PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ASO NC E5 Andrews—Murphy, NC [New]

Andrews—Murphy, NC

Point In Space Coordinates

(Lat. 35°11′10″ N, long. 83°52′57″ W)

That airspace extending upward from 700 feet or more above the surface within a 6-mile radius of the point in space (lat. 35°11′10″ N, long 83°52′57″ W) serving Andrews—Murphy NC; excluding that airspace within the Knoxville. TN, Class E airspace.

* * * * *

Issued in College Park, Georgia, on January 31, 2000.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–3302 Filed 2–11–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, 19, and 25

[Docket No. 99N–4783]

Administrative Practices and Procedures; Good Guidance Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations to codify its policies and procedures for the development, issuance, and use of guidance documents. This action is necessary in order to comply with requirements of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA codifies certain parts of the agency's current ''Good Guidance Practices'' (GGP's) and directs the agency to issue a regulation that is consistent with the Federal Food, Drug, and Cosmetic Act (the act) and 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: Submit written comments and recommendations by May 1, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Presidential Memorandum on Plain Language issued on June 1, 1998, directs FDA to ensure that all of its documents are clear and easy-to-read. Part of achieving that goal involves having readers of a regulation feel that it is speaking directly to them. The agency has attempted to incorporate plain language concepts through the use of pronouns and other plain language in this regulation as much as possible. For example, the agency will be using the term ''you'' to refer to all affected parties outside of the agency. For purposes of this regulation, ''you'' and ''public'' are used interchangeably. The agency would like your comments on how effectively it has used plain language in this regulation, and whether this has made the document more clear and easy to understand.

II. History

In May 1995, the Indiana Medical Device Manufacturer's Council filed a citizen's petition with the agency, which requested, among other things, that FDA establish greater controls over the initiation, development, and issuance of guidance documents to assure the appropriate level of meaningful public participation. In response to this petition, the agency issued a proposed guidance document that set forth the agency's position on how it would proceed in the future with respect to guidance document development, issuance, and use (61 FR 9181, March 7, 1996).

The agency invited public comment on its proposal, and on April 26, 1996, the agency held a public meeting to discuss it. After reviewing and considering all of the comments received during the meeting and the public comment period, the agency finalized its procedures. In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing the agency's GGP's guidance document (the 1997 GGP document).

The 1997 GGP document provided a definition of guidance; established a standard way of naming guidance documents; described the legal effect of guidance documents; established practices for developing guidance documents and receiving public input; established ways for making guidance documents available to the public; and provided information concerning the agency's existing appeals processes for disputes regarding guidance documents.

On November 21, 1997, the President signed FDAMA into law (Public Law No. 105–115). Section 405 of FDAMA, which added section 701(h) to the act (21 U.S.C. 371(h)), establishes certain aspects of the 1997 GGP document as the law. It also directs the agency to evaluate the effectiveness of the 1997 GGP document and then develop and issue regulations specifying its policies and procedures for the development, issuance, and use of guidance documents. The agency conducted an internal evaluation of the effectiveness of the 1997 GGP document and now is proposing changes to its existing part 10 (21 CFR part 10) regulations to clarify its procedures for development, issuance, and use of guidance documents. The proposal, in large part, tracks the 1997 GGP document. As discussed below in part V.A of this document, any changes from the 1997 GGP document that FDA is proposing are based on the language in FDAMA, or FDA's internal evaluation of GGP's. Your comments on the proposal will help FDA further evaluate the effectiveness of its 1997 GGP document.

III. 1997 GGP Document

The 1997 GGP document issued by the agency in February 1997 provided a great deal of information regarding the agency's procedures for the development, issuance, and use of guidance documents. Below is a brief overview of the key parts of the 1997 GGP document.

First, the 1997 GGP document explained its purpose. The purpose of GGP's is to ensure that agency guidance

documents are developed with the proper amount of your participation, that you have easy access to guidance documents, and that guidance documents are not treated as binding requirements on you or on FDA. The agency also wanted to ensure that every part of the agency followed these policies and procedures the same way.

The 1997 GGP document also clarified what does and does not constitute a guidance document, and it provided examples.

The 1997 GGP document stated that guidance documents themselves do not create rights or responsibilities under the law, and guidance documents are not legally binding on you or on the agency. Instead, guidance documents explain how the agency believes the law applies to certain regulated activities. The 1997 GGP document also noted, however, that a guidance document represents the agency's current thinking on the subject addressed in the document, and it is intended to ensure consistency in the application of laws and regulations. Therefore, FDA supervisors will take steps to ensure that their employees do not make determinations that are different from what is in a guidance document without appropriate justification and supervisory concurrence.

The 1997 GGP document described several different ways that the agency receives your input regarding guidance documents before, during, and after a document's development. The 1997 GGP document also described the internal FDA clearance process for guidance documents.

Under the 1997 GGP document, the agency adopted a two-level approach to the development of guidance documents. Level 1 guidance documents were defined as those documents directed primarily to applicants/sponsors or other members of the regulated industry that set forth first interpretations of statutory or regulatory requirements, changes in interpretation or policy that are of more than a minor nature, unusually complex scientific issues, or highly controversial issues. Level 2 guidance documents included all other documents.

For a Level 1 guidance document, which the agency defined as generally more controversial or new, FDA calls for public input, in most cases, before the document goes into effect. For a Level 2 document, which is generally less novel or controversial in nature, FDA calls for your comments when the document is issued.

The 1997 GGP document established certain standard elements that are included in all guidance documents, including: A standard way of referring to guidance documents; a statement of nonbinding effect; the absence of any language implying that the document is mandatory; and other standard information, such as date of issuance and whether a document is draft or final.

The 1997 GGP document also clarified that FDA will educate and train all current and new FDA employees involved in the development, issuance, and use of guidance documents about the agency's GGP's and will monitor staff to ensure that they are appropriately following GGP's. The GGP guidance also stated that the agency would evaluate whether GGP's are achieving their purpose. According to the 1997 GGP document, lists of guidance documents and the documents themselves will be available to you. The agency will maintain and update this list.

Finally, the 1997 GGP document described an appeals process that provides you with an opportunity to raise an issue regarding whether FDA staff have followed GGP's.

IV. Statutory Requirements Under FDAMA

Section 701(h) of the act (21 U.S.C. 371(h)) codifies certain parts of the 1997 GGP document. Section 701(h)(1)(A) of the act requires the agency to develop guidance documents with public participation and to ensure that information identifying the existence of such documents and the documents themselves are made available to you both in written form and, as feasible, through electronic means.

Section 701(h)(1)(A) of the act further explains that guidance documents shall not create or confer any rights for or on any person, although they represent the views of the agency on matters within its jurisdiction.

Section 701(h)(1)(B) of the act states that guidance documents shall not be binding on the agency, and that the agency shall ensure that its employees do not deviate from such guidances without appropriate justification and supervisory concurrence. Under the statute, the agency is required to: (1) Provide training to employees on how to develop and use guidance documents, and (2) monitor the development and issuance of guidance documents.

For certain categories of guidance documents, the statute requires that the agency ensure public participation in their development prior to implementation. (See section 701(h)(1)(C) of the act.) These categories include documents that: (1) Set forth initial interpretations of a statute or regulation; (2) contain changes in interpretation or policy that are of more than a minor nature; (3) contain complex scientific issues; or (4) contain highly controversial issues. Prior public participation is required for these categories of documents unless the agency determines that such prior public participation is not feasible or appropriate. In such cases, the agency is required to provide for public comment upon implementation and to consider any comments received.

For guidance documents that set forth existing practices or minor changes in policy, section 701(h)(1)(D) of the act requires the agency to provide you with an opportunity to comment upon implementation.

Section 701(h)(2) of the act requires the agency to ensure uniform nomenclature for guidance documents and uniform internal procedures for approval of guidance documents. The agency is also required to ensure that new and revised guidance documents are properly dated and indicate the nonbinding nature of the documents. The statute also requires the agency to conduct periodic reviews of all guidance documents and, where appropriate, revise such documents.

Section 701(h)(3) of the act requires the agency to maintain a list of guidance documents which must be kept electronically, updated, and published periodically in the **Federal Register**. FDA must also make copies of the guidance documents available to the public.

Section 701(h)(4) of the act requires the agency to have an effective appeals mechanism to address complaints that FDA is not developing and using guidance documents in accordance with this provision of the law.

Finally, section 701(h)(5) of the act requires the agency to evaluate the effectiveness of the 1997 GGP document and then to issue regulations specifying its policies and procedures for developing, issuing, and using guidance documents by July 1, 2000.

V. Proposed Regulations

A. Overview

To evaluate the strengths and weaknesses of its GGP's as required by FDAMA, and as stated in its 1997 GGP document, the agency conducted an informal internal survey. The survey solicited information regarding FDA employees' views on the effectiveness of GGP's and questioned whether FDA employees had received complaints regarding the agency's development, issuance, and use of guidance documents since the development of

GGP's. This internal review found that the agency's GGP's have generally been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees have generally been following GGP's.

As a result of the FDAMA provision and FDA's internal survey, FDA is proposing certain minor changes to the procedures described in its 1997 GGP document. These changes and the reasons for them will be discussed below. As part of its continuing effort to evaluate and improve the development, issuance, and use of guidance documents, the agency is inviting public comment not only on the specific provisions described in the proposed regulation, but also on the 1997 GGP document. FDA is interested in hearing how you view the effectiveness of the procedures described in the 1997 GGP document.

B. Definitions

Proposed § 10.115(a) explains that ''Good Guidance Practices (GGP's) set forth FDA's policies and procedures for developing, issuing, and using guidance documents.''

Proposed § 10.115(b)(1) defines the term ''guidance document.'' While FDAMA did not explicitly require that the agency define the term ''guidance document,'' the agency did so in the 1997 GGP document and has found that a definition helps to increase clarity for affected parties within and outside of the agency. To eliminate certain redundancies, the agency has modified that definition and included it in this proposed regulation. The agency defines guidance documents as those prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.

The proposed regulation states that guidance documents include, but are not limited to, documents that relate to: (1) The design, production, manufacturing, and testing of regulated products; (2) the processing, content, and evaluation/approval of submissions; and (3) inspection and enforcement policies.

In addition, the agency is clarifying what is not a guidance document. As discussed in the 1997 GGP document, documents that would fall into the nonguidance category include: (1) Those relating to internal FDA procedures, (2) agency reports, (3) general information documents provided to consumers and health professionals, (4) speeches, (5) journal articles and editorials, (6) media interviews, (7) press materials, (8) warning letters, or (9) other communications directed to individual persons or firms.

In clarifying what is not a guidance document, the proposal has added general information documents provided to health professionals and memoranda of understanding. General information documents for health professionals would include documents such as ''Dear Health Professional'' letters. These documents, like general information documents provided to consumers, might describe a public health alert or emergency. In addition, FDA has added memoranda of understanding to the list of documents that would not be considered guidance documents because memoranda of understanding are agreements that FDA makes with other Federal or State government organizations in order to determine who will enforce certain laws. These documents do not articulate agency policy, and therefore they fall outside the definition of a guidance document.

In defining guidance documents, the agency recognizes that there are certain documents directed to its own staff that also would provide guidance to you. The agency, therefore, considers those documents to be guidance documents. However, among FDA's internal documents, there is another category of documents that describe FDA's day-to-day business. While such documents might be interesting to you, they do not fall within the definition of guidance documents. Examples of such documents could include: Staff guides regarding personnel information or leave policies or directives on how to route documents for review within the agency.

Consistent with the distinction drawn in section 701(h)(1)(C) of the act, the agency is proposing in § 10.115(c) to define two levels of guidance documents, which, as discussed below, will be subject to different levels of public participation before issuance. This is the same approach that the agency took in the 1997 GGP document. Level 1 guidance documents include guidance documents that: (1) Set forth initial interpretations of statutory or regulatory requirements; (2) set forth changes in interpretation or policy that are of more than a minor nature; (3) discuss complex scientific issues; or (4) cover highly controversial issues. As discussed below, for Level 1 documents, the agency is generally required by the statute to ensure public participation in their development prior to implementation.

In contrast, Level 2 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. As discussed below, according to the statute, for Level 2 documents, the agency is not required to seek comments from you before publication of the document, but the agency must provide for your comment upon implementation.

As discussed above, proposed § 10.115(c)(3) defines ''you'' as all affected parties outside of the agency. ''You'' does not refer to agency employees because the procedures they must follow under GGP's are different than the procedures that you would follow; *e.g.,* FDA employees follow different procedures when they would like to deviate from a guidance document. Under this proposed regulation, ''you'' and ''public'' are used interchangeably.

C. Legal Effect of Guidance Documents

Consistent with section 701(h)(1)(A) and (h)(1)(B) of the act, proposed § 10.115(d) describes the nonbinding effect of guidance documents. Specifically, it provides that guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind you or the agency.

Proposed § 10.115(d) further provides that you may choose to use an approach other than the one set forth in a guidance document. However, the alternative approach must comply with the relevant statutes and regulations. If you would like to choose an alternate approach, FDA is willing to discuss that approach with you to ensure that it complies with all relevant laws and regulations.

The proposed regulation also clarifies that 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.

Because the agency's issuance of GGP's is an attempt to make its processes for initially communicating new or different regulatory expectations to a broad public audience consistent across the agency, proposed § 10.115(e) clarifies that FDA should not use other methods or documents to informally provide this information. Consistent with the 1997 GGP document, the agency is proposing that GGP's must be followed whenever interpretations of law or policy that are not readily apparent from the statute or regulations

are first communicated to a broad public audience.

D. Public Participation in the Development and Issuance of Guidance

Section 701(h)(1)(A) of the act requires FDA to develop guidance documents with your participation. Proposed § 10.115(f) describes how you may participate in the development and issuance of FDA's guidance documents. These mechanisms for your input include: (1) Suggestions for areas of guidance document development; (2) submission of drafts of guidance documents to FDA for consideration; (3) suggestions about revisions of an existing guidance document; (4) submission of comments on an annual list of possible topics for future FDA guidance documents; and (5) submission of comments on specific proposed and final guidance documents.

The 1997 GGP document stated that the agency would issue its list of possible topics for future FDA guidance document development or revision twice a year. However, given its experience with GGP's thus far, the agency has determined that publishing the list once a year would be more workable and just as informative. If the agency were to publish such a list semiannually, it would likely publish essentially the same list twice.

The 1997 GGP document also provided that FDA would not be bound by its list of possible topics for future FDA guidance documents. In other words, FDA would not be required to issue a guidance document on every topic identified in that list. Similarly, FDA would not be stopped from issuing a guidance document on a topic not identified on the list. FDA will apply that same principle to the annual list.

If you want FDA to draft a guidance document on a particular issue or to revise an existing guidance document, you should contact the Center or Office that is responsible for the regulatory activity covered by the guidance document. For purposes of this regulation, FDA is using the term ''office'' to refer to offices that are agency components comparable to a Center, *e.g.* Office of the Commissioner, Office of Regulatory Affairs, or Office of the Chief Counsel, not offices with a given Center. You should include a statement explaining why the new or revised document is necessary. If FDA agrees to draft or revise a guidance document, it will follow the procedures described in proposed § 10.115(g).

Proposed § 10.115(g) describes the agency's procedures for the development and issuance of a guidance document. These procedures are similar to those described in the 1997 GGP document. As stated above in proposed § 10.115(c), the agency will determine, depending on its content, whether each guidance document is a Level 1 or Level 2 document.

1. Level 1 Procedures

Proposed § 10.115(g)(1) describes the procedures for developing and issuing most Level 1 guidance documents. Under proposed § 10.115(g)(1), before FDA drafts a Level 1 guidance document, FDA may seek or accept early input from individuals or groups outside the agency. For example, FDA may do this by participating in or holding meetings and workshops.

After FDA prepares a draft of a Level 1 guidance document, FDA will publish a notice in the **Federal Register** announcing that the draft guidance document is available. FDA will post the draft on the Internet and make it available in hard copy. FDA will invite your comments on the draft guidance document. Procedures for submission of your comments on guidance documents are described in proposed § 10.115(h).

After it prepares a draft of a Level 1 guidance document, FDA may also hold additional public meetings or workshops, or it may present the draft guidance document to an advisory committee for review.

After providing an opportunity for your comment on a draft Level 1 guidance document, FDA will review any comments it has received. FDA will prepare the final version of the guidance document that incorporates suggested changes, when appropriate. FDA then will publish a notice in the **Federal Register** announcing that the guidance document is available. FDA will post the guidance document on the Internet and make it available in hard copy. As discussed in the 1997 GGP document, when FDA issues a final guidance document, FDA is not obligated to address each comment specifically.

After providing an opportunity for comment, FDA may decide that it is appropriate to issue another draft of the guidance document. In this case, FDA will again solicit comment by publishing a notice in the **Federal Register**, posting a draft on the Internet, and making the draft available in hard copy. FDA would then proceed to issue a final version of the guidance document in the manner described above.

Proposed § 10.115(g)(1) is consistent with the 1997 GGP document. Minor changes have been made to clarify the types of early input that FDA may accept. In addition, FDA has clarified that it does not post a separate notice of availability of a guidance document on the Internet, but rather it posts the actual guidance document on the Internet. Copies of the **Federal Register** notices of availability are available on the Internet at http://www.fda.gov.

Section 701(h)(1)(C) of the act provides that the agency is not required to seek your comment before it implements a Level 1 guidance document if your prior participation is not feasible or appropriate. Proposed § 10.115(g)(2) mirrors the words of the statute. In the 1997 GGP document, the agency provided that it would not seek your comment before implementing a Level 1 guidance document if: (1) There are public health reasons for 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. The agency plans to continue to apply the same three exceptions, but it reserves the authority to provide for other exceptions that are consistent with section 701(h)(1)(C) of the act, if the need arises.

Proposed § 10.115(g)(3) describes the procedures that FDA will use for developing and issuing Level 1 guidance documents that fall under the exception discussed above. For that certain small class of guidance documents, FDA will: (1) Publish a notice in the **Federal Register** announcing that the guidance document is available; (2) post the guidance document on the Internet and make it available in hard copy; and (3) seek your comment when it issues or publishes the guidance document. If FDA receives comments on one of the excepted guidance documents, FDA will review those comments and revise the guidance document, when appropriate.

2. Level 2 Procedures

Proposed § 10.115(g)(4) describes the procedures for developing and issuing Level 2 guidance documents, as defined in § 10.115(c)(2). As set forth in section 701(h)(1)(D)of the act, FDA may implement a Level 2 guidance document at the same time that it issues the document and solicits public comment. After it prepares a Level 2 guidance document, FDA will publish the guidance document on the Internet and provide an opportunity for your comment at that time. Similar to the procedures for Level 1, if FDA receives comments on a Level 2 guidance document, FDA will review those comments and revise the document,

when appropriate. FDA may also, at its discretion, seek public comment before it implements a Level 2 guidance document.

You will know when a Level 2 guidance document has been issued because it will be posted on the Internet. In addition, FDA's electronic comprehensive list will be updated within 30 days of issuance and FDA's annual **Federal Register** list will identify all guidance documents that have been issued since the previous list was published.

In an effort to make the agency's guidance document development process as open as possible, proposed § 10.115(g)(5) provides that you may submit comments on any guidance document (Level 1 or Level 2, draft or final) at any time. FDA will review all of the comments that it receives and will revise guidance documents in response to your comments, when appropriate. When draft Level 1 guidance documents are issued under proposed § 10.115(g)(1), and when Level 1 guidance documents are issued under proposed § 10.115(g)(3), there will be a period of time established for the receipt of comments. All comments received during that period will be reviewed and considered immediately. Comments received after the closing date of the specified comment period will be reviewed as soon as possible and issues raised in those comments may be addressed in a future revision of the document, as the agency deems appropriate.

Proposed § 10.115(h) tells you how to submit comments on guidance documents. If you choose to submit comments on a guidance document, you must send them to the Dockets Management Branch. The comments submitted should identify the docket number on the guidance document, if such a docket number exists. For documents that do not have a docket number assigned, the comments should refer to the title of the document. Once comments have been received on a guidance document, the Dockets Management Branch will establish a docket for that document, and all additional comments will be routed to that docket. Comments will be available to the public in accordance with FDA's regulations at § 10.20(j).

Such comments will be available at the Dockets Management Branch, and, when feasible, on the Internet. In its 1997 GGP document, the agency directed all comments on Level 1 documents to the Dockets Management Branch, and comments on all Level 2 documents to the document's originating office. Based on its internal review, the agency has decided that it can better track comments if they are all submitted to the docket, as proposed in § 10.115(h).

E. FDA's Internal Procedures

Consistent with section 701(h)(2) of the act and the 1997 GGP document, proposed § 10.115(i) describes the standard elements that must be included in each guidance document. The agency is proposing that all guidance documents: (1) Include the term ''guidance;'' (2) identify the Center or Office issuing the document; (3) identify the activity and people to which the document applies; (4) include a statement of the document's nonbinding effect; (5) include the date of issuance; note if it is a revision to a previously issued guidance document and identify the document that it replaces; and (6) contain the word ''draft'' if the document is a draft guidance document.

Historically, FDA has issued regulatory guidance to its field staff through documents called Compliance Policy Guides (CPG's), and those documents have come to be recognized by that name. Therefore, the agency will continue to issue CPG's, but each CPG will also include the term ''guidance'' in its subtitle in order to clarify that it does fall within the definition of a guidance document.

Consistent with the 1997 GGP document, the statement of nonbinding effect will generally read as follows: ''This guidance document represents the agency's current thinking on * * *. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.''

Proposed § 10.115(i)(2) also provides that, due to the nonbinding nature of guidance documents, certain mandatory language cannot be included in guidance documents, unless the agency is using these words to describe a statutory or regulatory requirement. Examples of such language includes words like ''shall,'' ''must,'' ''required,'' or ''requirement.''

Consistent with section 701(h)(2) of the act, proposed § 10.115(j) provides that all FDA Centers and Offices must have procedures for the internal clearance of guidance documents that ensure that this responsibility is given to the appropriate senior agency officials. Under the 1997 GGP document, an Office Director in a Center or an Office of Regulatory Affairs equivalent or higher approves a Level 1 guidance before it goes out to the public in draft or final. The Office of Chief Counsel approves a draft or final guidance document that describes new legal interpretations. The Office of Policy approves the release of a draft or final guidance document that describes significant changes in agency policy.

Under the 1997 GGP document, an official at Division Director level or higher approves a Level 2 guidance document before it goes out to the public. Because, by definition, Level 2 documents are less controversial or novel, the clearance of a Level 2 guidance document does not usually involve as many senior agency officials.

FDA's current plan is to keep the minimum sign off procedures described in the 1997 GGP document. The agency is not including them in its proposal because it does not think it is appropriate to describe these internal procedures in a regulation. Moreover, some Centers or Offices have chosen to have their guidance document sign-off take place at a level that is higher than that described in the 1997 GGP document. Nothing in this regulation will affect that practice.

Proposed § 10.115(k) describes procedures for FDA review and revision of existing guidance documents. Under these procedures, the agency will review periodically existing guidance documents to determine whether they need to be changed or withdrawn. 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. In addition, your comments may at any time suggest that FDA revise a guidance document. Those suggestions should address why the guidance document should be revised and how it should be revised.

Proposed § 10.115(l) describes procedures for how the agency plans to ensure consistent application of GGP's. Under these procedures, 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.

In addition, on a regular basis, FDA Centers and Offices will monitor the development, issuance, and use of guidance documents to ensure that employees are following good guidance practices.

The 1997 GGP document provided that the agency would educate the public about the legal effect of guidance and that FDA staff should take the opportunity to state and explain the legal effect of guidance when speaking to the public about guidance

documents. Although the agency believes that the 1997 GGP document, the inclusion of the statement of the nobinding effect on all guidance documents, and the FDA public pronouncements about the legal effect of guidance have made great strides in educating the public about the legal effect of guidance, the agency believes that it is important that these education efforts continue. Therefore, as part of its employee training, FDA will direct its employees to continue educating the public about the nonbinding effect of guidance.

F. Public Access to Guidance Documents

Section 701(h)(1)(A) of the act requires FDA to ensure that information about the existence of guidance documents and guidance documents themselves are made available to you in written form, and, as feasible, through electronic means. Proposed § 10.115(m) and (n) incorporate that requirement.

Proposed § 10.115(m) provides that FDA will make copies available in hard copy and, as feasible, through the Internet. All new recently issued guidance documents have been made available through the Internet, but there are some documents that were issued prior to issuance of the 1997 GGP document that are not available in an electronic version that can be easily included on the Internet.

Proposed § 10.115(n) tells you how you can get a list of all of FDA's guidance documents. Under proposed § 10.115(n), FDA will maintain a current list of all guidance documents on the Internet at www.fda.gov/opacom/morechoices/industry/guidedc.htm. New documents will be added to this list within 30 days of issuance. Although the agency recognizes that the Internet is an a easy and efficient tool for distribution of public information, it will continue to make its guidance document list available through the **Federal Register**. Once a year, FDA will publish a comprehensive list of guidance documents in the **Federal Register**.

In the 1997 GGP document, the agency stated that it would provide quarterly updates to the annual comprehensive **Federal Register** list. However, the agency has been unable to issue timely updates. The agency believes that the annual **Federal Register** list plus the current list on the Internet is more workable for the agency and is consistent with the statutory requirement. However, the agency would like to receive your comments on this proposed change.

FDA's guidance document lists will include: (1) The name of the guidance document, issuance and revision dates; and (2) information on how to obtain copies of the document.

G. Dispute Resolution

Section 701(h)(4) of the act requires the agency to have adequate procedures in place to address complaints regarding the development and use of guidance documents. Proposed § 10.115(o) describes such procedures. If you believe that someone at FDA did not follow the procedures in § 10115(o) 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 at that level, you should contact the next highest supervisor. If the issue still remains unresolved at the level of the Center or Office Director 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.

H. Conforming Changes

The agency is also proposing conforming changes to its regulations at § 10.90(b) that describe the agency's procedures for guidelines. For many years, the agency issued documents articulating regulatory guidance that were referred to as ''guidelines.'' However, since the development of GGP's, the agency has moved to referring to all documents that provide you with guidance as ''guidance documents.'' To make these regulations consistent, the agency is proposing to revise § 10.90(b) to eliminate reference to the term guideline, and instead cross-reference the procedures for development, issuance, and use of guidance documents at § 10.115. In addition, the agency is proposing to make conforming changes throughout parts 10, 14, 19, and 25 (21 CFR parts 14, 19, and 25) to ensure that the term ''guidance document'' replaces the term ''guideline,'' as appropriate.

VI. Comments Received by the Agency

After the passage of FDAMA, the agency was faced with a large burden in the implementation of the new statute. In an effort to make the agency's processes more open and transparent, as well as to solicit your input on how various FDAMA provisions should be implemented, the agency issued a notice in the **Federal Register** establishing special FDAMA dockets (63 FR 40719, July 30, 1998). These dockets, which were assigned to specific provisions of the statute, allowed you to submit comments or proposals to the agency regarding how the provisions should be implemented.

The agency received one such comment on section 405 of FDAMA. The comment raised several suggestions as to how this provision should be implemented. These suggestions and FDA's responses are discussed below.

1. The comment suggested that FDA solicit input before it solidifies its views on an approach for a new guidance.

The agency agrees that it is important to solicit your input at the earliest possible time. That is why it is proposing to create several mechanisms for your early input, including: (1) An opportunity to suggest new or revised guidance, (2) notification that it is considering new or revised guidance, (3) notification that it is issuing certain guidance documents, and (4) the ability to hold meetings or workshops before a draft document is developed. In addition, the reason that FDA solicits comments on a guidance document is because its views are not solidified, and the agency seeks your input regarding decisions about what final guidance documents will contain.

2. The comment noted that the legislative history accompanying section 405 of FDAMA stated that Congress ''intends that FDA will waive [the] requirement for prior public participation only in rare and extraordinary circumstances where there is a compelling rationale.'' The comment reads this standard to mean situations involving a public health emergency.

The agency does not interpret this exception so narrowly. In the 1997 GGP document, the agency provided limited exceptions to the prior public participation requirement, including situations where: (1) There are public health reasons for 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. The agency continues to believe that these exceptions are both consistent with the intent of Congress in FDAMA and necessary for the timely issuance of important guidance documents.

3. The comment suggested that the agency accept input on whether a planned guidance document involves a significant or minor change in policy, *i.e.,* whether it is a Level 1 or Level 2 guidance document. Again, the agency welcomes your input on all of its guidance documents, including

comment regarding whether the documents have been appropriately classified as Level 1 or Level 2.

FDA will review comments received about designation as a Level 1 or Level 2 document, but in the interest of issuing guidance in a timely manner, the agency does not believe that it is necessarily beneficial to systematically receive comment on all of these designations prior to issuance of guidance documents.

4. The comment noted that section 405 of FDAMA provided that FDA employees should not deviate from guidance documents without appropriate justification and supervisory concurrence. Therefore, the comment requests that FDA provide a requester with written notice when it determines to deviate from a guidance document, and state the given reasons for such deviation.

While the agency completely agrees that FDA employees should not deviate from guidance without appropriate justification and supervisory concurrence, it disagrees that it should provide the requester with written notice stating the reasons for such deviations. However, the agency will, upon request, explain why it is deviating from the guidance at the time that it makes its decision to do so.

Moreover, if a requester disagrees with how a guidance document has been applied, or not applied, FDA has an appeals process set up for requesters to raise concerns.

5. The comment noted the importance of training FDA staff on how to develop and use guidance documents in a manner consistent with section 405 of the statute, and recommends that the agency should collaborate with industry and other stakeholders on training, where appropriate.

The agency agrees with this comment, and has numerous mechanisms in place to train FDA employees effectively about the appropriate development and use of guidance documents. In addition, the agency recognizes the importance of collaboration with its stakeholders. While the agency welcomes your suggestions about how its training could be most effective, the agency believes that FDA should conduct its own training of FDA staff.

6. The comment suggested that FDA should work to ensure consistency in the application of guidance documents across the Centers.

The agency agrees and will work to ensure consistent application of guidance documents by receiving comment from around the agency regarding certain cross-cutting guidance documents, and ensuring appropriate clearance by various Centers or Offices, if they are affected by the guidance document. The focus of GGP's is to achieve this goal, and the agency believes that the proposed regulations seek to address concerns about consistent application of guidance across the agency.

7. The comment noted that the statute requires that FDA ensure that an effective appeals mechanism be in place to address complaints about the development or use of guidance documents. The comment suggested that the agency be committed to resolve these disputes as quickly and amicably as possible through the cooperative exchange of views, in accordance with current dispute resolution policies. In addition, the comment requested that when multiple requesters raise complaints in a particular area, it should trigger a special inquiry by senior agency policy staff, and renewed training, if appropriate.

The agency agrees with this comment. FDA will seek to resolve disputes quickly and efficiently. When multiple problems arise, FDA will engage senior policy officials in the dispute, and will retrain staff, when appropriate.

8. The comment noted the importance of FDA's periodic review of existing guidance documents, with revisions made to those documents, as necessary. It suggested that FDA set up a system for periodic review that fosters individual accountability for updating guidance documents. The comment suggested that such a process might include soliciting public input as quickly as possible, accepting proposals from the public on guidance documents, and responding in writing to all such proposals within 60 days.

The agency agrees that it should conduct periodic reviews of guidance documents, but reserves the discretion to set up an informal system for this review process. Because of resource constraints and in the interest of issuing all guidance documents in a timely manner, the agency declines to require itself to respond in writing to suggested guidance proposals within a given timeframe. However, the agency is committed to ensuring that guidance documents are updated and revised as frequently as necessary, and to reviewing public input regarding those potential revisions. The agency is also committed to reviewing all of your proposals submitted for future regulatory guidance, but declines to set up a system whereby all written proposals are responded to in writing.

9. Lastly, the comment stated that section 405 of FDAMA makes clear that FDA should not develop or modify policies and procedures through informal mechanisms such as speeches or statements at meetings that it has not previously dealt with through regulation or prior guidances.

The agency agrees with this comment. The fundamental premise behind GGP's is increased consistency in the development, issuance, and use of guidance documents; ensuring consistency of procedures is the goal of the proposed regulations. The agency is committed to ensuring that these principles are upheld, and urges you to notify FDA if you become aware of FDA employees first communicating agency policy through informal mechanisms such as speeches or statements at meetings.

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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 would be required.

VIII. Analysis of Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under 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). Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This proposed rule does not impose any mandates on State, local, or tribal governments, nor is it a significant

regulatory action under the Unfunded Mandates Reform Act. Furthermore, the agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

IX. Paperwork Reduction Act of 1995

FDA concludes that this proposed regulation would impose no reporting or recordkeeping requirements. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Comments

Interested persons may, on or before May 1, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 10

Administrative practices and procedures, News media, Good Guidance Practices.

21 CFR Part 14

Administrative practices and procedures, 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.

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, it is proposed that 21 CFR parts 10, 14, 19, and 25 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. 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, 10.45, and 10.85 [Amended]

2. In 21 CFR part 10, remove the words ''guideline'' and ''guidelines'' wherever they appear and add in their place the words ''guidance document'' and ''guidance documents'', respectively, in the following places:

a. Section 10.20(j)(1)(v),

b. Section 10.45(d), and

c. Section 10.85(d)(5).

3. In § 10.90, remove the words ''guideline'' and ''guidelines'' wherever they appear and add in their place the words ''guidance document'' and ''guidance documents'', respectively, and revise the section heading and paragraph (b) to read as follows:

§ 10.90 Food and Drug Administration regulations, guidance documents, recommendations, and agreements.

* * * * *

(b) *Guidance documents.* FDA guidance documents, as that term is defined in § 10.115, will be developed, issued, and used according to the requirements at § 10.115.

* * * * *

4. 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) set forth FDA's policies and procedures for developing, issuing, and using guidance documents.

(b) How is the term ''guidance document'' defined?

(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, manufacturing, and testing of regulated products; the processing, content, and evaluation/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 and 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 may provide input on guidance documents that FDA is developing under the procedures described in paragraph (g) of this section.

(2) You may suggest areas for guidance document development. Your suggestions should address why a guidance document is necessary. You may also submit drafts of guidance documents to FDA to consider.

(3) You may, at any time, suggest that FDA revise an already existing guidance

document. Your suggestion should address why the guidance document should be revised and how it should be revised.

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

(5) To participate in the development and issuance of guidance documents through one of the mechanisms described in paragraph (f)(1), (f)(2), or (f)(3) of this section, you should contact the Center or Office that is responsible for the regulatory activity covered by the guidance document.

(6) If FDA agrees to draft or revise a guidance document, under a suggestion made under paragraph (f)(1), (f)(2), or (f)(3) of this section, you may 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 may seek or accept early input from individuals or groups outside the agency. For example, FDA may 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 may:

(A) Hold additional 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, you should 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) Implement the guidance document when it is made available; 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) Implement the guidance document when it is made available, unless FDA indicates otherwise; 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 may 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) Include 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

(vi) 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.

(j) Who, within FDA, can approve issuance of guidance documents? Each Center and Office must have in place appropriate 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 a current list of all guidance documents on the Internet. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish its comprehensive list of guidance documents in the **Federal Register**. 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. If you are unable to resolve the issue at the level of the Center/Office Director 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

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

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

§§ 14.27 and 14.33 [Amended]

6. In 21 CFR part 14, remove the word ''guidelines'' and add in its place the word ''guidance documents'' in the following places:

a. Section 14.27(b)(3) and

b. Section 14.33(c).

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

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

Authority: 21 U.S.C. 371.

§ 19.10 [Amended]

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

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

9. 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]

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

Dated: February 8, 2000.

Margaret Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–3344 Filed 2–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 990

[Docket No. FR–4425–N–09]

Negotiated Rulemaking Committee on Operating Fund Allocation; Meeting

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Negotiated Rulemaking Committee meetings.

SUMMARY: This document announces a meeting of the Negotiated Rulemaking Committee on Operating Fund Allocation. These meetings are sponsored by HUD for the purpose of discussing and negotiating a proposed rule that would change the current method of determining the payment of operating subsidies to public housing agencies (PHAs).

DATES: The committee meeting will be held on February 16 and February 17, 2000. On February 16, 2000, the meeting will begin at approximately 9:30 am and end at approximately 5:30 pm. On February 17, 2000, the meeting will begin at approximately 9:00 am and end at approximately 4:00 pm.

ADDRESSES: The committee meeting will take place at the Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza East, SW, Washington, DC 20024; telephone 1–800–635–5065 or (202) 484–1000; FAX (202) 863–4497 (With the exception of the ''800'' telephone number, these are not toll-free numbers).

FOR FURTHER INFORMATION CONTACT: Steve Sprague, Acting Director, Funding and Financial Management Division, Office of Public and Indian Housing, Room 4216, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–0500; telephone (202) 708–1872 (this telephone number is not toll-free). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of HUD has established the Negotiated Rulemaking Committee on Operating Fund Allocation to negotiate and develop a proposed that would change the current method of determining the payment of operating subsidies to public housing agencies (PHAs). The establishment of the committee is required by the Quality Housing and Work Responsibility Act of 1998 (Pub. L. 105–276, approved October 21, 1998) (the ''Public Housing Reform Act''). The Public Housing Reform Act makes extensive changes to HUD's public and assisted housing programs. These changes include the establishment of an Operating Fund for the purpose of making assistance available to PHAs for the operation and management of public housing. The Public Housing Reform Act requires that the assistance to be made available from the new Operating Fund be determined using a formula developed through negotiated rulemaking procedures.

II. Negotiated Rulemaking Committee Meeting

This document announces a meeting of the Negotiated Rulemaking Committee on Operating Fund Allocation. The next committee meeting will take place as described in the **DATES** and **ADDRESSES** section of this document.

The agenda planned for the committee meeting includes the development and review of draft regulatory and preamble language; and the scheduling of future meetings, if necessary.

The meeting will be open to the public without advance registration. Public attendance may be limited to the