adding, in their place, the words ''FAA Order 7400.9H''.

§ 71.79 [Amended]

10. Section 71.79 is amended by removing the words ''FAA Order 7400.9G'' and adding, in their place, the words ''FAA Order 7400.9H''.

§ 71.901 [Amended]

11. Paragraph (a) of § 71.901 is amended by removing the words ''FAA Order 7400.9G'' and adding, in their place, the words ''FAA Order 7400.9H''.

Issued in Washington, DC, September 8, 2000.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 00–23673 Filed 9–18–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ACE–13]

Amendment to Class E Airspace; Fairfield, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Fairfield, IA.

DATES: The direct final rule published at 65 FR 40991 is effective on 0901 UTC, November 30, 2000.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (861) 329–2525.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on July 3, 2000 (65 FR 40991). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on November 30, 2000. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Dated: Issued in Kansas City, MO on September 6, 2000.

Richard L. Day,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 00–2394 Filed 9–18–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 7, 10, 14, 19, 25, 101, 107, 110, 114, 170, 310, 312, 314, 316, 500, 514, 601, 803, 814, and 860

[Docket No. 99N–4783]

Administrative Practices and Procedures; Good Guidance Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its administrative regulations to codify its policies and procedures for the development, issuance, and use of guidance documents. This action is necessary to comply with requirements of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The Modernization Act codified certain parts of the agency's current ''Good Guidance Practices'' (GGP's) and directed the agency to issue a regulation consistent with the act that specifies FDA's policies and procedures for the development, issuance, and use of guidance documents. The intended effect of this regulation is to make the agency's procedures for development, issuance, and use of guidance documents clear to the public.

DATES: This rule is effective October 19, 2000.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 405 of the Modernization Act (Public Law 105–115), statutory provisions on guidance documents were added to the Federal Food, Drug, and Cosmetic Act (the act) in section 701(h) (21 U.S.C. 371(h)). In the **Federal Register** of February 14, 2000 (65 FR 7321), we (FDA) proposed changes to our existing part 10 (21 CFR part 10) regulations to clarify our procedures for the development, issuance, and use of guidance documents. Interested parties were given until May 1, 2000, to comment on the proposal.

II. Description of the Final Rule

A. Comments and Agency Response

We received 18 comments on the proposed rule, largely from trade organizations. The comments we received generally supported the policies and procedures described in the GGP's.

1. General Comment

(Comment 1) One comment recommended that we include in this preamble a list of generally accepted principles of a good guidance document. The comment nominated several principles for inclusion on the list.

We decline to develop a list of generally accepted principles of a ''good'' guidance document because we believe that the procedures described in § 10.115 reflect generally accepted principles for developing, issuing, and using guidance documents. For example, a good guidance document represents our current thinking on a matter and clearly states that it does not establish legally enforceable requirements. We expect each guidance document developed, issued, and used under the rule to have the characteristics of a good guidance document.

2. Definition of Guidance Documents

(Comment 2) One comment suggested that we include in the definition of guidance documents those documents that describe our current policies regarding labeling and promotion.

In our proposal, we defined guidance documents to include, among other kinds of documents, those that relate to the design, production, manufacturing, and testing of regulated products and those that relate to inspection or enforcement policies. We interpret our definition to include guidance documents about product labeling and promotion. We are amending the definition in § 10.115(b)(2) to clarify our intent to include such topics as subjects for guidance documents.

3. Comprehensive List of Guidance Documents and Guidance Document Agenda

(Comment 3) Several comments discussed the annual publication of the comprehensive list of guidance documents and the guidance document

agenda. Some suggested that we continue to publish these lists on a semiannual basis.

Some comments stated that yearly publication of the comprehensive list is acceptable, particularly given that we maintain a current list on the Internet.

One comment stated that annual publication of the guidance document agenda would be reasonable if we include the status of each item on the list and identify the highest priority guidance documents. Another comment recommended that the agenda be posted on the Internet.

We believe that we provide adequate notice of and access to all available guidance documents through two mechanisms. We annually publish a comprehensive list of guidance documents in the **Federal Register** and we maintain current (i.e., updated within 30 days of the issuance of a new or newly revised guidance document or the deletion of an obsolete guidance document) lists of guidance documents on the Internet.

We also believe that we provide adequate notice of the guidance document agenda through its annual publication in the **Federal Register**. We will not include the status of each document on the agenda. Each document listed on the agenda is being developed; further description of document status would not be practical because it would be too difficult to differentiate the stages of guidance document development. We also do not believe it would be feasible to prioritize the documents on the agenda. Often, resources allocated to the development of a particular document are diverted to creating guidance documents regarding other areas of greater public health need. As a result, our priorities may change throughout the year and priorities stated on the agenda would not remain accurate for an extended period of time. We try to maintain a current (i.e., updated at least semiannually) guidance document agenda on the Internet.

In efforts separate from this rulemaking, we are considering ways to enhance our lists of guidance documents maintained on the Internet. For example, we are trying to make the lists easier to navigate and search. These enhancements may allow you to more efficiently find the information you seek on the comprehensive list and the agenda.

(Comment 4) One comment suggested that we include a brief statement describing each document on the comprehensive list.

We understand that much of the value of the comprehensive list lies in its ability to convey the subject matter of each document on the list. To provide this information adequately, we plan to ensure that the titles or subtitles of documents convey the subject of the document more precisely. The comprehensive list could become too cumbersome and difficult to use if we added a description of the subject of each document. Therefore, we will not include a separate statement describing each document on the comprehensive list.

(Comment 5) A comment stated that the comprehensive list should identify guidance documents that have been revised or are currently being considered for revision.

Through the lists that we publish under the procedures previously described, we already make the information requested in the comment available to the public. On the comprehensive list, we include the date of the last revision of a guidance document. This enables you to identify those guidance documents that have been revised and the date of the revision. In our guidance document agenda, we list guidance documents that are under consideration for development or revision.

(Comment 6) In § 10.115(c), we define two levels of guidance documents, Level 1 and Level 2. The two levels of guidance documents are subject to different procedures for public participation before issuance. One comment suggested that we include the designation for each document as Level 1 or Level 2 in the prospective list of guidance documents.

We decline the suggestion to include the Level 1 or Level 2 designation for all documents on the guidance document agenda. Generally, at the time we issue the agenda, we do not know the full content of the proposed documents. Thus, a determination of whether a document meets the criteria for a Level 1 designation (§ 10.115(c)(1)) would be premature.

(Comment 7) One comment suggested that we make the guidance document agenda more user-friendly by separating guidance documents on cross-cutting issues from those that are technology-specific.

The purpose of the guidance document agenda is to notify you of guidance documents we are developing so you may comment on topics for new documents and possible revisions to existing documents. We believe the guidance agenda is currently organized to disseminate this information most effectively. The documents on the agenda are organized by the issuing center or office and generally are further grouped by topic categories. By separating guidance documents according to the issuing center or office, we enable those of you who have interest in a particular issue or type of product (e.g., food products) to focus on documents that are being developed in one of the centers or offices (e.g., the Center for Food Safety and Applied Nutrition). Guidance documents that are being developed in more than one center or office will appear on the agenda for each participating center or office. Grouping documents on the agenda by subject category (e.g., electronic submissions) provides you greater ability to focus on specific areas of interest. After the effective date of the rule, we will group all guidance documents on the agenda by subject category. This format is consistent with the format of the comprehensive list of guidance documents. We believe that the format suggested in the comment could make the agenda difficult to use because you would not be able to concentrate effectively on a particular topic of interest.

4. Public Input

(Comment 8) One comment suggested that we implement procedures to give you the opportunity to comment on designation of a document as a Level 1 or Level 2 guidance document before the decision is made.

We decline to adopt this suggestion. It is in the best interest of promoting and preserving the public health that we be able to develop guidance documents in a timely and efficient manner. If we solicited comment on the level designation for each guidance document, we would create a procedural hurdle that could significantly slow the guidance development process. This delay in the development of guidance documents would not serve us or you.

We determine whether a document is Level 1 or Level 2 based on the criteria described in § 10.115(c). If you disagree with the designation of a document (e.g., if you believe that a guidance issued as a Level 2 should have been issued as a Level 1), you may send us an explanation of your reasons for disagreeing with our determination when you comment on the guidance document. If, after issuance, you still have a disagreement, you can appeal our designation using the dispute resolution process.

(Comment 9) One comment suggested that we announce the development and issuance of Level 2 documents in the **Federal Register**. Another comment recommended that we receive comments on Level 2 guidance

documents before we issue them as final guidance.

We decline to amend our procedures for announcing and receiving comment on Level 2 guidance documents. When we issue Level 2 documents, they are immediately posted on the Internet. Also, their issuance is announced in the comprehensive list of guidance documents that is published annually in the **Federal Register** and maintained on the Internet.

Under section 701(h)(1)(D) of the act, we must solicit public comments ''upon implementation'' of guidance documents that describe existing practices or minor changes in agency policy. We believe the provisions of § 10.115(g)(4) are consistent with the act and describe adequate provisions for developing and issuing Level 2 guidance documents.

(Comment 10) Under § 10.115(g)(1)(v), we may issue a second draft of a guidance document and solicit comment on the document after providing an opportunity for comment on the first draft. One comment stated that two situations usually merit this procedure: When the first draft guidance on a medical or scientific topic is highly controversial and when the first draft guidance is in conflict with other widely recognized sources of scholarly guidance (e.g., International Conference on Harmonization guidance, pharmacopeial standards).

We agree that it may be appropriate for us to issue a second draft of a guidance document in the two situations described in the comment. In addition, it may also be appropriate for us to issue a second draft guidance in other circumstances. For example, if we revise a document for clarification, we may want to issue a second draft guidance document to receive comment on whether our revisions made the document easier to understand.

(Comment 11) One comment suggested that we allow the public to request the deletion of guidance documents that are no longer useful.

Under § 10.115(f), you can suggest that a document on the comprehensive list of guidance documents or on the guidance document agenda be revised or withdrawn if you find that the document is no longer relevant or accurate. We amended the final rule to explicitly state that you can suggest that a guidance be withdrawn (§ 10.115(f)(4)).

(Comment 12) Many comments urged us to include a provision in the regulation requiring us to provide written responses to public comments or suggestions for revising guidance documents. One comment stated that we should respond to each suggestion for a revision to an existing guidance document within 90 days. Other comments stated that we should explain to the public why we changed, or why we did not change, a guidance document between the draft and final stages. Some comments recommended that we provide general responses to comments grouped by topic. Others suggested that we be required to issue a written response when certain criteria are met (e.g., when a majority of the comments on a guidance document concern the same issue).

We believe that it is in the public interest to have an efficient process for developing guidance documents. The guidance document development process would be hampered if we were required to respond to each comment. When comments received are very significant or cause us to revise a guidance, we often discuss those comments in the notice of availability (NOA) for the final guidance or in the final guidance document. We intend to continue this practice. However, making a firm commitment to provide a written response to all comments when issuing a final guidance would unnecessarily delay the issuance of the document.

(Comment 13) Two comments suggested that we be required to respond to your proposals for draft guidance documents.

We agree with this comment. When you have taken the time to develop a guidance document and submit it to us for review, you should receive, at a minimum, an acknowledgment of receipt of the document. Therefore, we are now accepting guidance document submissions at the Dockets Management Branch. If you submit a document to us, you should designate it as a ''Guidance Document Submission,'' include the name of the center or office with oversight over the subject matter covered by the guidance document, and submit the document to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The Dockets Management Branch will ensure that the document is assigned a public docket number and it is sent to the appropriate office or center. All proposed guidance documents will be available through the public docket. We will send you a written acknowledgment that we have received your document, and to the extent feasible, we also will inform you of our actions regarding the document you have submitted. These changes to the final rule are included in revised § 10.115(f)(3).

(Comment 14) We received many comments on early collaboration and meetings to discuss guidance documents as they are being developed. Generally, the comments were very supportive of our efforts to facilitate early interaction with you. Some comments suggested that we issue a clear policy about the procedures for collaboration and early meetings. One suggested that we provide a means for industry to recommend a particular collaborative approach for a guidance document under development. Another comment recommended that we provide opportunities for you to engage in ''real time dialogues'' with us before we begin to write a draft or final guidance. The comment noted a number of avenues for this type of collaboration, including joint task forces, public and private meetings, advisory committee meetings, and e-mail correspondence. Other comments stated that certain agency components had refused to meet about a guidance document before that document was issued in draft. One comment specifically requested that we use more mandatory language regarding preproposal collaboration with you.

We agree that early collaboration (i.e., input from you in the early stage of developing the approach we will take in a new or revised guidance document) can be a very valuable tool in developing regulatory guidance. We have created several mechanisms to encourage early input, including the following:

- We provide an opportunity to suggest new or revised guidance.
- We publish an agenda of the guidance documents that we are working on and request your comments on the agenda.
- We notify you when we issue draft guidance documents and request your comments on the drafts.
- We may hold meetings or workshops even before we develop a draft document.

We encourage your involvement in our development of guidance documents. Often, we develop guidance documents based on your suggestions. We solicit your comments on draft guidance documents because our views are not yet finalized and we want your input on the contents of the final guidance.

We understand that you would like to meet with us more regarding the development of guidance documents. Our policies on meeting with the public on guidance development are evolving. In efforts separate from this rulemaking, we are exploring ways to increase this interaction within the confines of applicable statutes and regulations, and

are considering our need to provide all interested parties access to the process, our interest in issuing documents in a timely manner, and our resource constraints. We welcome your suggestions in this area.

(Comment 15) One comment proposed establishing a mechanism in § 10.115(g) whereby companies can fund a market research initiative that would permit us, through questionnaires, focus groups, and other techniques, to obtain input on proposed policies directly from patients, doctors, and other stakeholders.

We welcome input from patients, doctors, and other stakeholders. We believe that the procedures described in § 10.115, especially our increased use of the Internet to disseminate information, provide adequate avenues for patient, doctor, and stakeholder involvement in the development of our policies. We decline at this time to establish a funded market research initiative because administering such a program would divert personnel resources from other public health priorities.

(Comment 16) One comment suggested that we consider interactive techniques, such as town hall meetings, that may encourage industry input on setting priorities for the development of guidance documents listed on the agenda.

We welcome industry input on prioritizing our development of guidance documents. We believe that the procedures described in the GGP's on the guidance document agenda, especially our increased use of the Internet to disseminate the agenda and our request for comments on the agenda, provide adequate avenues for industry and others to assist us in prioritizing guidance documents. Furthermore, the agenda is only one of several mechanisms we use to solicit input on prioritizing the guidance documents we are developing. For example, we may participate in public meetings and public hearings and may raise guidance document issues at advisory committee meetings. At this time, we decline to change the GGP's in the manner suggested but will continue to consider avenues for encouraging input at all stages of guidance development.

(Comment 17) One comment suggested that any proposed guidance documents submitted to advisory committees be made public in a manner that provides sufficient time for review before the meeting.

We agree that proposed guidance documents submitted to advisory committees should be made public as soon as practicable to allow for a review of those materials. We are working to ensure that this information is made available in a timely manner.

5. Legal Effect of Guidance Documents

(Comment 18) We received several comments on the legal effect of guidance documents. A number of comments referred to the statement in the proposed regulation that we are willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations (§ 10.115(c)(3)). The comments stated that if a guidance document is not binding, the discussion of alternative approaches should not be required.

The comments misinterpreted the intent of the statement in § 10.115(c)(3). If you take an alternative approach, you are not required to discuss that approach with us. Instead, we are offering our assistance to make sure that any alternative approach you take meets the appropriate statutory or regulatory requirements. Discussing alternative approaches may help you understand our interpretation of the applicable statutes and regulations and may further our understanding of the merits of your approach.

(Comment 19) Two comments suggested that compliance with a guidance document should provide a company with a safe harbor from FDA enforcement action. The comments recommended that we change the regulation to require us to amend, or at least publish a proposal to amend, a guidance document before initiating an enforcement action against a company that acted in accordance with a guidance. The comments also noted that if we do not provide a safe harbor from enforcement, at a minimum, a company's action in accordance with a guidance document should be evidence of the company's intent to comply with our regulations.

Section 701(h)(1)(B) of the act provides that guidance documents ''shall not be binding on the Secretary.'' Creating a ''safe harbor'' in a guidance document that would preclude us from taking action would impermissibly bind us. In issuing enforcement-related guidance documents, we express our current thinking regarding regulatory matters and believe this provides useful information. However, you always remain independently responsible for complying with applicable statutes and regulations. Whether you have complied with the law is determined from the facts of each case.

(Comment 20) We received two comments suggesting that we clarify to our staff that FDA may not cite failure to follow a guidance document in any observation on Form FDA 483 (List of Inspectional Observations).

We agree with this comment. Guidance documents are not binding. An enforcement action may be taken only when we find a violation of statutory or regulatory requirements. If a guidance document contains a reference to a regulatory or statutory requirement, then enforcement action may be taken if the regulation or statutory requirement is violated. Of course, enforcement action may be taken if a requirement in a regulation or statute is violated whether or not there is a reference to the requirements in any guidance document. We discuss this issue in the GGP training we provide employees under § 10.115(l)(1).

(Comment 21) We received one comment on how we should interpret a draft guidance document during the time that it is out for comment, before the document has been finalized. The comment suggested that we maintain three categories of guidance documents: Draft, approvable, and approved.

We believe the provisions of § 10.115(g) sufficiently describe both the process for issuing draft Level 1 guidance documents for comment and the process of implementing Level 1 guidance documents without comment when prior public participation is not feasible or appropriate. We do not believe that adding more categories will improve the process; instead, it could confuse the users of the documents. Early in the process of developing the GGP's, comments strongly urged the agency to streamline and simplify the nomenclature for guidance documents. We have done so. If you are concerned about FDA's thinking on an issue that is reflected only in a draft guidance, you should contact the appropriate office within FDA to discuss the issue.

While a draft Level 1 guidance document is out for comment, you may be concerned that the guidance will change based on comments received. Because a guidance document represents the agency's current thinking on a subject but it is not ever binding on FDA or outside parties, you should not rely on any guidance document, draft or final. If you have questions about compliance with statutory or regulatory requirements, you can discuss those issues with an FDA employee.

6. Standard Elements

(Comment 22) We received two comments suggesting that the designation as Level 1 or Level 2 be a standard element of each guidance document.

We believe that the comment misinterpreted the significance of the Level 1 or Level 2 designation. The designation of a guidance as Level 1 or Level 2 is only relevant when a guidance document or revision to a guidance document is being developed. The designation is used to indicate whether the proposed document or revision is significant enough to warrant public comment before implementation. If the Level 1 or Level 2 determination remains with the document as a standard element, it may be confusing. For example, if we make a very minor revision to a guidance document that contains highly significant issues, this revision would warrant a Level 2 determination for the purposes of receiving comments. Affected parties should not assume that the document contains issues that are less significant because of the Level 2 designation, but rather that the change being made is not significant.

(Comment 23) One comment suggested that we require as an element in each guidance document a statement that explains why the document is needed.

Guidance documents should be issued only when a need for guidance exists. In each document, we generally include a background section that states the reason for its issuance. We will continue to do this in the future. However, although we acknowledge the utility of stating the need for each guidance, we do not believe the statement should be required. The advice we provide in a guidance document represents our current thinking, regardless of whether we adequately explain the need for the guidance. Therefore, we decline to make this information a required element in our guidance documents.

(Comment 24) One comment suggested that statements of nonbinding effect be prominently displayed on all guidance documents.

We agree with the comment. It is critical that all parties understand that guidance documents do not bind us or you. We are amending the regulation at § 10.115(i)(1)(iv) to require that a statement of the guidance document's nonbinding effect be displayed on prominently each document. In the future, this statement will be placed immediately below the title of the guidance document on the first page of text and it will be in prominent (e.g., bold or italic) print.

7. Our Procedures

(Comment 25) In the proposed rule, we stated that we would not seek public input prior to implementing a Level 1 guidance document if we determine that prior public participation is not feasible or appropriate (proposed § 10.115(g)(2)). Several comments discussed this exception to the prior public participation requirement. Two comments stated that we should use the exception only in rare and extraordinary circumstances. Other comments suggested that we only use this exception in cases where there is a real, demonstrated public health emergency, not just a theoretical emergency. Another comment stated that when we use these procedures, we should provide a statement of our reasons for not soliciting prior public participation.

Under section 701(h)(1)(C) of the act, we must ensure public participation prior to the implementation of guidance documents unless we determine that such prior public participation is not feasible or appropriate. As discussed in the preamble to the proposed rule, § 10.115(g)(2) reflects the standard stated in the statute (65 FR 7321 at 7324). We anticipate that this exception will generally be used when: (1) There are public health reasons for the immediate implementation of the guidance document; (2) there is a statutory requirement, executive order, or court order that requires immediate implementation; or (3) the guidance document presents a less burdensome policy that is consistent with public health. We agree that we should explain why a document is being issued without prior public participation when we issue the document. Generally, this explanation is included in the NOA for the guidance document. We will continue to follow this procedure in the future.

(Comment 26) One comment suggested that we adopt a 30-day grace period for Level 1 guidance documents issued without prior public participation.

A grace period would not be needed for a guidance document because guidance is not binding on us or you. We do not enforce guidance documents; we enforce applicable statutory and regulatory requirements.

We are committed to ensuring that you have the opportunity to participate in guidance document development as much as possible. Therefore, we will issue a Level 1 guidance document without prior public participation only if it is not feasible or appropriate to solicit your comments (e.g., a public health emergency or a court order requires the issuance of the guidance and we need to make the document available to the public as quickly as possible). A delay in implementation would not be appropriate in such circumstances.

(Comment 27) One comment noted that there are times when a Level 2 guidance document may become controversial and suggested that we adopt procedures whereby a Level 2 document could be withdrawn, redesignated as a Level 1 document, and reissued in draft for public comment.

We believe that the GGP's implicitly provide us with the ability to act as the comment describes. If our initial determination to issue a guidance document or amended guidance document using Level 2 procedures proves to be an incorrect decision because the document is highly controversial when issued, we may withdraw the guidance document and reissue it as a draft guidance document following Level 1 procedures (i.e., publish an NOA in the **Federal Register** for the draft guidance document and solicit comments on the draft). We do not believe the rule should be amended to reflect these procedures.

(Comment 28) Two comments suggested that we use the Internet to the greatest extent possible to disseminate guidance documents. Several comments specifically requested that we allow submission of comments on guidance documents through e-mail.

We use the Internet as our primary means of disseminating guidance documents. In most cases, newly issued or revised guidance documents are available on the Internet at the same time they are available through other means (e.g., through the Dockets Management Branch). We are developing new ways to use Internet technology to enhance our ability to disseminate information to the public. In particular, we are developing a system for providing access to all documents on the Internet and facilitating e-mail submission of comments on guidance documents.

(Comment 29) One comment suggested that we publish a new guidance document within 30 days of changing our current thinking on a given subject. This comment also urged us to amend the regulations to clarify that the information in a guidance document may be relied on to be currently acceptable to FDA.

We agree that guidance documents should reflect our current thinking on a given subject. We try to ensure that our documents are current. However, we allocate our limited resources to the areas of greatest public health need. Although GGP's help to ensure a greater level of public participation in guidance development, following these procedures often means that it takes

longer to issue guidance documents. Therefore, we will not commit ourselves to issuing guidance documents within a specific timeframe. We need flexibility to allocate our resources as we see fit, for example, to an area that presents more significant public health issues.

In response to the second part of the comment, § 10.115(d)(3) of the final rule clearly states that guidance documents represent the agency's current thinking on the subject of the document, and that FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

(Comment 30) One comment stated that if we depart from a guidance document on multiple occasions, we should consider revising the document. A similar comment noted that when a change in policy allows deviation from a guidance document, we should amend the document to indicate the existence of limited exceptions.

As discussed previously, guidance documents should represent our current thinking on the matters discussed in the documents. Our consistent deviation from a guidance document might suggest that we should revise it. Furthermore, we should amend guidance documents to clarify any changes in our interpretation of a guidance document. As resources allow, we will continue to update and revise guidance documents to reflect our current thinking.

(Comment 31) One comment suggested that we provide written justification for deviating from a guidance document.

As discussed in the preamble to the proposed rule (65 FR 7321 at 7327), we agree that our employees should not deviate from guidance without appropriate justification and supervisory concurrence. However, because guidance documents are not legally binding, we do not believe that we should provide written notice stating the reasons for such deviations. If we are asked to explain why we are deviating from a guidance document, we will do so.

(Comment 32) One comment suggested that we consolidate guidance documents addressing identical topics, those covering one topic that applies to several premarketing application types, and those containing identical premarketing application elements for similar product lines. This comment also noted that some currently available guidance documents are obsolete, redundant, or no longer appropriate.

We consolidate similar guidance documents when feasible and appropriate. Our primary concern is to issue documents that represent our current thinking on a particular matter. On balance, the benefit of having consolidated guidance documents is often outweighed by the burden of reissuing the documents. Furthermore, consolidated documents may be too cumbersome to be user-friendly.

We agree that documents that are obsolete, redundant, or no longer appropriate should be revised or withdrawn so they do not create confusion. During the past few years, we have tried to eliminate or revise documents when appropriate, given our resource constraints. We will continue this practice. Section 10.115(f) provides you with an opportunity to suggest documents that should be eliminated or revised.

(Comment 33) One comment noted that we should not use guidance documents as a replacement for notice-and-comment rulemaking.

We agree with this comment and believe that in certain circumstances regulations should be issued, while in other circumstances issuance of a guidance document is more appropriate. We carefully consider whether a document that contains binding requirements should be issued. This decision ultimately determines whether it is more appropriate for us to issue regulations or guidance on a given subject.

(Comment 34) We received several comments on our dispute resolution process. One comment suggested that we establish a systematic review process for external auditors to examine the decisions of our staff and to determine whether the application of a guidance document was appropriate. One comment encouraged us to develop an appeals process to address complaints about our development and use of guidance documents, stating that this appeals process is required by the Modernization Act. Other comments suggested that we describe the normal appeals process for disputes about the content of a guidance document in this final rule.

We appreciate the importance of providing effective mechanisms for dispute resolution and recognize that guidance documents need to be developed, issued, and used in a manner that is consistent with GGP's. However, we believe that an evaluation of our current dispute resolution system by an external auditor is unnecessary. We are required under section 405 of the Modernization Act to ensure that an effective appeals mechanism is in place to address complaints about our development and use of guidance documents. We believe that we have such a mechanism in place.

If you believe that an FDA staff member did not follow the GGP's, including any situation where you believe a staff member treated a guidance document as binding, under § 10.115(o) you can raise the issue with that staff member's supervisor. If the issue cannot be resolved, you can continue raising it through the chain of command. These procedures complement our dispute resolution regulation in § 10.75 (internal review of decisions). You can also use the procedures in § 10.75 to appeal a decision on the GGP's. We are amending the final rule to provide another means for raising an issue about our implementation of the GGP's. Under amended § 10.115(o), you can contact the ombudsman of the center or office with which you have a dispute and seek the ombudsman's assistance in resolving the issue. Finally, if you feel that you are not making progress or if you are unable to resolve the issue at the center or office level, you can request that our Chief Mediator and Ombudsman become involved. Each center and office has made or will make available its own guidance documents on specific procedures for resolving disputes.

You may also petition us under § 10.30 (citizen petitions) and request that we formally resolve your issue.

(Comment 35) One comment suggested that we explicitly state that guidance documents apply to all parties who work in the area addressed by the document. The comment stated that historically, we have not applied guidance documents uniformly to work undertaken by different individuals.

In each document, we generally include an introductory section that states the intended audience of the guidance document (e.g., applicants, reviewers). The guidance document applies to all members of the intended audience. If you believe that an FDA staff member is not interpreting the document appropriately, you can follow the dispute resolution procedures described previously and in § 10.115(o).

(Comment 36) One comment suggested that we post the names and titles of the supervisors for each center/office on our Internet home page (www.fda.gov).

We agree that information about the individuals to contact regarding the resolution of a dispute should be readily available. This information is currently on the Internet for all of the centers and offices. You can find the organizational charts at the following Internet addresses:

TABLE 1.

Center or Office	Organizational Chart Internet address
Center for Biologics Evaluation and Research	www.fda.gov/cber/inside/orgchart.pdf
Center for Devices and Radiological Health	www.fda.gov/cdrh/organiz.html
Center for Drug Evaluation and Research	www.fda.gov/cder/cderorg.htm
Center for Food Safety and Applied Nutrition	vm.cfsan.fda.gov/¢dms/orgchart.html
Center for Veterinary Medicine	www.fda.gov/cvm/fda/mappgs/contactcvm.html
Office of Regulatory Affairs	www.fda.gov/ora/inspect__ref/iom/IOMORADIR.html

(Comment 37) In § 10.115(l)(2), we state that our centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed. One comment suggested that we consider using a center ombudsman (e.g., the new ombudsman in the Center for Devices and Radiological Health) to perform this monitoring function.

We agree that it is important to ensure that guidance documents are developed and issued consistently by all centers and offices. Therefore, each center and office will designate one or more persons to monitor the development and issuance of its guidance documents. The center or office can designate the ombudsman and/or other individuals to perform this function.

As discussed previously, under § 10.115(o) you may seek the assistance of a center or office ombudsman or the Office of the Chief Mediator and Ombudsman if you believe that someone at FDA is not following the GGP's.

(Comment 38) One comment said that if we are serious about ensuring that our employees do not develop policy through speeches and other informal mechanisms, we should update and enforce internal written procedures on this subject. Another comment suggested that we state that our employees may not make statements at advisory committee meetings as a means to communicate new regulatory expectations.

We stated in the proposed regulation at § 10.115(e) that we may not use documents and other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to the public for the first time. We are maintaining this language in the final rule. Part of our GGP training for employees includes the understanding that policy is not to be communicated initially to a broad audience through speeches. Statements at advisory committee meetings often depend on the context of the statement. If, for example, a marketing application under consideration raises a novel issue, it may be appropriate for an FDA employee to comment on that issue as it relates to a specific application during a public advisory committee meeting. If there are questions raised by an advisory committee member that are not about a specific application, an individual employee can express a view, but this would not reflect official agency policy.

(Comment 39) One comment suggested that we examine our processes for training, evaluation, and related internal guidance to ensure that our directives to staff reinforce the appropriate use of guidance documents.

Section 701(h)(1)(B) of the act requires us to provide training for employees on how to develop and use guidance documents. We train employees about guidance documents in new employee orientation and/or as part of continuing employee education and training programs. Internal procedural documents are examined before they are issued to ensure that they are consistent with our GGP policies.

(Comment 40) Several comments recommended that there be better internal coordination among centers in the development, issuance, and use of guidance documents. In particular, one comment suggested that FDA ensure closer communication among centers, clarify the role of each center in oversight, and communicate clearly the enforcing center's expectation of a firm's responsibility for following a guidance document.

One comment referred to the ''enforcing'' center. We note that guidance is not enforceable. It is not binding on you or us.

In section 123 of the Modernization Act, Congress directed us to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)). We have made a concerted effort to minimize those differences and otherwise streamline the regulation of products that may involve dual jurisdiction of our centers. As part of this effort, we have issued numerous joint guidance documents.

We also have several checks within the guidance document development process that help to ensure that there is communication among centers on multicenter topics. For example, Level 1 guidance documents that describe new legal interpretations or significant changes in our policy are reviewed by the Office of the Chief Counsel and the Office of Policy before issuance. These offices are aware of cross-cutting issues and can ensure appropriate coordination.

(Comment 41) A comment suggested that we define the minimum levels of approval authority for sign-off on guidance documents.

We understand that having the appropriate level of clearance on guidance documents is important for purposes of quality control and to achieve the greatest level of consistency across the agency. However, we believe that we should maintain flexibility by providing discretion to the various centers and offices to determine their appropriate levels of clearance. Therefore, we decline the suggestion to mandate minimum levels of approval authority for guidance documents.

(Comment 42) One comment suggested that we clarify the status of advisory opinions and determine whether they are guidance documents.

We issue advisory opinions under § 10.85. We anticipate modifying § 10.85 and explaining the effect of § 10.115 on previously issued advisory opinions in a separate rulemaking effort. As such, the comment is outside the scope of this rulemaking.

(Comment 43) Two comments suggested that we clarify the status of guidelines. One recommended that we designate them as Level 1 guidance.

Our ability to issue guidelines was described in § 10.90(b). In the conforming amendments to the proposed rule, we proposed to delete all references to guidelines in § 10.90(b) and replace the provision with the statement that guidance documents will be developed, issued, and used

according to the requirements at § 10.115. On further consideration, we have decided not to include a provision on guidance documents in § 10.90(b) because it is not necessary to state that guidance documents will be regulated under § 10.115. Therefore, we are removing and reserving § 10.90(b).

As described in the preamble to the proposed rule, all guidelines are now treated as guidance documents (65 FR 7321 at 7326). Because we no longer issue guidelines, we need not determine whether they would warrant a Level 1 or Level 2 determination. If any documents previously issued as guidelines are amended, we will follow the same procedures used for amending guidance documents (i.e., we will determine whether modifying the document meets the criteria for a Level 1 or Level 2 change).

(Comment 44) One comment asked whether we ensure that all broadly disseminated letters are posted on the Internet and whether we have procedures in place for quality control of this process.

We currently post all broadly disseminated letters on the Internet, including ''Dear Doctor'' letters, and letters that are broadly circulated but do not provide the agency's current thinking on a regulatory issue. All broadly disseminated letters that fall under the definition of guidance documents are issued under the procedures described in this rule. Each center and office has personnel who determine whether a broadly disseminated letter meets the criteria for a guidance document and should be issued as such.

(Comment 45) One comment asked whether we post on the Internet letters containing information about public health alerts.

In § 10.115(b)(3), we clarify that guidance documents do not include general information documents provided to consumers or health professionals. Public health alerts fall within this category of documents. While public health alerts are not guidance documents, and the comment is beyond the scope of this rulemaking, we do post such information on the Internet, as appropriate.

(Comment 46) One comment questioned whether we have a mechanism in place for receiving and evaluating suggestions for novel or more efficient procedures. The same comment suggested that we create a data base that contains all correspondence issued to a company. The comment also requested that we post on the Internet all of our speeches and the preamble to the September 29, 1978, current good manufacturing practices (CGMP's) regulation.

These comments are beyond the scope of this rulemaking.

B. Guidance Documents Resulting From International Negotiations

In addition to amending the final rule as described previously in response to comments, we are making one revision that will improve our ability to participate in international negotiations on guidance documents. As described in § 10.115(i)(1) and (i)(2), a guidance document must: (1) Include the term ''guidance,'' (2) identify the center(s) or office(s) issuing the document, (3) identify the activity to which and the people to whom the document applies, (4) include a statement of the document's nonbinding effect, (5) include the date of issuance, (6) note if it is a revision to a previously issued guidance, and (7) contain the word ''draft'' if the document is a draft guidance. Furthermore, guidance documents must not include mandatory language such as ''must'' or ''required'' unless we use those words to describe a statutory or regulatory requirement.

In accordance with our mission, we actively participate in international efforts to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements (section 903(b)(3) of the act 21 U.S.C. 393(b)(3)). Through these efforts, we frequently negotiate guidance documents with representatives of other countries. For example, our participation in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has allowed us to work with representatives of regulatory authorities from Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to develop numerous guidance documents on the regulation of human drug and biological products.

When draft documents are negotiated with representatives of other countries, we seek public comment on the resulting documents. We believe it is important to publish draft documents for comment at the same time as other countries so we may review the public comments and resume negotiations in a timely manner. However, other countries do not follow our GGP's; therefore internationally negotiated draft documents often do not comply with all of the provisions of § 10.115(i)(1) and (i)(2). For example, documents negotiated through ICH do not include the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research as issuing offices. Differences in language and use of certain terms often result in wording that implies the draft documents establish mandatory requirements. Therefore, to facilitate the development and issuance of draft documents resulting from international negotiations, we have modified the final rule to state that when issuing ''draft'' guidances that are the product of international negotiations, we need not apply the provisions of § 10.115(i)(1) and (i)(2). However, we recognize and the final rule provides that final guidances that are the product of international negotiations must comply with all of the provisions of § 10.115(i). We anticipate that this amendment will provide many advantages, including our ability to: (1) Provide more time for public comment on draft guidance documents that are the result of international negotiations, (2) receive more public comments on these draft documents, (3) negotiate based on issues raised in public comments more effectively, and (4) resume international negotiations in a timely manner.

III. Conforming Amendments

We refer to guidelines issued under former § 10.90(b) throughout our regulations. Because we are revising our administrative regulations by deleting guidelines and adding guidance documents issued under § 10.115, we are making conforming amendments to 21 CFR parts 7, 10, 14, 19, 25, 101, 107, 110, 114, 170, 310, 312, 314, 316, 500, 514, 601, 803, 814, and 860 to reflect our changes. We are also adding § 601.29, Guidance documents, to the biologics regulations, to be consistent with §§ 312.145, 314.445, and 814.20. These conforming amendments will ensure the accuracy and consistency of the regulations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required statement would be required.

V. Analysis of Impact

We have examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and,

when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

We believe that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in these two statutes. This rule does not impose any mandates on State, local, or tribal governments. The rule will not be significant as defined by the Executive Order and will not require further analysis under the Regulatory Flexibility Act. The Unfunded Mandates Reform Act does not require us to prepare a statement of costs and benefits for the rule because the rule in any 1-year expenditure would not exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

VI. Paperwork Reduction Act of 1995

This regulation would impose no additional reporting or recordkeeping requirements. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 7

Administrative practice and procedure, Consumer protection, Reporting and recordkeeping requirements.

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 19

Conflict of interests.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

21 CFR Part 110

Food packaging, Foods.

21 CFR Part 114

Food packaging, Foods, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 316

Administrative practice and procedure, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCB's).

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedures, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 7, 10, 14, 19, 25, 101, 107, 110, 114, 170, 310, 312, 314, 316, 500, 514, 601, 803, 814, and 860 are amended as follows:

PART 7—ENFORCEMENT POLICY

1. The authority citation for 21 CFR part 7 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

§ 7.1 [Amended]

2. In § 7.1, remove the word ''guidelines'' and add in its place the word ''guidance''.

Subpart C [Amended]

3. In the heading for subpart C, consisting of §§ 7.40 through 7.59, remove the word ''guidelines'' and add in its place the word ''guidance''.

§ 7.40 [Amended]

4. In 7.40(a), remove the word ''guidelines'' and add in its place the word ''guidance''.

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

5. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–

397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.20 [Amended]

6. In § 10.20(j)(1)(v), remove the phrase ''guidelines filed under § 10.90(b)'' and add in its place the words ''guidance documents developed under § 10.115''.

§ 10.45 [Amended]

7. In § 10.45(d), remove the words ''on a guideline issued under § 10.90,''.

§ 10.85 [Amended]

8. In § 10.85, remove paragraph (d)(5).

§ 10.90 [Amended]

9. In § 10.90, remove ''guidelines,'' from the section heading and remove and reserve paragraph (b).

10. Add § 10.115 to subpart B to read as follows:

§ 10.115 Good guidance practices.

(a) *What are good guidance practices*? Good guidance practices (GGP's) are FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) *What is a guidance document*?

(1) Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

(2) Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.

(3) Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms.

(c) *What other terms have a special meaning*?

(1) ''Level 1 guidance documents'' include guidance documents that:

(i) Set forth initial interpretations of statutory or regulatory requirements;

(ii) Set forth changes in interpretation or policy that are of more than a minor nature;

(iii) Include complex scientific issues; or

(iv) Cover highly controversial issues.

(2) ''Level 2 guidance documents'' are guidance documents that set forth existing practices or minor changes in interpretation or policy. Level 2 guidance documents include all guidance documents that are not classified as Level 1.

(3) ''You'' refers to all affected parties outside of FDA.

(d) *Are you or FDA required to follow a guidance document*?

(1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

(2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.

(3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

(e) *Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience*? The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGP's must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.

(f) *How can you participate in the development and issuance of guidance documents*?

(1) You can provide input on guidance documents that FDA is developing under the procedures described in paragraph (g) of this section.

(2) You can suggest areas for guidance document development. Your suggestions should address why a guidance document is necessary.

(3) You can submit drafts of proposed guidance documents for FDA to consider. When you do so, you should mark the document ''Guidance Document Submission'' and submit it to Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(4) You can, at any time, suggest that FDA revise or withdraw an already existing guidance document. Your suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

(5) Once a year, FDA will publish, both in the **Federal Register** and on the Internet, a list of possible topics for future guidance document development or revision during the next year. You can comment on this list (e.g., by suggesting alternatives or making recommendations on the topics that FDA is considering).

(6) To participate in the development and issuance of guidance documents through one of the mechanisms described in paragraphs (f)(1), (f)(2), or (f)(4) of this section, you should contact the center or office that is responsible for the regulatory activity covered by the guidance document.

(7) If FDA agrees to draft or revise a guidance document, under a suggestion made under paragraphs (f)(1), (f)(2), (f)(3) or (f)(4) of this section, you can participate in the development of that guidance document under the procedures described in paragraph (g) of this section.

(g) *What are FDA's procedures for developing and issuing guidance documents*?

(1) FDA's procedures for the development and issuance of Level 1 guidance documents are as follows:

(i) Before FDA prepares a draft of a Level 1 guidance document, FDA can seek or accept early input from individuals or groups outside the agency. For example, FDA can do this by participating in or holding public meetings and workshops.

(ii) After FDA prepares a draft of a Level 1 guidance document, FDA will:

(A) Publish a notice in the **Federal Register** announcing that the draft guidance document is available;

(B) Post the draft guidance document on the Internet and make it available in hard copy; and

(C) Invite your comment on the draft guidance document. Paragraph (h) of this section tells you how to submit your comments.

(iii) After FDA prepares a draft of a Level 1 guidance document, FDA also can:

(A) Hold public meetings or workshops; or

(B) Present the draft guidance document to an advisory committee for review.

(iv) After providing an opportunity for public comment on a Level 1 guidance document, FDA will:

(A) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate;

(B) Publish a notice in the **Federal Register** announcing that the guidance document is available;

(C) Post the guidance document on the Internet and make it available in hard copy; and

(D) Implement the guidance document.

(v) After providing an opportunity for comment, FDA may decide that it should issue another draft of the guidance document. In this case, FDA will follow the steps in paragraphs (g)(1)(ii), (g)(1)(iii), and (g)(1)(iv) of this section.

(2) FDA will not seek your comment before it implements a Level 1 guidance document if the agency determines that prior public participation is not feasible or appropriate.

(3) FDA will use the following procedures for developing and issuing Level 1 guidance documents under the circumstances described in paragraph (g)(2) of this section:

(i) After FDA prepares a guidance document, FDA will:

(A) Publish a notice in the **Federal Register** announcing that the guidance document is available;

(B) Post the guidance document on the Internet and make it available in hard copy;

(C) Immediately implement the guidance document; and

(D) Invite your comment when it issues or publishes the guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review those comments and revise the guidance document when appropriate.

(4) FDA will use the following procedures for developing and issuing Level 2 guidance documents:

(i) After it prepares a guidance document, FDA will:

(A) Post the guidance document on the Internet and make it available in hard copy;

(B) Immediately implement the guidance document, unless FDA indicates otherwise when the document is made available; and

(C) Invite your comment on the Level 2 guidance document. Paragraph (h) of this section tells you how to submit your comments.

(ii) If FDA receives comments on the guidance document, FDA will review those comments and revise the document when appropriate. If a version is revised, the new version will be placed on the Internet.

(5) You can comment on any guidance document at any time. Paragraph (h) of this section tells you how to submit your comments. FDA will revise guidance documents in response to your comments when appropriate.

(h) *How should you submit comments on a guidance document*?

(1) If you choose to submit comments on any guidance document under paragraph (g) of this section, you must send them to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(2) Comments should identify the docket number on the guidance document, if such a docket number exists. For documents without a docket number, the title of the guidance document should be included.

(3) Comments will be available to the public in accordance with FDA's regulations on submission of documents to the Dockets Management Branch specified in § 10.20(j).

(i) *What standard elements must FDA include in a guidance document*?

(1) A guidance document must:

(i) Include the term ''guidance,''

(ii) Identify the center(s) or office(s) issuing the document,

(iii) Identify the activity to which and the people to whom the document applies,

(iv) Prominently display a statement of the document's nonbinding effect,

(v) Include the date of issuance,

(vi) Note if it is a revision to a previously issued guidance and identify the document that it replaces, and

(vii) Contain the word ''draft'' if the document is a draft guidance.

(2) Guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''required,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

(3) When issuing draft guidance documents that are the product of international negotiations (e.g., guidances resulting from the International Conference on Harmonisation), FDA need not apply paragraphs (i)(1) and (i)(2) of this section. However, any final guidance document issued according to this provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section.

(j) *Who, within FDA, can approve issuance of guidance documents*? Each center and office must have written procedures for the approval of guidance documents. Those procedures must ensure that issuance of all documents is approved by appropriate senior FDA officials.

(k) *How will FDA review and revise existing guidance documents*?

(1) The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

(2) When significant changes are made to the statute or regulations, the agency will review and, if appropriate, revise guidance documents relating to that changed statute or regulation.

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(l) *How will FDA ensure that FDA staff are following GGP's*?

(1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents*? FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available*?

(1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the **Federal Register** its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document.

(o) What can you do if you believe that someone at FDA is not following these GGP's? If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

11. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.27 [Amended]

12. In § 14.27(b)(3), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

§ 14.33 [Amended]

13. In § 14.33(c), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

14. The authority citation for 21 CFR part 19 continues to read as follows:

Authority: 21 U.S.C. 371.

§ 19.10 [Amended]

15. In § 19.10(c), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

16. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

§ 25.30 [Amended]

17. In § 25.30(h), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

PART 101—FOOD LABELING

18. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

§ 101.9 [Amended]

19. In § 101.9(b)(7)(vi), remove the word ''guideline'' wherever it appears and add in its place the words ''guidance document''.

PART 107—INFANT FORMULA

20. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

§ 107.270 [Amended]

21. In § 107.270, remove the word ''guidelines'' and add in its place the word ''guidance''.

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

22. The authority citation for 21 CFR part 110 continues to read as follows:

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

§ 110.80 [Amended]

23. In § 110.80, remove the word ''guidelines,'' in paragraphs (a)(3) and (a)(4).

PART 114—ACIDIFIED FOODS

24. The authority citation for 21 CFR part 114 continues to read as follows:

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

§ 114.100 [Amended]

25. In § 114.100(a), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

PART 170—FOOD ADDITIVES

26. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

§ 170.39 [Amended]

27. In § 170.39(h), remove the word ''guidelines'' wherever it appears and add in its place the words ''guidance documents''.

PART 310—NEW DRUGS

28. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379(e); 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

§ 310.500 [Amended]

29. In § 310.500(e), remove the words ''guidelines'' and ''guideline'', respectively, and add in their place the words ''guidance'' and ''guidance on'', respectively.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

30. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

§ 312.23 [Amended]

31. In § 312.23(a)(8), remove the word ''guidelines'' and add in its place the words ''guidance documents.''

32. Revise § 312.145 to read as follows:

§ 312.145 Guidance documents.

(a) FDA has made available guidance documents under § 10.115 of this chapter to help you to comply with certain requirements of this part.

(b) The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) maintain lists of guidance documents that apply to the centers' regulations. The lists are maintained on the Internet and are published annually in the **Federal Register**. A request for a copy of the CDER list should be directed to the Office of Training and Communications, Division of Communications Management, Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. A request for a copy of the CBER list should be directed to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

33. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

§ 314.50 [Amended]

34. In § 314.50, in the introductory text remove the word ''guidelines'' and add in its place the words ''guidance documents''.

§ 314.70 [Amended]

35. In § 314.70(a), remove the words ''guideline, notice,'' and add in their place the word ''notice''.

§ 314.94 [Amended]

36. In § 314.94, in the introductory text remove the words ''guidelines'' and add in its place the words ''guidance documents''.

§ 314.105 [Amended]

37. In § 314.105(c), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

§ 314.420 [Amended]

38. In § 314.420(c), remove the words ''under § 10.90(b) a guideline'' and add in their place the word ''guidance''.

39. Revise § 314.445 to read as follows:

§ 314.445 Guidance documents.

(a) FDA has made available guidance documents under § 10.115 of this chapter to help you to comply with certain requirements of this part.

(b) The Center for Drug Evaluation and Research (CDER) maintains a list of guidance documents that apply to CDER's regulations. The list is maintained on the Internet and is published annually in the **Federal Register**. A request for a copy of the CDER list should be directed to the Office of Training and Communications, Division of Communications Management, Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

PART 316—ORPHAN DRUGS

40. The authority citation for 21 CFR part 316 continues to read as follows:

Authority: 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

41. Revise § 316.50 to read as follows:

§ 316.50 Guidance documents.

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the **Federal Register**. A request for a copy of the list should be directed to the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

PART 500—GENERAL

42. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

§ 500.80 [Amended]

43. In § 500.80(a), remove the word ''guidelines'' wherever it appears and add in its place the words ''guidance documents''.

PART 514—NEW ANIMAL DRUG APPLICATIONS

44. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

§ 514.1 [Amended]

45. In § 514.1(d)(2), remove the word ''guidelines'' wherever it appears and add in its place the words ''guidance documents''.

PART 601—LICENSING

46. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

47. Add § 601.29 to subpart C to read as follows:

§ 601.29 Guidance documents.

(a) FDA has made available guidance documents under § 10.115 of this chapter to help you comply with certain requirements of this part.

(b) The Center for Biologics Evaluation and Research (CBER) maintains a list of guidance documents that apply to the center's regulations. The lists are maintained on the Internet and are published annually in the **Federal Register**. You may request a copy of the CBER list from the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448.

PART 803—MEDICAL DEVICE REPORTING

48. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

§ 803.14 [Amended]

49. In § 803.14(b), remove the word ''guidelines'' and add in its place the words ''guidance documents''.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

50. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

51. In § 814.20, revise paragraph (g) to read as follows:

§ 814.20 Application.

* * * * *

(g) FDA has issued a PMA guidance document to assist the applicant in the arrangement and content of a PMA. This guidance document is available on the Internet at http://www.fda.gov/cdrh/dsma/pmaman/front.html. This guidance document is also available upon request from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, FAX 301–443–8818.

* * * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

52. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

§ 860.3 [Amended]

53. In § 860.3(c)(2), remove the words ''guidelines'' and ''guidelines for'' and add in their place the words ''guidance documents'' and ''guidance on'', respectively.

Dated: September 1, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–23887 Filed 9–18–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket No. 92N–0297]

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administration Procedures; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to discuss certain requirements of the final rule implementing the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA) and the FDA Modernization Act of 1997 (Modernization Act), which published in the **Federal Register** of December 3, 1999 (64 FR 67720), (hereinafter referred to as the PDMA final rule). The purpose of the hearing is to elicit comment from interested persons, including professional groups and associations, the regulated industry, health care professionals, and consumers, on the potential impact of certain requirements in the PDMA final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by