be small for purposes of RFA. Interpretive Ruling and Policy Statement (IRPS) 87–2 as amended by IRPS 03–2. The proposal clarifies and expands the lending rules to incorporate recent OGC opinions. The NCUA has determined and certifies that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small credit unions. Accordingly, the NCUA has determined that a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

NCUA has determined that the proposed rule would not increase paperwork requirements under the Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget (OMB). NCUA currently has OMB clearance for § 701.21's collection requirements (OMB No. 3133–0139).

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on State and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. The proposed rule applies only to federal credit unions. NCUA has determined that the proposed amendments will not have a substantial direct effect on the States, on the connection between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this proposed rule does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act, 1999—-Assessment of Federal Regulations and Policies on Families

NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Pub. L. 105–277, 112 Stat. 2681 (1998).

Agency Regulatory Goal

NCUA's goal is clear, understandable regulations that impose a minimal regulatory burden. We request your comments on whether the proposed rule is understandable and minimally intrusive if implemented as proposed.

List of Subjects in 12 CFR Part 701

Credit unions, Loans.

By the National Credit Union Administration Board on November 18, 2004.

Mary Rupp,

Secretary of the Board.

Accordingly, the National Credit Union Administration proposes to amend 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATIONS OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789.

2. Amend § 701.21 by revising paragraphs (e), (f) and (g)(1) to read as follows:

§ 701.21 Loans to members and lines of credit to members.

* * * * *

(e) *Insured, guaranteed and advance commitment loans.* A loan secured, in full or in part, by the insurance or guarantee of, or with an advance commitment to purchase the loan, in full or in part, by the Federal Government, a State Government or any agency of either, may be made for the maturity and under the terms and conditions, including rate of interest, specified in the law, regulations or program under which the insurance, guarantee or commitment is provided.

(f) *20-year loans.* (1) Notwithstanding the general 12-year maturity limit on loans to members, a federal credit union may make loans with maturities of up to 20 years in the case of:

(i) A loan to finance the purchase of a mobile home if the mobile home will be used as the member-borrower's residence and the loan is secured by a first lien on the mobile home, and the mobile home meets the requirements for the home mortgage interest deduction under the Internal Revenue Code;

(ii) A second mortgage loan (or a nonpurchase money first mortgage loan in the case of a residence on which there is no existing first mortgage) if the loan is secured by a residential dwelling which is the residence of the member-borrower; and

(iii) A loan to finance the repair, alteration, or improvement of a residential dwelling which is the residence of the member-borrower.

(2) For purposes of this paragraph (f), mobile home may include a recreational vehicle, house trailer or boat.

(g) *Long-term mortgage loans*—(1) *Authority.* A federal credit union may make residential real estate loans to members, including loans secured by manufactured homes permanently affixed to the land, with maturities of up to 40 years, or such longer period as may be permitted by the NCUA Board on a case-by-case basis, subject to the conditions of this paragraph (g)).

* * * * *

[FR Doc. 04–25996 Filed 11–24–04; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter 1

[Docket No. 2002N–0434]

Withdrawal of Certain Proposed Rules and Other Proposed Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of proposed rules.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of certain advance notice of proposed rulemakings (ANPRMs), proposed rules, and other proposed actions that published in the **Federal Register** more than 5 years ago. These proposals are no longer considered viable candidates for final action at this time. FDA is taking this action to reduce its regulatory backlog and focus its resources on current public health issues. The FDA's actions are part of an overall regulatory reform strategy initiated by Health and Human Services (HHS) Secretary Tommy G. Thompson.

DATES: The proposed rules are withdrawn as of November 26, 2004.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Regulations Policy and Management Staff (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

On June 8, 2001, Secretary Thompson announced his regulatory reform initiative designed to reduce regulatory burdens in health care and respond faster to the concerns of health care providers, State and local governments, and individual Americans who are affected by HHS rules. In December 2001, the Secretary announced the membership of his Regulatory Reform Committee designed to carry out his initiative. In November 2002, the Committee released its final report with over 255 specific recommendations for simplifying, streamlining, and generally reducing the regulatory burden while

continuing to require accountability by those doing business with HHS and its agencies. Over 25 of the recommendations have been adopted, and the Secretary charged the Office of the Assistant Secretary for Planning and Evaluation to continue the efforts of the Regulatory Reform Committee. FDA's continuing efforts to finalize or withdraw regulations that have been proposed but not finalized are part of this overall initiative.

In 1990, FDA began this process of conducting periodic, comprehensive reviews of its regulations process that included reviewing the backlog of ANPRMs, notices of proposed rulemaking, and other notices for which no final action or withdrawal notice had been issued. In the **Federal Register** of December 30, 1991 (56 FR 67440), FDA issued its first notice withdrawing 89 proposed rules that had published before December 31, 1985, but had never been finalized. Then again, in the **Federal Register** of January 20, 1994 (59 FR 3042), the agency withdrew an additional nine outstanding proposed rules.

Once again, on April 22, 2003, FDA published a notice in the **Federal Register** (68 FR 19766) announcing its intent to withdraw 84 proposed rules and other proposed actions that had published in the **Federal Register** more than 5 years ago, but that had never been finalized. Included in this list were 19 proposed rules that were originally proposed for withdrawal in 1991, but at that time the agency decided to defer its decision to withdraw or finalize them until a later date.

The agency undertook this most recent review because it believes that the backlog of pending proposals dilutes its ability to concentrate on higher priority regulations that are mandated by statute or are necessary to address current public health issues. Because of the agency's limited resources and changing priorities, FDA has been unable to: (1) Consider, in a timely manner, the issues raised by the comments on these proposals and (2) complete the action on them. Additionally, because many of the proposals have become outdated in the time that has elapsed since their publication, the agency would need to obtain further comment on them before proceeding to final action. FDA has determined that the proposals identified in this document are lower in priority than those on the Unified Agenda and the Regulatory Plan. It is unlikely that the agency will have sufficient resources in the foreseeable future to further consider or prioritize these proposed rules. Although not required to do so by the Administrative Procedure Act or by regulations of the Office of the Federal Register, the agency believes the public interest is best served by withdrawing the proposals identified in this document. In some instances, the agency has already completed action on alternatives (e.g., the issuance of guidance or inclusion of provisions in related regulations) that have obviated the need to complete the proposed action. In addition, the agency notes that upon reviewing the comments and other records related to the rulemaking, the agency found that ''Amend Animal Care Regulations'' (Docket No. 89P–0320 (July 3, 1990, 55 FR 27476)) was the subject of a petition, and the agency assigned another docket number to that action. This action was finalized on July 15, 1991 (56 FR 32087), and therefore it is not necessary to be included in this withdrawal notice.

The withdrawal of the proposals identified in this document does not preclude the agency from reinstituting proceedings to issue rules concerning the issues addressed in the proposals listed in table 1 of this document. Should FDA decide to undertake such a rulemaking sometime in the future, it will repropose the actions and provide new opportunities for comment.

The agency notes that withdrawal of a proposal is not intended to affect whatever utility the preamble statements may currently have as indications of FDA's position on a matter at the time the proposal was published, and in some cases the preambles of these proposals may still reflect the current position of FDA on the matter addressed. Anyone unsure whether a statement in one of the preambles reflects the agency's current thinking should contact FDA.

II. Summary of and Responses to Comments

FDA received a total of 37 letters, each containing 1 or more comments, in response to its notice of intent to withdraw certain proposed rules. The following is a discussion of the comments and the agency's response to those comments.

A. General Comments

(Comment 1) One comment provided recommendations on FDA's overall withdrawal process and the way information in the notice of intent was presented to the public. The comment requested that the agency identify how it intended to handle each individual item included in the notice of intent including reasons for withdrawal and future actions. The comment also requested that the agency identify which preambles will continue to reflect the agency's current thinking even after the proposed rule has been withdrawn. Finally, the comment thought that FDA should have made all the proposed actions listed in the notice of intent available on FDA's Web site for easy access to all interested parties.

(Response) The agency disagrees with these comments. The agency's decisions on the items proposed to be withdrawn were based on the general factors described in the notice of intent and whether the proposals fell within the listed factors. When the agency published the notice of intent, it did not have definite future plans for any of the items listed. The reason the agency stated that it may take future action was to emphasize that the withdrawals were based on resources and priorities. A withdrawal does not prevent the agency from taking action in the future on its own initiative or as a result of being prompted by the public. Also, a withdrawal of a proposed rule neither affirms nor rejects the views contained in the preamble. If someone wants a clarification of any agency policy or position, they should contact FDA.

While not providing copies on its Web site, the agency provided the title, docket number, and **Federal Register** publication date and cite. The agency believes that, in most cases, this information was sufficient to allow readers to find the documents whether online or in a library. Also, the agency provided the name, address, and phone number of an FDA contact who was prepared to provide copies of each proposal, if requested. Therefore, none of these issues raised by this comment would have affected the ability of the public to comment on the items listed in the notice of intent.

(Comment 2) One comment opposed the withdrawal of all the proposed generally recognized as safe (GRAS) actions listed in the notice of intent unless FDA could provide assurance that the agency would continue to permit the use of these food ingredients as detailed in the preamble statements.

(Response) This withdrawal does not affect the regulatory status of the ingredients listed in these documents. Furthermore, the comment did not raise any issues not considered by FDA before publication of the notice of intent to withdraw. Therefore, FDA is withdrawing all the GRAS proposed rules listed in the notice of intent.

(Comment 3) One comment recommended that the agency withdraw an ANPRM on hearing aids (58 FR 59695, November 10, 1993) that was not included in the notice of intent.

(Response) While the agency agrees that this ANPRM is a good candidate for withdrawal, because it was not included in the original notice of intent, we will withdraw or take other action with respect to this proposal separately, in a future **Federal Register** notice.

B. Specific Comments

The agency received specific comments on 17 of the documents listed in the notice of intent. These comments generally supported FDA's attempt at streamlining the regulations process, and in some cases, supported the agency's decision to withdraw a certain proposed rule. However, several of these comments opposed the agency's decision to withdraw a proposal. The specific comments received, and the agency's responses are as follows:

1. Cosmetic Products Containing Certain Hormone Ingredients—Docket No. 91N–0245, September 9, 1993, 58 FR 47611

FDA received 9 comments opposing the withdrawal of this proposed rule.

(Comment 4) These comments argued that the withdrawal of this proposed rule would call into question the findings presented in the proposed rule and possibly change the marketing status of cosmetic products containing hormone ingredients.

(Response) With regard to the first concern, as stated previously in this document, this withdrawal neither affirms nor rejects statements contained in the preamble. With regard to the second concern, the proposed rule was never finalized, and therefore withdrawal of the proposed rule does not affect the marketing status of these products. The agency intends to issue a new proposed rule regarding these products in the future.

2. Caffeine in Nonalcoholic Carbonated Beverages—Docket No. 82N–0318, May 20, 1987, 52 FR 18923

3. Shellac and Shellac Wax; Proposed Affirmation of GRAS Status With Specific Limitations as Direct Human Food Ingredients—Docket No. 89N–0106, July 26, 1989, 54 FR 31055

4. Unmodified Food Starches and Acid-Modified Starches; Proposed Affirmation of GRAS Status as Direct and Indirect Food Ingredient—Docket No. 84N–0341, April 1, 1985, 50 FR 12821

5. Caffeine; Deletion of GRAS Status; Proposed Declaration That No Prior Sanction Exists and Use on an Interim Basis Pending Additional Study—Docket No. 80N–0418, October 21, 1980, 45 FR 69817

6. Protein Hydrolysates and Enzymatically Hydrolyzed Animal (Milk Casein) Protein; Proposed GRAS Status—Docket No. 82N–0006, December 8, 1983, 48 FR 54990

7. Cellulose Derivatives; Affirmation of GRAS Status—Docket No. 78N–0144, February 23, 1979, 44 FR 10751

(Comment 5) FDA received five comments on these six GRAS proposed rules. The majority of the comments opposed the withdrawal of these proposals.

(Response) None of the comments raised issues not considered by the agency before publication of the notice of intent to withdraw. Therefore, FDA is withdrawing all the GRAS proposed rules listed in the notice of intent. However, this withdrawal does not affect the regulatory status of the ingredients listed in these documents.

8. Reclassification of Electroconvulsive Therapy—Docket No. 82P–0316, September 5, 1990, 55 FR 36578

(Comment 6) FDA received one comment supporting the withdrawal of this proposed rule. However, the comment was concerned that the information contained in this docket (i.e., reports of adverse reactions) would be disregarded when the proposed rule was withdrawn.

(Response) The agency is withdrawing this proposed rule, and in the future, intends to start a new proceeding on this matter. The agency will retain the data and information contained in this docket and consider it at that time.

9. Food Labeling; Declaration of Ingredients; Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; ''and/or'' Labeling for Soft Drinks—Docket No. 90N–361M, January 6, 1993, 58 FR 2950

(Comment 7) FDA received 15 comments supporting and one comment opposing the withdrawal of this proposed rule. The comment opposing the withdrawal of this proposed rule stated that the proposed rule memorialized the development of the agency's policy on ''and/or'' labeling for sweeteners in soft drinks and is the sole source of reference on these matters. The comment expressed concern that withdrawal may call into question current and future labeling practices of the soft drink industry regarding sweeteners in soft drinks.

(Response) The agency disagrees with this comment's implication that the proposed rule announced a final FDA policy decision on ''and/or'' labeling for sweeteners in soft drinks. By definition, a proposed rule only states the agency's tentative conclusions; with limited exceptions not applicable here, final decisions in the rulemaking context must be issued in a final rule after public notice and opportunity for comment (see 5 U.S.C. 553(b) to (c)). Further, the agency stated in the preamble to the proposed rule (58 FR 2950 at 2953) that its final decision on whether to revise its regulations to permit ''and/or'' labeling for sweeteners in soft drinks would be based largely on whether comments in response to the proposed rule included data demonstrating that it is impracticable to produce the limited number of versions of a label that would be necessary if ''and/or'' labeling were not permitted. The agency received no such data and therefore did not have sufficient basis to proceed to a final rule allowing ''and/or'' labeling for soft drinks. Accordingly, this comment does not persuade the agency to reconsider the withdrawal of this proposed rule.

Comments supporting the withdrawal of this proposal asked that the agency initiate enforcement action against soft drink manufacturers that use ''and/or'' labeling. The agency acknowledges that it has not pursued any enforcement action against soft drink manufacturers who are using ''and/or'' labeling because of the pending rulemaking. The agency is considering its position on the use of ''and/or'' labeling.

10. Yogurt Products; Frozen Yogurt, Frozen Lowfat Yogurt; and Frozen Nonfat Yogurt; Petitions to Establish Standards of Identity and to Amend Existing Standards—Docket Nos. 89P–0208 and 89P–0444, May 31, 1991, 56 FR 24760

(Comment 8) The agency received one comment supporting the withdrawal of this proposed rule. The comment agreed that there is no need to complete this rulemaking since the agency issued an ANPRM (68 FR 39873) in 2003 to address this issue.

(Response) The agency agrees. Therefore, FDA is withdrawing this proposed rule.

11. Canned Pineapple; Proposal to Amend Standards of Identity and Quality—Docket No. 88P–0224, March 24, 1989, 54 FR 12237

FDA received two comments opposing the withdrawal of this proposed rule.

(Comment 9) One comment requested that, if FDA withdraws the proposed rule, FDA allow marketing for canned pineapple as a nonstandardized product.

(Response) FDA is denying this request because a product that purports to be or is represented as a food for which a standard of identity has been prescribed (e.g., canned pineapple) that does not comply with the provisions of that standard is misbranded under

section 403(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(g)). FDA notes, however, that regulations in § 130.17 (21 CFR 130.17) provide that manufacturers may market foods that deviate from established standards of identity if they receive temporary marketing permits from FDA.

(Comment 10) The second comment stated that there are temporary marketing permits issued under this proposal that would not be valid if the proposal is withdrawn.

(Response) The comment is incorrect. There are no active temporary marketing permits to market test a ''whole'' style of canned pineapple that are the basis of this proposed rule. There were two temporary market permits that were issued in 1988 to Dole Packaged Foods Co. (53 FR 16471, May 9, 1988) and to Del Monte Corp. (53 FR 23602, June 22, 1988), which expired after 15 months. The agency is withdrawing this proposed rule.

12. Current Good Manufacturing Practices; Proposed Exemption From Active Ingredient Identity and Strength Testing for Homoeopathic Drug Products—Docket No. 79P–0265, April 1, 1983, 48 FR 14003

(Comment 11) The agency received one comment opposing the withdrawal of this proposed rule which would have exempted homeopathic drugs from the current good manufacturing practice (CGMP) requirements that drug products be tested for identity and strength of each active ingredient prior to release for distribution. The comment expressed concerns about possible changes in our enforcement policy towards final release testing of homeopathic drugs.

(Response) There may be instances where testing of a homeopathic product for identity and strength of the active ingredients prior to release for distribution would be appropriate and consistent with protection of the public health. For example, in instances where a product includes an active ingredient that at certain levels could be toxic or otherwise pose a public health concern, finished product testing may be appropriate because the testing could identify a significant manufacturing or labeling error. Since requiring this testing when necessary to protect the public health is consistent with FDA's mandate, we are withdrawing the proposed rule.

13. Pineapple Juice; Proposal to Amend U.S. Standards of Identity and Quality—Docket No. 86P–0338, May 21, 1987, 52 FR 19169

FDA received two comments opposing the withdrawal of this proposed rule.

(Comment 12) One comment requested that if FDA withdraws the proposed rule, FDA allow marketing for pineapple juice as a nonstandardized product.

(Response) FDA is denying this request because a product that purports to be or is represented as a food for which a standard of identity has been prescribed (e.g., pineapple juice) that does not comply with the provisions of that standard is misbranded under section 403(g) of the act. FDA notes, however, that regulations in § 130.17 provide that manufacturers may market foods that deviate from established standards of identity if they receive temporary marketing permits from FDA.

(Comment 13) The second comment stated that this proposed rule allowed the addition of pineapple juice from concentrate to pineapple juice to increase the brix level. Because the proposed rule addressed the use of pineapple juice from concentrate, the comment asks the agency either to complete this rulemaking or to publish a notice of policy that 21 CFR 102.33 (which applies to nonstandardized juices) would apply to pineapple juice.

(Response) The comment is incorrect in stating that the proposed rule allowed the addition of pineapple juice from concentrate to increase the brix level of pineapple juice in § 146.185 (21 CFR 146.185). The proposed rule only proposed to amend the standard of identity to allow this change. This amendment would not be effective until the rule was finalized. Thus, currently, the standard of identity for pineapple juice in § 146.185 does not permit the use of pineapple juice from concentrate to increase the brix level. A manufacturer who wishes to market pineapple juice with added pineapple juice from concentrate to increase the brix level may apply for a temporary marketing permit to do so. The agency is withdrawing this proposed rule.

14. Regulation of Medical Foods—Docket No. 96N–0364, November 29, 1996, 61 FR 60661

(Comment 14) The agency received one comment opposing the withdrawal of this ANPRM. The comment stated that manufacturers are marketing therapeutic products directly to consumers without prior FDA approval of health claims or FDA review of the suitability of the ingredients for the intended population. The comment stated that current FDA policies in this area create a loophole for manufacturers to make unauthorized health claims and use ingredients that may not be GRAS.

(Response) This comment does not persuade FDA that the ANPRM should not be withdrawn. Because of competing priorities that have tied up FDA's limited resources, the agency has been unable to consider, in a timely manner, the issues raised by comments on the ANPRM, and does not foresee having sufficient resources in the near term to do so. Therefore, the agency is withdrawing this ANPRM. However, FDA believes that the basic principles described in the ANPRM provide an appropriate framework for understanding the regulatory paradigm governing medical foods. Therefore, FDA advises that it will continue to refer to the basic principles described in the ANPRM and in FDA's Medical Foods Compliance Program (CP 7321.002) when evaluating medical foods. With regard to the specific points made in the comment regarding regulation of medical foods, the comment is correct that the act exempts medical foods from the nutrition labeling, health claim and nutrient content claim requirements that are applicable to most other foods. However, all statements on food labels (including medical foods) must be truthful and not misleading (see section 403(a)(1) of the act). FDA advises that medical foods with false or misleading labeling are subject to enforcement action. The agency also advises that withdrawal of this ANPRM does not change the requirement that all ingredients used in medical foods must be approved food additives, GRAS, or otherwise exempt from the food additive definition. Medical foods that do not comply with this requirement are subject to enforcement action.

15. Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food—Docket Nos. 96N–0421 and 94P–0453/CP1, December 20, 1996, 61 FR 67243

(Comment 15) FDA received one comment opposing the withdrawal of this proposed rule. The comment states that misleading claims are being made by producers of products that contain nondigestible fat, including olestra, and that the total amount of fat in a product—regardless of whether it is digestible or nondigestible—should be declared to avoid consumer deception. The proposed rule responds in part to a citizen petition requesting use of digestibility coefficients in determining the quantity of fat declared in the label.

(Response) Currently, FDA regulations require that nutrition labeling and claims reflect the total amount of fat, which is defined as total lipid fatty acids and expressed as triglycerides § 101.9(c)(2) (21 CFR 101.9(c)(2)). The only exceptions to this general requirement are provided in the following: (1) The voluntary nutrition

labeling final rule for raw fruit, vegetables, and fish (61 FR 42742, August 16, 1996) with respect to total fat in orange roughy fish and (2) the final rule for olestra (61 FR 3118, January 30, 1996) (61 FR 67243 at 67246). In the final rule for olestra, FDA specified that olestra need not be considered as a source of fat or calories for purposes of nutrition labeling or nutrient content claims (21 CFR 172.867(e)(5)).

By withdrawing this proposed rule, FDA will not be authorizing the use of digestibility coefficients, so that the total amount of fat in a product must be declared on the label whether it is digestible or nondigestible as provided in § 101.9(c)(2). However, withdrawing this proposed rule will have no effect on the nutrition labeling of products containing olestra or how the agency calculates the fat content of orange roughy for the purpose of voluntary nutrition labeling of that raw fish. Due to the agency's limited resources and other higher priority matters, the agency is withdrawing this proposed rule.

16. Food Labeling; Nutrient Content Claims and Health Claims; Special Requirements—Docket No. 95N–0103, February 2, 1996, 61 FR 3885

(Comment 16) The agency received one comment opposing the withdrawal of this proposed rule. The comment states that FDA access to records needed to evaluate the validity of nutrient content claims and health claims is essential to prevent consumer deception and ensure fair competition.

(Response) FDA continues to believe that, for health and nutrient content claims that pose particular enforcement difficulties, it would be valuable for the agency to have access to information that the manufacturer relied on in determining that the food meets the requirements of the claims. As the agency stated in the proposed rule (61 FR 3385 at 3889), the claims that are likely to present enforcement difficulties are those based on new food technology or a new use of food technology, those based on the results of novel or non-standardized testing procedures, and those which the agency cannot evaluate without information because the information is available only to the manufacturer. However, other higher priority matters require the agency's resources at this time, and therefore, the agency is withdrawing this proposed rule.

17. Food Labeling; Declaration of Free Glutamate in Food—Docket No. 96N–0244, September 12, 1996, 61 FR 48102

(Comment 17) FDA received two comments supporting the withdrawal of this ANPRM.

(Response) Thus, the agency is withdrawing this ANPRM.

For the reasons set forth previously, and under the act, the agency announces the withdrawal of the following documents, published in the **Federal Register** on the dates indicated in table 1:

TABLE 1.

Title	Docket No.	FR Publication Date and Cite
Radioactive Drugs, Including Biological Products	75N–0069	July 25. 1975, 40 FR 31314
Conditions for Use of Methadone; Notice of Proposed Rulemaking	75N–0125	April 29, 1976, 41 FR 17922
Pasteurized Milk Ordinance and Interstate Milk Shippers	75N–0243	May 5, 1975, 40 FR 19513
Oral Contraceptive Drug Products; Physician and Patient Labeling	75N–0304	December 7, 1976, 41 FR 53633
Penicillin Streptomycin Powder; Penicillin-Dihydrostreptomycin Powder; Proposed Revocation of Certification Provision	75N–0374	July 9, 1976, 41 FR 28313
Conditions for Use of Methadone; Physiologic Dependence, Staffing, and Urine Testing Requirements	76N–0098	April 29, 1976, 41 FR 17926
Sorbic Acid and Its Salts; Proposed Affirmation and Deletion of GRAS Status	77G–0379[1]	March 10, 1978, 43 FR 9823
Butylated Hydroxytoluene; Use Restrictions	77N–0003[1]	May 31, 1977, 42 FR 27603
Color Additives; Proposed Use of Abbreviations for Labeling Foods, Drugs, Cosmetics, and Medical Devices	77N–0009 and 78P–0164	June 6, 1985, 50 FR 23815
Brown and Yellow Mustard and Their Derivatives; Proposed Affirmation of GRAS Status as Direct Human Food Ingredients	77N—0033[1]	August 26, 1977, 42 FR 43092
Acrylonitrile Copolymers Intended for Use in Contact With Food; Proposed Rulemaking	77N—0078	March 11, 1977, 42 FR 13562
Gelatin; Affirmation of GRAS Status as a Direct and Indirect Human Food Ingredient	77N–0232[1]	November 11, 1977, 42 FR 58763 and May 12, 1993, 58 FR 27959 (tentative final rule)
New Animal Drugs for Use in Animal Feeds; Animal Feeds Containing Penicillin and Tetracycline	77N–0318	January 20, 1978, 43 FR 3032
Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	77N–0424[1]	June 23. 1978, 43 FR 27474
Label Designation of Ingredients in Cheese and Cheese Products	77P–0146	July 19, 1984, 49 FR 29242
Food Chemicals Codex Monographs; Opportunity for Public Comment on Revisions	78N–0072	April 18, 1978, 43 FR 16413

TABLE 1.—Continued

Title	Docket No.	FR Publication Date and Cite
Cellulose Derivatives; Affirmation of GRAS Status	78N–0144[1]	February 23, 1979, 44 FR 10751
Tocopherols and Derivatives; Proposed Affirmation of GRAS Status for Certain Tocopherols and Removal of Certain Others From GRAS Status as Direct Human Food Ingredients	78N–0213[1]	October 27, 1978, 43 FR 50193
Chlortetracycline-Sulfamethazine Tablets; Proposed Rulemaking	78N–0247	September 22, 1978, 43 FR 43036
Phosphates; Proposed Affirmation of and Deletion From GRAS Status as Direct and Human Food Ingredients	78N–0272	December 18, 1979, 44 FR 74845
Biotin; Proposed Affirmation of GRAS Status	78N–0308[1]	January 14, 1983, 48 FR 1739
Lard and Lard Oil; Proposed Affirmation of GRAS Status as Indirect Human Food Ingredients	78N–0336[1]	May 18, 1979, 44 FR 29102
Glycerin; Affirmation of GRAS Status as a Direct Human Food Ingredient	78N–0348[1]	February 8, 1983, 48 FR 5758
Medical Devices; Classification of Sponges for Internal Use	78N–1074	November 28, 1978, 43 FR 55697
Medical Devices; Classification of Powered Myoelectric Biofeedback Equipment	78N–1183	August 28, 1979, 44 FR 50464
Porcine Burn Dressing	78N–2670	January 19 1982, 47 FR 2828
Food Ingredient Labeling; Emulsifiers and Stabilizers; Exemptions	78P–0052	April 17, 1985, 50 FR 15177
Sodium Dithionite and Zinc Dithionite; Proposed Affirmation of GRAS Status	79N–0095[1]	January 25, 1980, 45 FR 6117 and September 17, 1982, 47 FR 41137 (tentative final rule)
Current Good Manufacturing Practice in Manufacture Processing, Packing, or Holding; Proposed Exemption From Active Ingredient Identity and Strength Testing for Homeopathic Drug Products	79P–0265	April 1, 1983, 48 FR 14003
Hydrochloric Acid; Proposed Affirmation of GRAS Status as a Direct Human Food Ingredient	80N–0148[1]	April 26, 1984, 49 FR 17966
Cheeses and Related Cheese Products; General Standard of Identity for ''Certain Other Cheeses''	80N–0373	April 23, 1984, 49 FR 17018
Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study	80N–0418[1]	October 21, 1980, 45 FR 69817
Policy for Recognizing Carcinogenic Chemicals in Food and Color Additives; Advance Notice of Proposed Rulemaking	81N–0281	April 2, 1982, 47 FR 14464
Magnesium Gluconate, Potassium Gluconate, Sodium Gluconate, Zinc Gluconate, and Gluconic Acid: Proposed GRAS Status as Direct and Indirect Human Food Ingredients	81N–0382	October 29, 1982, 47 FR 49028
Protein Hydrolysates and Enzymatically Hydrolyzed Animal (Milk Casein) Protein; Proposed GRAS Status	82N–0006[1]	December 8, 1983, 48 FR 54990
Zinc Salts: Proposed Affirmation of GRAS Status	82N–0167[1]	October 26, 1982, 47 FR 47441
Regenerated Collagen; Proposed GRAS Status as a Direct Human Food Ingredient	82N–0219[1]	April 26,1983, 48 FR 18833
Ascorbic Acid and Its Sodium and Calcium Salts, Erythorbic Acid and Its Sodium Salt, and Ascorbyl Palmitate; Proposed Affirmation of GRAS Status and Removal of Calcium Ascorbate From the List of GRAS Ingredients	82N–0246[1]	January 14, 1983, 48 FR 1735
Caffeine in Nonalcoholic Carbonated Beverages	82N–0318	May 20, 1987, 52 FR 18923
Common or Usual Names for Nonstandardized Foods; Diluted Fruit or Vegetable Juice Beverages	82N–0389	June 1, 1984, 49 FR 22831
Neurological Devices, Proposed Rule to Reclassify the Electroconvulsive Therapy Device Intended for Use in Treating Severe Depression	82P–0316	September 5, 1990, 55 FR 36578
New Drug and Antibiotic Application Review; Proposed User Charge	84N–0101	August 6, 1985, 50 FR 31726

TABLE 1.—Continued

Title	Docket No.	FR Publication Date and Cite
Proposed Uses of Vinyl Chloride Polymers	84N–0334	February 3, 1986, 51 FR 4177
Unmodified Food Starches and Acid Modifled Starches—Proposed Affirmation of GRAS Status as Direct and Indirect Human Food Ingredients	84N–0341[1]	April 1, 1985, 50 FR 12821
Use of Acrylonitrile Copolymers	85N–0145	March 8, 1990, 55 FR 8476
Hematology and Pathology Devices; Premarket Approval of the Automated Blood Cell Separator Intended for Routine Collection of Blood and Blood Components	85N–0241	February 19, 1988, 53 FR 5108
New Drugs for Human Use: Proposed Clarification of Requirements for Application Supplements	86N–0077	June 4, 1986, 51 FR 20310
Quality Standards for Foods With No Identity Standards; Bottled Water	86N–0445	September 16, 1988, 53 FR 36063
Pineapple Juice; Proposal to Amend U.S. Standards of Identity and Quality	86P–0338	May 21, 1987, 52 FR 19169
New Animal Drug Regulations	88N–0058	December 17, 1991, 56 FR 65544
Current Good Manufacturing Practice for Blood and Blood Components; Proficiency Testing Requirements	88N–0413	June 6, 1989, 54 FR 24296
Canned Pineapple; Proposal To Amend Standards of Identity and Quality	88P–0224	March 24, 1989, 54 FR 12237
Shellac and Shellac Wax; Proposed Affirmation of GRAS Status With Specific Limitations as Direct Human Food Ingredients	89N–0106	July 26, 1989, 54 FR 31055
Erythromycin Capsules; Proposed Amendment of Dissolution Standard of Erythromycin Capsules	89N–0378[1]	October 26, 1989, 54 FR 43592
Yogurt Products; Frozen Yogurt, Frozen Lowfat Yogurt, and Frozen Nonfat Yogurt; Petitions To Establish Standards of Identity and To Amend the Existing Standards	89P–0208 and 89P–0444	May 31, 1991, 56 FR 24760
Exemption From Preemption of State and Local Hearing Aid Requirements; Vermont	89P–0314	October 30, 1990, 55 FR 45615
Food Labeling; Declaration of Ingredients, Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; ''and/or'' Labeling for Soft Drinks	90N–0361M	January 6, 1993, 58 FR 2950
Use of Aseptic Processing and Terminal Sterilization in the Preparation of Sterile Pharmaceuticals for Human and Veterinary Use	91N–0074	October 11, 1991, 56 FR 51354
Cosmetic Products Containing Certain Hormone Ingredients; Notice of Proposed Rulemaking	91N–0245	September 9, 1993, 58 FR 47611
Substances in Food-Contact Articles in the Household, Food Service Establishments, and Food Dispensing Equipment; Food Additive Status	74–8424	April 12, 1974, 39 FR 13285
Drug Listing Compliance Verification Reports	92N–0291	September 2, 1993, 58 FR 46587
Food Labeling: Metric Labeling Requirements	92N–0406	May 21, 1993, 58 FR 29716
Food Labeling: Net Quantity of Contents; Compliance	92P–0441	March 4, 1997, 62 FR 9826
Cardiovascular Devices; Effective Date of Requirement for PMA of Nonroller-Type Cardiopulmonary Bypass Blood Pump	93M–0150	July 6, 1993, 58 FR 36290
Laser Products; Proposed Amendment to Performance Standards	93N–0044	March 24, 1999, 64 FR 14180
Quality Standards for Foods With No Identity Standards; Bottled Water	93N–0200	October 6, 1993, 58 FR 52042
Metric Labeling; Quantity of Contents Labeling Requirement for Foods, Human and Animal Drugs, Animal Foods, Cosmetics, and Medical Devices	92N–0406 and 93N–0226	December 21, 1993, 58 FR 67444
Lead in Food and Color Additives and GRAS Ingredients; Request for Data	93N–0348	February 4, 1994, 59 FR 5363
Substances Prohibited From Use in Animal Food or Feed; Specified Offal From Adult Sheep and Goats Prohibited in Ruminant Feed; Scrapie	93N–0467	August 29, 1994, 59 FR 44584

TABLE 1.—Continued

Title	Docket No.	FR Publication Date and Cite
Dental Devices; Effective Date of Requirement for Premarket Approval of Over-the-Counter (OTC) Denture Cushions or Pads and OTC Denture Repair Kits	95N–0034	July 11, 1995, 60 FR 35713
Food Labeling; Nutrient Content Claims and Health Claims; Special Requirements	95N–0103	February 2, 1996, 61 FR 3885
Maltodextrin; Food Chemicals Codex Specifications	95N–0189	September 21, 1995, 60 FR 48939
Beverages: Bottled Water	95N–0203	November 13, 1995, 60 FR 57132
Dental Devices; Effective Date of Requirement for Premarket Approval of Partially Fabricated Denture Kits	95N–0298	November 29, 1995, 60 FR 61232
Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Proposed Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims for Fat, Fatty Acids and Cholesterol Content of Food	95P–0250	November 9, 1995, 60 FR 56541
Food Standards; Reinvention of Regulations Needing Revisions, Request for Comments on Certain Existing Regulations	96N–0149	June 12, 1996, 61 FR 29701
Reinvention of Certain Food Additive Regulations	96N–0177	June 12, 1996, 61 FR 29711
Food Labeling; Declaration of Free Glutamate In Food	96N–0244	September 12, 1996, 61 FR 48102
Regulation of Medical Foods	96N–0364	November 29, 1996, 61 FR 60661
Food Labeling: Nutrient Content Claims Pertaining to the Available Fat Content of Food	96N–0421 and 94P–0453/CP1	December 20, 1996, 61 FR 67243
Food Labeling; Serving Sizes; Reference Amounts for Candies	96P–0023 and 96P–0179	January 8, 1998, 63 FR 1078

[1]Denotes documents that were included in the December 1991 withdrawal notice, but were not withdrawn at that time.

Dated: August 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–26234 Filed 11–24–04; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–149519–03]

RIN 1545–BC63

Section 707 Regarding Disguised Sales, Generally

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the treatment of transactions between a partnership and its partners as disguised sales of partnership interests between the partners under section 707(a)(2)(B) of the Internal Revenue Code (Code). The proposed regulations affect partnerships and their partners, and are necessary to provide guidance needed to comply with the applicable tax law. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by February 24, 2005. Requests to speak and outlines of topics to be discussed at the public hearing scheduled for March 8, 2005, at 10 a.m. must be received by February 24, 2005.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–149519–03), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–149519–03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS internet site *http://www.irs.gov/regs* or via the Federal eRulemaking Portal site at *http://www.regulations.gov* (indicate IRS and REG–149519–03). The public hearing will be held in the IRS Auditorium, Seventh Floor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Deane M. Burke or Christopher L. Trump, (202) 622–3070; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Treena V. Garrett, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by