equipment used to hoist or erect in conjunction with the crew of a specialty trade.

CLASS II:

Cranes, shovel, clamshell, dragline, backhoe, derrick, tower crane, cableway, cohorete spreader (servicing two pavers), asphalt spreader, asphalt mixer plant engineer, dipper op., dipper dredge craneman, dual purpose truck (boom or winch), leverman or engineman (hydraulic dredge), mechanic, paving mixer with tower attached (two operators required), pile driver, boom tractor, stationary, protable or floating mixing plant, trenching machine, cleaning and priming machine, endloader (one half cubic yard or over, on basement excavation work), backfiller (throw bucket), locomotive engineer, Qualified welder tow or push boat concrete paver, seaman trav-L-plant or similar machines, CMI autograder or similar machines, slip form paver, caisson augering machine, muching machines, asphalt heater-planer unit hydraulic cranes.

CLASS III:

Athey, Barber-Green, euclid or hasis loader, asphalt pug mill, Fireman and drier, concrete pump, concrete spreader (servicing one paver), bulldozer, endloader (other than mentioned above), forklift, elevating grader, group equipment greaser, letourneapull and similar machines, IW-10, straddle carrier, hysrer winch and similar machines, motor patrol, power blade push cat, tractor pulling elevating grader or power blade, tractor operating scoop or scraper, tractor with power attachment, roller on asphalt ro blacktop, single drum hoist, Jaeger mix and place machine, pipe bending machine, welding machines (3 or 4), fuller kenyon cement pump or similar machines, automatic cement and gravel batch platns (one stop set-up), Seaman pulvi-mixer or similar mcahines, propelled sheep foot roll or compactor (used in conjunction with a grading spreader), mud jack, underground boring machine (over 8"), apsco spreader or similar machine.

DECISION NO. IL75-2051

POWER EQUIPMENT OPERATORS CONT'D - ROCK ISLAND: MERCER COUNTIES; & WESTERN ½ OF HENRY COUNTY

CLASS IV:

Asphalt booster, fireman and pump operator at asphalt plant, compressor (500 cu., ft. and over), concrete finishining machine, form grader with roller on earth, mixers (3 bag to 16E), power operated bull float, tractor without power attachment, Dope pot (agitating motor), Dope chop machine, distributor (back end), Flexaplane or similar machines, portable machine fireman, Hydrohammer, power winch on paving work, self-propelled roller or compactor (other than provided for above), pump operator crusher operator, trench machine (20 H.P. and under), power sub grader (on forms) or similar machines, ashpalt spreader screed operator, conveyor.

CLASS V:

Oiler, mechanic & helper, water pump (pumping water to paver), mechanical heater (other than steam boiler) belt machine, small outboard motor boat.

CLASS VI:

Air compressor (275 c.f.m. or over) driver on truck cranes or similar machines, light plant, mixers (1 or 2 bags), power batching machine (cement auger or conveyor), boiler (engineer or fireman, water pumps, welding machine, mechanical broom, automatic cement & grabel plants (two or three stop set-up), small backhoes or endloaders), self-propelled curing machine.

DECISION NO. IL75-2051

POWER EQUIPMENT OPERATORS: KNOX CO. & EASTERN ½ OF HENRY CO

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP I	8.92	.45	.55		.05
GROUP 2	8.72	.45	.55		.05
GROUP 3	8.445	.45	.55		.05
GROUP 4	8.17	.45	.55		.05
GROUP 5	8.06	.45	.55		.05

POWER EQUIPMENT OPERATORS - KNOX COUNTY & EASTERN ½ OF HENRY CO.

GROUP 1:

Cranes, escalated rate on crane, derricks, booms, $.01 per hour, per foot, after 80 feet of boom including job, overhead cranes, gradall, cherry pickers (and similar types, over 15 tons lifting capacity (required oiler), mechanics, central concrete mixing plant operator, road pavers (27E-dual drum-tri batchers), blacktop plant operators and plant engineers, 3 drum hoist, derricks, hydro cranes, shovels skimmer scoops, koehrings scoopers, draglines, backhoe, hoptoes-crane-type that requires oilers, derricks boats, pile drivers and skid rigs, clamshells. locomotive cranes, dredge (all types), motor patrol, power blades dumore-elevating and similar types tower cranes (crawler mobile) and stationary, cranes-type backfiller, drott yumbo and similar types considered as cranes, caisson rigs (require oilers)-dozer, tourna-dozer, work boats, rose carrier and helicopter

GROUP 2:

Trench machine, pumperete-belt crete-squeeze cretes-screw-type pumps and gypsum bulker and pump, dinkeys, power launches, tournapulls (all), multiple unit, earth movers, $ 25 per hour for each scoop over one, scoops (all sizes), push cats, endloaders (all types), side booms, P-H one pass soil-cement machine (and similar types), wheel tractors (industrial or farm type w/dozer-hoe-end-loader or other attachments), pugmill with pump backfillers, ashplat surfacing machine, euclid loader, forklifts, formless finishing machine, jeeps w/ditching machine, or other attachments, tune-luger, rock crushers, automatic cement and gravel batching plants, mobile drills (soil testing and similar types), (requir oiler), flaherty spreader or similar types (require oiler), heavy equipment greaser (top greaseron spread), gurries and similar type), 1 and 2 drum hoists (buck hoists and similar types freight and passenger elevator Chicago boom, boring machine and pipe jacking, machine, hydro boom, starting engineer or pipeline, C.M.I. and similar types (require oiler) straw blower, hydro seeder and F.W.D. and similar types

DECISION NO. IL75-2051

POWER EQUIPMENT OPERATORS (CONT D) - KNOX CO.& EASTERN ½ OF HENRY CO.,

GROUP 3:
Tractor (track type) without power unit pulling rollers, rollers on ashplat, brick or macadam, concrete breakers, concrete spreaders, mule pulling rollers, center stripper, cement finishing machines, barber greene or similar loaders, vibro tamper (all similar types), self-propelled, winch or boom truck, mechanical bull floats, mixer over 3 bags to 27E, tractor pulling power blade or elevating grader, porter rex rail, clary screed, pugmill (without pump) screed man on laydown machine, fireman and spray machine on paving

GROUP 4:
Air compressor, all air and steam valves, power subgrader, oil distributor, straight tractor, tra-air without attachments, curb machines, truck crane oilers, and truck type hoptoe oilers

GROUP 5:
Herman Nelson heater, Dravo, Warner, Silent glo, and similar types, one engineer will operate 1.5 and after 5, two operators will be required, self-propelled concrete saws, assistant heavy equipment greaser on spread, roller, 5 tons and under on earth or gravel, form grader, pump 1 or 2, generator (1) or (2), welding machine (1) or (2)-300 amp. or over, mixer (3) bad and under (standard capacity), bulk cement plant, crawler crane and skid rig oilers

DECISION NO. IL75-2051

TRUCK DRIVERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP I	8.10	.45	a13.00		
GROUP II	8.50	.45	a13.00		
GROUP III	8.70	.45	a13.00		

TRUCK DRIVERS

GROUP I:
Drivers on 2 axle trucks hauling less than 9 tons, air compressor and welding machine including those pulled by separate units, truck driver helpers, warehouseman, mechanic helpers, greasers & tiremen, pick-up trucks when hauling materials, tools, or men to and from and on the jobs site; Fork lifts up to 6,000 lbs., capacity.

GROUP II:
2 or 3 exle trucks hauling more than 9 ton, but hauling less than 16 tons A-frame winch trucks, hydrolifts trucks, or similar equipment when used for tranportation purposes: Fork lifts over 6,000 lb. capacity; winch trucks; 4-axle combination units; ticket writers

GROUP III:
2-3 or 4 axle trucks hauling 16 ton or more, drivers on oil distributors, water pulls, mechanics & working foreman; 5-axle or more combination units; dispatchers.

FOOTNOTES:
a.-Per Week Per Employee.

SUPERSEDEAS DECISION

STATE: IOWA

COUNTY: BENTON, IOWA, JOHNSON (EXCLUDIN IOWA CITY), KEOKUK, MAHASKA, POWESHIEK, TAMA, & WASHINGTON

DECISION NO.: IA75-4066

DATE: DATE OF PUBLICATION

Supersedeas Decision No. AR-74, dated November 1, 1974, in 39-FR-38798

DESCRIPTION OF WORK: HIGHWAY CONSTRUCTION

HIGHWAY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
CARPENTERS:					
Zone I-Keokuk	$6.55	.31			
Zone II -Benton, Iowa, Johnson, Mahaska, Poweshiek, Tama & Washington	5.25				
CEMENT MASONS	4.49				
LABORERS:					
Unskilled:					
Zone I-Keokuk	3.59				
Zone II-Benton, Iowa, Johnson, Mahaska, Poweshiek, Tama & Washington	5.10				
POWER EQUIPMENT OPERATORS:					
Asphalt plants	3.00				
Bulldozers, cranes, derricks, draglines	6.30	.40	.30		.03
Backhoes	5.17				
Front end loaders	4.58				
Mechanics	5.13				
Motor patrols, finish	5.71				
Motor patrols, rough	4.60	.40	.20		.01
Scrapers, self-loading	4.72				
Slip-form paver	4.80	.40	.20		.01
TRUCK DRIVERS:					
Single axle	3.80	.20			
Tandem	3.90	.20			

SUPERSEDEAS DECISION

STATE: Pennsylvania COUNTY: Luzerne
DECISION NO.: 75-PA-3025 DATE: Date of Publication
Supersedeas Decision No. 75-PA-3018, dated February 21, 1975, in 40 FR-7856.
DESCRIPTION OF WORK: Building construction, including single family homes and garden type apartments up to and including 4 stories.

40-PA-1- W 1 of 4

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Asbestos workers	$9.00	.50	.35		.01
Boilermakers	10.20	.65	1.00		.01
Bricklayers and Stonemasons					
Avoca, Exeter, & Pittston	8.30	.20		c	
Hazleton, Berwick & Freeland:					
Commercial	8.30	.35	.50		
Nescopeek, Hollenback & Salem Twps.	8.25	.30	.50		
Remainder of County	9.15	.35	.50		
Carpenters:					
Hazleton, Freeland, Black Creek, Butler, Dennison, Foster, Hazle, Hollenback, Nescopeck, Sugarloaf and lower part of Salem Twps.	8.13	.25	.35		.02
Remainder of County	8.60	.25	.35		.02
Cement Masons:					
Pittston, Yatesville, Laflin, Exeter Wyoming, Duryea & Avoca	8.40	.40	.40		
Hazleton and Freeland	8.075				
Remainder of County	9.20				
Electricians (Hazleton)					
Commercial	9.12	.35	1%+.25	f	k
Remainder of County	9.15	.30	1%+.35	.35	.005
Elevator Constructors	9.04	.445	.29	3%+a+b	.02
Elevator Constructors' helpers	6.33	.445	.29	3%+a+b	.02
Elevator Constructors' helpers (Prob)	4.52				
Glaziers	8.25	.35	.40		
Ironworkers:					
Structural and Ornamental	9.85	.64	1.06		.10
Reinforcing	9.75	.64	1.06		.10
Laborers (Hazleton)	6.23	.25	.35		
Mason Tenders including Scaffold Builders	6.63	.25	.35		
Pneumatic, electrical & mechanical tool operators, 2" pumps-non metallic pipelaying and making joint clay, terra cotta, ironstone vitrified concrete, handling of burning torches asphalt or other hot materials, cement finishers and blasters helpers, power buggies, walk along hoist	6.33	.25	.35		

75-PA-3025 P. 2

40-PA-1- W 2 of 4

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Plasterers tenders, blasters, and wagon drill operators	$6.48	.25	.35		
Laborers: Remainder of County					
Unskilled laborers	7.17	.25	.35		
Semi skilled laborers, Pneumatic and other mechanical tool ops; 2" pump or under, handling and mixing of all material used by masons from stock pile to mason, Non-metallic pipelayer and making of joints, clay, terra cotta, ironstone, vitrified concrete, handling of burning torches asphalt or other hot material, cement finishers and blasters helpers	7.37	.25	.35		
Plasterers tenders, blaster, wagon drill ops.	7.49	.25	.35		
Mason tenders & scaffold builders	7.57	.25	.35		
Lathers:					
Pittston, Avoca, Dupont & Duryea	8.79		.10		.01
Remainder of County	9.08		.15		.01
Leadburners	9.25	.35		e	.01
Line Construction:					
Linemen, Dynamiteman, Heavy equipment operator	9.50	.20	1%		
Groundman	6.46	.20	1%		
Groundman - truck driver	6.74	.20	1%		
Marble setters:					
Pittston	8.15	.20			
Hazleton	7.80	.35	.50		
Remainder of County	8.82				
Millwrights	9.18	.25	.35		.02
Painters:					
Pittston:					
Commercial Brush	6.20		.25		
Industrial Brush	6.99		.25		
Remainder of County					
Brush	7.25	.30	.30		.05
Tapers	7.51	.30	.30		.05
Hazardous	8.51	.30	.30		.05
Piledrivermen	9.92	1.28	.90	g	.07

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Plasterers:					
Hazleton	$7.05				
Pittston, Yatesville, Laflin, Exeter, Wyoming, Duryea and Avoca	7.85	.40	.40		
Remainder of County	8.25				
Plumbers:					
Pittston	7.77	.35	.75		.06
Hazleton:					
Commercial	9.35	.30	.25		
Wilkes Barre	9.54	.35	.75		.03
Roofers, composition & Kettlemen	8.25	.50	.40		
Sheet metal workers	8.97	.55	.40		.04
Soft floor layers	7.79	.25	.35		.02
Sprinkler fitters	9.60	.50	.70		.08
Steamfitters:					
Wilkes Barre	9.29	.35	.50		.04
Pittston	7.77	.35	.70		.06
Hazleton	9.35	.30	.25		
Truck Drivers: Pittston:					
Truck Drivers:					
Class I					
Helper, Stake Body Truck (single axle Dumpster)	6.57				
Class II					
Dump Trucks, Tandem & Batch Trucks, Semi-Trailers, Agitator Mixer Trucks, Ready Mix and Dumperete Type Vehicles Asphalt Distributors, Farm Tractor when used for transportation, Stake Body Truck (Tandem)	6.64				
Class III					
Euclid Type, Off-Highway Equipment - Back or Belly Dump Trucks and Double-Hitched Equipment, Straddle (Ross) Carrier, Low-Bed Trailers	7.13				
Remainder of County:					
Pickups service dump and flat incl. 2 license	7.32	h	j		

BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
Truck Drivers (CONT'D)					
All trucks over 2 license	$7.37	h	j		
Fork lifts, tow motors, front and pneumatic tired loaders	7.33	h	j		
Welder receive rate for craft					

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day- F- Christmas Day.

FOOTNOTES:

a. Employer contributes 4% basic hourly rate for 5 years or more of service or 2% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

b. Six paid holidays: A through F.

c. Paid Holiday: July 4th.

d. Employer contributes $1.50 per hour to health and welfare and pension fund.

e. Eight(8) paid holidays, A through F, Washington's Birthday, Good Friday and Christmas Eve, provided the employee has worked 45 days for the employer during the 120 days prior to the holiday, and is available for work the days preceding and following the holiday.

f. Paid Holidays: July 4th and Labor Day, Thanksgiving Day.

g. Paid Holidays: Washington's Birthday, Good Friday; Memorial Day; Labor Day; Presidential Election Day; Veterans' Day; and Thanksgiving Day.

h. $41.00 per month for employees who have worked 60 hours or more during the month.

j. $25.00 per month to employee employed for over 13 weeks.

k. Employer shall contribute .12 per day per employee.

PA-22-FEO-1-A 1 of 2

POWER EQUIPMENT OPERATORS BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP 1	$10.19	4.6%	9.5%	a	1.2%
GROUP 2	9.90	4.6%	9.5%	a	1.2%
GROUP 3	9.02	4.6%	9.5%	a	1.2%
GROUP 4	8.25	4.6%	9.5%	a	1.2%
GROUP 5	7.77	4.6%	9.5%	a	1.2%
GROUP 6	6.85	4.6%	9.5%	a	1.2%
GROUP 7	10.44	4.6%	9.5%	a	1.2%
GROUP 7-A	10.69	4.6%	9.5%	a	1.2%
GROUP 7-B	10.94	4.6%	9.5%	a	1.2%

GROUP 1: Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above

GROUP 2: All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above

GROUP 3: Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above

GROUP 4: Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seaman pulverizing mixer, power broom, seeding spreader, tireman (for power equipment), machines similar to above

GROUP 5: Fireman, grease truck

GROUP 6: Oilers and deck hands (personnel boats), core drill helper

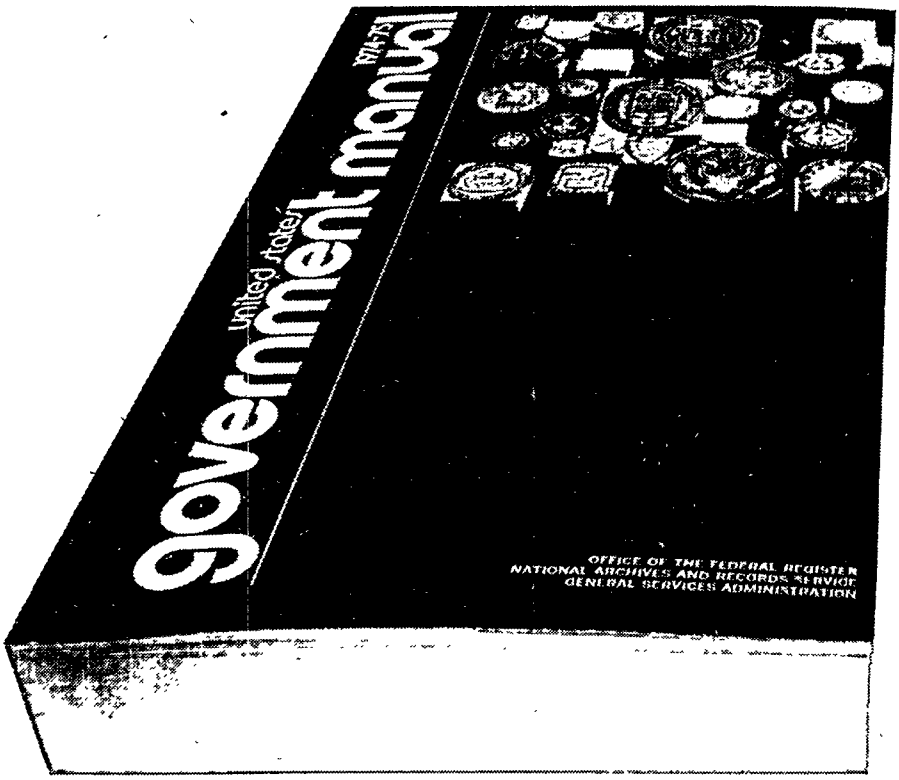
GROUP 7: All machines with booms (including jib, masts, leads, etc.): 100 ft. and over

GROUP 7-A: 150 ft. and over

GROUP 7-B: 200 ft. and over

FOOTNOTE:
a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day, provided the employee works the day before and after the holiday.

[FR Doc.75-7191 Filed 3-20-75;8:45 am]



an invaluable reference tool

1974–75 Edition

This official guidebook provides useful information about U.S. Government agencies, including:

- Major programs and functions
- Listings of key officials
- Organization charts for many agencies

Most agency descriptions include a "Sources of Information" section that gives addresses and telephone numbers for obtaining specifics on employment, government contracts, environmental programs, small business opportunities, publications, speakers and films available to civic and educational groups, and other topics of public interest.

This handbook is a "must" for teachers, students, librarians, researchers, businessmen, and lawyers who need current official information about the U.S. Government.

$5.75
per copy. Paperbound, with charts

THE NATIONAL ARCHIVES OF THE UNITED STATES • 1934 •

MAIL ORDER FORM To:

Superintendent of Documents, Government Printing Office, Washington, D.C. 20402

Enclosed find $..... (check, money order, or Supt. of Documents coupons). Please send me ..... copies of the UNITED STATES GOVERNMENT MANUAL, 1974–75, *at $5.75 per copy. (Catalog No. GS 4.109:974) (Stock No. 2203–00907)*

Please charge this order to my Deposit Account No. .....

Name .....

Street address .....

City and State ..... *ZIP Code* .....

For Use of Supt. Docs.
.....Enclosed.....
To be mailed later.....
.....Subscription.....
Refund.....
Coupon refund.....
Postage.....

☆ GPO : 1975—O-39-000