MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the February 10, 1997, Board member meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Briefings by National Finance Center and Board staff on:
   a. National Finance Center;
   b. Thrift Savings Plan system replacement effort;
   c. Thrift Savings Plan improvements;
   d. Capability maturity model;
   e. Software methodology;
   f. Project tracking and controls;
   g. Service Office enhancements;
   h. Local area network; and
   i. Thrift Savings Plan costs.

CONTACT PERSON FOR MORE INFORMATION: Tom Trabucco, Director, Office of External Affairs (202) 942–1640.

Dated: February 24, 1997.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95P–0110]

The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a document entitled ''Good Guidance Practices'' (GGP's), which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents. Issues relating to FDA's development and issuance of guidance documents were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC) (see Docket No. 95P–0110). In an effort to improve its guidance document procedures, FDA has adopted the GGP's described and included in this notice.

DATES: Although the agency already has begun to follow the procedures set forth in the GGP's, the GGP's will not be fully implemented until FDA's proposal to amend its regulations in part 10 (21 CFR part 10) to clarify that advisory opinions and guidelines do not bind the agency (57 FR 47314, October 15, 1992) is finalized and in effect.

FOR FURTHER INFORMATION CONTACT: Margaret M. Dotzel, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION: The IMDMC petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that assure the appropriate level of meaningful public participation. In response to the petition, FDA agreed to take steps to improve the agency's guidance document procedures. In the Federal Register of March 7, 1996 (61 FR 9181), FDA published a notice, which set forth its proposal on how best to improve its guidance document procedures and solicited comment on these and additional ideas for improvement (the March 7 Notice). On April 26, 1996, the agency held a public meeting to further discuss these issues (the April 26 public meeting). The comment period for the March 7 Notice closed on June 5, 1996. This notice: (1) Sets forth the agency's position on how it will proceed in the future with respect to guidance document development, issuance, and use; and (2) includes the agency's GGP's, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents.

I. Definition of Guidance

In the March 7 Notice, FDA provided the following definition for guidance documents:

> [T]he term ''guidance documents'' means: (1) Documents prepared for FDA review staff and applicants/sponsors relating to the processing, content, and evaluation/approval of applications and relating to the design, production, manufacturing, and testing of regulated products; and (2) documents prepared for FDA personnel and/or the public that establish policies intended to achieve consistency in the agency's regulatory approach and establish inspection and enforcement procedures. Guidance documents do not include agency reports, general information provided to consumers, documents relating to solely internal FDA procedures, speeches, journal articles and editorials, media interviews, warning letters, or other communications or actions taken by individuals at FDA or directed to individual persons or firms.

A number of the comments submitted in response to the March 7 Notice suggested alternative definitions for ''guidance document.'' One comment suggested that the term include all internal documents intended to direct activities of FDA staff. Another suggested that a guidance document be defined as any document or other communication that in effect announces a regulatory expectation to a broad audience. And yet another suggested that a guidance document be defined as any statement that may substantively impact a regulatory evaluation or determination.

Documents relating to internal procedures, warning letters, information directed at individuals or individual firms, and speeches, journal articles, editorials, media interviews, press materials, agency reports, and general information documents provided to consumers are not guidance documents. FDA disagrees with suggestions for a definition of guidance documents that would effectively broaden the scope of the term ''guidance document'' to include such documents. Definitions such as ''any document that announces a regulatory expectation,'' ''any statement that may substantively impact a regulatory evaluation or determination,'' or ''any agency-issued writing that establishes methods of compliance'' would include some or all of these excluded documents. A definition such as ''all internal documents that direct activities of FDA staff'' would include all documents relating to internal FDA procedures, even if they have no bearing on the regulated industry. Accordingly, FDA is rejecting these suggestions.

In the GGP document, attached to this notice, the agency is using the same basic definition as set forth in the March 7 Notice, with minor revisions to clarify what is and is not in the universe of guidance documents. It provides:

> The term ''guidance documents'' includes documents prepared for FDA staff, applicants/sponsors, and the public that (1) relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. ''Guidance documents'' do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

Despite the agency's reluctance to broaden the definition of guidance, the agency is sensitive to the concern expressed during the April 26 public meeting and in the comments that too narrow a definition might permit agency employees to use documents or communications such as speeches, editorials, or journal articles to announce regulatory expectations without following the GGP's discussed herein. Although FDA employees should be able to respond to questions about how an established policy applies

to a specific situation or to questions about areas that lack established policy, the agency should not use these other means of communication to release guidance. The GGP's explicitly state that when the agency is first communicating new or different regulatory expectations not readily apparent from the applicable statute or regulations to a broad public audience, the GGP's and officially-designated guidance document procedures should be followed. As part of the agency's effort to monitor the use of guidance documents (see section III. of this document), the agency will spot check its staff to ensure that ''unofficial'' guidance documents or other means (such as speeches) are not being used to first transmit to a broad public audience new or different regulatory expectations that are not readily apparent from the applicable statute or regulations.

II. Nomenclature

In the March 7 Notice, FDA suggested that a standardized nomenclature for guidance might help the public better understand the nature and legal effect of guidance documents and might help to eliminate any confusion regarding which documents are guidance. Both the discussion at the April 26 public meeting and comments submitted to the docket indicated overwhelming support for a standardized nomenclature for guidance documents. Nevertheless, some comments cautioned the agency not to elevate form over substance. Moreover, there was no real consensus on what the standardized nomenclature should be.

Some comments suggested that the nomenclature be based on the intended use of the guidance, (e.g., compliance guidance versus 510(k) review guidance); others suggested that it be based on the intended user (e.g., guidance for industry versus guidance for reviewers). A number of comments suggested that FDA differentiate guidance documents on the basis of their type or function (e.g., educational, interpretive, and descriptive or premarket review, compliance/enforcement, and educational). Some comments even suggested that the distinction be drawn on the basis of what procedure is used to develop the guidance.

Specific suggestions included calling all guidance either ''guidance documents'' or ''compliance policy guides'' or calling all guidance either ''guidelines'' or ''recommendations.'' A number of comments suggested using an umbrella term (such as guidance or guideline) together with additional identifying information, such as the Center producing the document, the intended users, and the industrial, regulatory, or professional activities to which the document applies.

After considering these comments and the universe of guidance documents, the agency has decided that all guidance documents should include the following: (1) The umbrella term ''guidance;'' (2) information that identifies the Center or Office producing the document; and (3) the regulatory activity to which the document applies and/or the intended users of the document. The agency anticipates that, in practice, the majority of guidance documents will be called ''compliance guidance,'' ''guidance for industry,'' or ''guidance for FDA reviewers/staff.'' The agency believes that this approach incorporates a number of the suggestions made during the April 26 public meeting and in the comments and ensures that guidance document nomenclature is uniform and informative (i.e., by identifying the producing Center or Office and the regulatory activity to which and/or the persons to whom the document applies).

One comment suggested that, as an additional means of ensuring uniformity and clarity, FDA should use a consistent format with headed paper for all guidance documents. Given the diversity of guidance documents and the subjects that they address, the agency believes that it would be difficult to use a consistent format. The agency believes, however, that the benefit that might be achieved from a consistent format could be achieved, more easily, by using a standardized cover sheet for all guidance. Therefore, the GGP's include a standardized cover sheet that should be used as a model for all future guidance documents.

Existing Guidance. In response to the agency's request for comment on what to do with existing guidance documents if a standardized nomenclature is adopted, most comments suggested that FDA update the nomenclature as documents are revised. In the meantime, it was suggested that the agency create an interim method of cross-referencing the older documents with the new nomenclature. One comment suggested that the agency agree to undertake the review and revision of all existing guidance within some specified period of time. Specifically, the comment suggested a ''managed review'' approach pursuant to which the agency would set progressive goals, with a defined percentage of the documents to be reviewed for nomenclature changes within a specified period of time (e.g., 25 percent per year for 4 years).

FDA agrees with the majority of comments, which suggested that the best approach would be to update the nomenclature of existing guidance documents as they are revised. In the meantime, when the agency publishes its comprehensive list of guidance (see section V. of this document), it will list guidance documents under the issuing Center or Office and, where possible, will separate guidance documents by their intended users and/or the regulatory activities to which they apply.

The agency will not undertake a ''managed review'' of all existing guidance documents pursuant to which the agency would review a defined percentage of documents for nomenclature changes within a specified period of time. While the agency agrees that guidance documents should be reviewed and updated as appropriate, the agency does not agree that the expenditure of resources for what may be mere name changes is warranted, particularly when those resources could be applied more productively to the development of new guidance documents. Over the past year, the Centers and Offices have been taking stock of their guidance documents and have been identifying obsolete guidance documents as well as those needing updates or revisions. Moreover, as set forth in section IV. of this document, the agency is providing the public an opportunity to identify guidance documents that need to be reviewed/updated. Thus, the agency believes that it is taking steps to ensure that any necessary updates and revisions to guidance documents will be made.

III. Effect of Guidance Documents

The March 7 Notice described the legal effect of guidance documents. Specifically, it stated that a guidance document is not binding on the agency or the public; rather, it represents the agency's current thinking on a certain subject. Most of the participants at the April 26 public meeting and the comments to the March 7 Notice agreed that guidance documents should not be binding. There was significant support for including a statement of the nonbinding effect of guidance on each guidance document and for education (particularly of FDA employees) regarding the legal effect of guidance. A number of comments suggested that the agency monitor FDA employees to ensure that they are not applying guidance as binding.

Nonbinding effect of guidance. Although most comments agreed with the agency's position that guidance should not be binding on the public, a

number did argue that FDA should be required to follow its own guidance (i.e., should not be able to require more than is stated in guidance documents). One comment argued that FDA's position about the nonbinding nature of guidance is inconsistent with its own part 10 regulations.

The only binding requirements are those set forth in the statute and FDA's regulations. Under the Administrative Procedure Act (§ l0.40(d)), in order to bind the public, FDA must (with limited exceptions) follow the notice and comment rulemaking process. Moreover, the principle that guidance documents are binding on FDA is inconsistent with *Community Nutrition Institute* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987), which calls into question FDA's procedures for issuing advisory opinions and guidelines that purport to bind the agency and thereby constrain the agency's discretion. In fact, consistent with the D.C. Circuit's decision in *CNI*, FDA proposed to revise its part 10 regulations to clarify that advisory opinions and guidelines do not bind the agency (57 FR 47314). The agency expects to publish that final rule shortly.[1] The GGP's will not be fully implemented until that final rule is in effect.

Although guidance documents cannot legally bind FDA or the public, the agency recognizes the value of guidance documents in providing consistency and predictability. A company wants assurance that if it chooses to follow a guidance document, FDA generally will find it to be in compliance with the statute and regulations. Moreover, FDA issues guidance to its staff so that they will apply the statute and regulations in a consistent manner. With these principles in mind, FDA's decisionmakers will take steps to ensure that their staff do not deviate from guidance documents without appropriate justification and without first obtaining concurrence from a supervisor. This practice will provide assurance to companies that choose to follow a guidance, yet will not legally bind the agency or its decisionmakers to a guidance document.

The statement of nonbinding effect. In the March 7, 1996 Federal Register Notice, FDA proposed to include language such as the following in each guidance document:

> Although this guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public it does represent the agency's current thinking on * * *.

A number of comments suggested changes to the proposed statement. Some of the recommended changes reflect the comments' position that guidance is binding. Others apparently seek to clarify that approaches other than those set forth in the guidance are permitted if the applicable statutory or regulatory requirements are met. Finally, a number of the comments opined that the statement alone would not ensure the public a real opportunity to rely on alternate methods to comply with the statute and regulations.

As set forth above, FDA disagrees with the concept that guidance documents are binding. In response to the comments regarding flexibility in complying the statute and regulations, FDA is changing the statement to read:

> 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, regulations, or both.

In addition, as part of GGP's, the agency is providing an opportunity for discussion regarding alternate methods of complying with the applicable statute and regulations.

Absence of Mandatory Language. Because guidance documents are not binding, the GGP's provide that mandatory words such as ''shall,'' ''must,'' ''require'' and ''requirement'' should not be used unless they are being used to describe or discuss a statutory or regulatory requirement. The GGP's further provide that, prior to issuance, all new guidance documents should be reviewed to ensure that mandatory language has not been used.

Education. In the March 7 Notice, FDA recognized the importance of educating both agency employees and the public regarding the nonbinding nature of guidance. Comments to the March 7 Notice agreed that education is an important step in assuring that guidance is not applied as a binding requirement. The comments suggested that FDA's GGP's include a section that describes the legal effect of guidance.

As part of its GGP's, FDA will provide all current and new FDA employees involved in the development, issuance, or application of guidance documents a copy of the GGP's, which include a section that describes the legal effect of guidance. FDA will direct these employees to review the GGP's and will provide additional training that describes, in more detail, how to develop and use guidance documents.

For purposes of educating the public, the comments suggested education through mailings and public service announcements in trade journals and newsletters. FDA agrees that it is important to take advantage of opportunities to educate the public about the legal effect of guidance. The GGP's and the statement of the nonbinding effect of guidance that will be included in all future guidance documents and on the list of guidance documents (see section V. of this document) should help to educate the public about the legal effect of guidance. In addition, as part of the GGP's, FDA is encouraging its employees to state and explain the effect of guidance when speaking in public about guidance documents. The agency believes that public education efforts will be most effective if targeted to specific discussions of guidance documents.

Monitoring. A number of the participants at the April 26 public meeting and a number of the comments to the March 7 Notice suggested that FDA monitor and evaluate the agency's performance in not applying guidance as binding. The agency agrees that it is important to monitor the agency's use of guidance. Therefore, as a part of GGP's, the Centers and Offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed. In addition, they will spot-check the use of guidance documents to ensure that they are not being applied as binding requirements and the use of documents and communications that are not defined as guidance, such as warning letters and speeches, to ensure that they are not being used to initially express new regulatory expectations to a broad public audience.

Three years after the GGP's have been implemented, the agency will convene a working group to review whether they have improved the agency's development and use of guidance documents. The working group will determine whether the GGP's are ensuring: (1) Appropriate public participation in the development of guidance, (2) that guidance documents are readily available to the public, and (3) that guidance documents are not being applied as binding requirements. The working group will review the results of the Center and Office monitoring efforts as well as the number and results of appeals relating to guidance documents.

IV. Development/Public Input

In the March 7 Notice, FDA committed to implementing an agency-wide practice of soliciting or accepting

[1] One comment asked FDA to retain § 10.45(d) (21 CFR 10.45(d)) and establish that the agency regards guidance documents as final agency action. FDA believes that this issue is more appropriately addressed in the final rule pertaining to the revisions to the part 10 regulations.

public input in connection with the development of guidance documents. FDA sought comment on a proposed three-tiered system, which encompassed a different approach to public comment for each of the three tiers. For the proposed Tier 1 documents, FDA would notify the public of its intent to issue a guidance and solicit comment before issuing that guidance. In addition, where appropriate (e.g., when complex scientific issues are raised), FDA might also hold a public meeting or workshop to discuss the guidance or could involve advisory committees in the development process. For the proposed Tier 2 documents, FDA would notify the public after it issues the guidance and solicit comment at that time. For the proposed Tier 3 documents, FDA would regularly notify the public of new guidance that recently has been issued and would not specifically solicit comment, but would accept comment.

FDA suggested that whether a guidance would be in Tier 1, 2, or 3 would depend on a number of factors. For example, Tier 1 guidance might be guidance that represents a significant change, is novel or controversial, or raises complex issues about which FDA would like to have significant public input; Tier 2 guidance might be guidance that merely states FDA's current practices or does not represent a significant or controversial change; Tier 3 guidance might be guidance directed largely to FDA's own staff and that has a limited effect on the public.

In the March 7 Notice, the agency opined that an approach such as the three-tiered one would allow it to make public input genuinely meaningful. The agency did not (and does not) want to make a commitment to extensive public participation in the development of large numbers of guidance documents and then find itself unable to issue needed guidance promptly.

Most of the speakers at the April 26 public meeting and many of the comments to the March 7 Notice did not support the agency's proposed three-tiered approach. The major criticisms were that it is too complicated, would not provide sufficient public participation, and would not sufficiently focus on public participation before a decision to issue guidance is made and before a proposed guidance is drafted. Some comments suggested changes to the tiers; others suggested completely different approaches.

Specific Criticism of the Proposed Three-Tiered Approach. A number of the comments on the March 7 Notice opined that FDA's proposed three-tiered approach would be too complex. Many thought that the proposed approach would make the classification itself a separate burden on the agency. Moreover, some thought that the agency's determination of ''significance'' would be problematic. For example, what might appear insignificant to the agency could be significant to the public.

Many of the comments stated that the three-tiered approach would not provide adequate public participation—particularly with respect to Tier 3. In addition, a number of comments criticized FDA's approach for focusing too much on revision of guidance that has already been drafted. These comments noted the importance of allowing participation at the earliest stages of the development process.

One comment opined that because guidance documents are used to explain interpretations of existing requirements, there is no need for an opportunity to comment. Rather, users should be encouraged to provide informal feedback at any time. If all of the public's comments are negative, FDA should consider rewriting the guidance.

Finally, one comment noted that FDA should not use the term ''tier'' because it will lead to confusion with the current ''tier'' system for device section 510(k) submissions.

Suggested Alternatives to the Three-Tiered Approach. Many of the comments agreed with a tiered approach, but suggested different ways of deciding which documents fall into each tier. A number suggested distinguishing between ''educational documents,'' ''interpretive documents,'' and ''descriptive documents.'' Some suggested distinguishing between ''significant public interest documents,'' ''general public interest documents,'' and ''FDA interest only documents.'' Others suggested looking at whether the documents: (1) Represent a significant change in policy, a complex issue, or are new and have wide applicability; (2) involve no significant or controversial changes; or (3) affect only FDA staff and have no effect on the public. A number of comments thought it important for FDA to look at the impact the guidance document has on the industry.

A comparable number of comments disagreed with a tiered approach. For example, one comment suggested that any agency statement having the potential for compliance or enforcement consequences must be subject to notice and comment rulemaking. Product specific guidance (e.g., bioequivalence protocols or biopharmaceutical guidance) alone could be excepted, provided the guidance is binding on FDA and industry unless a clearly demonstrated public health safety issue arises.

Some comments suggested that all guidance be available for comment before issuance through publication in the Federal Register (although an abbreviated procedure could be employed). Under this approach, a reasonable amount of time, at least 60 days, would be allowed for submission of comments.

One comment suggested that advanced public comment always be required except when it would not be in the public interest to wait for advanced public comment. The latter guidance documents would undergo comment after issuance.

Several comments recommended that the agency try processes other than soliciting comment from the public after a guidance document has been drafted. For example, some suggested that the agency employ a negotiated guidance development process, patterned after negotiated rulemaking. Another comment recommended creation of an internal task force to evaluate the agency's management procedures for ensuring consistency in the application of statutes and regulations, identifying interpretations of how to apply the statutes and regulations, and determining when the interpretations should be formed into guidance documents. Another recommended creation of a joint agency-industry committee to coordinate the development, promulgation, issuance, and overall management of guidance documents.

At least one comment suggested that FDA experiment with different models to determine how best to solicit public input in the long run.

In response to the agency's request for comment on how to treat the comments that are submitted for guidance documents, some suggested that all comments be available for public review; others said that it is inappropriate for the general public to have access to comments by named individuals regarding certain issues. Several comments indicated that comments need not be in the public docket. Rather, it would be sufficient to have them sent to the Center or Office issuing the guidance. Most of the comments agreed that it was important that the agency commit that all comments received will be considered, and not just filed.

FDA's Approach. FDA disagrees with many of the suggested alternatives because they fail to recognize that the agency does not have unlimited resources to dedicate to the development of guidance documents.

As set forth in the March 7 Notice, if FDA commits to a development process that is akin to rulemaking, it will not be able to issue many guidance documents. Moreover, what guidance documents could be issued, could not be issued promptly.

FDA disagrees with other suggested alternatives because they appear to be even more complex than FDA's proposed three-tiered approach. For example, under one approach FDA would have to determine whether a document is ''educational,'' ''interpretive,'' or ''descriptive'' before deciding what type of public participation should go into the development process. There is overlap between these different types of guidance documents and would likely be disagreement over the appropriate categorization of a guidance document. Under another suggested approach, FDA would have to look at whether a guidance is of ''significant public interest,'' ''general public interest,'' or ''FDA only interest.'' The latter would require very subjective determinations. Moreover, it is doubtful that many guidance documents would fall outside of the category of ''significant public interest.''

Nevertheless, FDA agrees with some of the criticisms to its proposed three-tiered approach and believes that many of the comments were constructive. As set forth below, FDA is revising its proposed approach to public input to: (1) Simplify it; (2) increase public participation; and (3) ensure that public participation will be at the earliest stages of the process. Moreover, FDA will not use the term ''tier'' in differentiating the degree of public participation.

As part of its GGP's, FDA will adopt a two-level approach. Level 1 documents generally will include guidances 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, and highly controversial issues. Level 2 guidance documents will include all other guidances.

For Level 1 guidance, the agency will solicit public input prior to implementation, unless: (1) There are public health reasons for immediate implementation; (2) there is a new statutory requirement, executive order, or court order that requires immediate implementation and guidance is needed to help effect such implementation; or (3) the guidance is presenting a less burdensome policy that is consistent with the public health. In the latter situations, the agency will solicit public input upon issuance/implementation. When the agency determines that even greater public participation is warranted, for example when there are highly controversial or unusually complex new scientific issues, the agency may hold a public workshop to discuss a draft guidance document. In these situations, the agency may also present a draft of the guidance document to an advisory panel.

In an effort to help ensure that public participation will occur at the earliest stages of the guidance development process, the agency is implementing policies pursuant to which the public will have an opportunity to suggest areas for guidance development or revision and to suggest drafts of guidance documents for adoption by the agency. (See ''Proposing New Guidance,'' below.) Through these processes, the agency often will solicit input prior to its decision to issue a guidance and/or prior to the development of a draft.

In addition, FDA may solicit or accept early input on the need for new or revised guidance or assistance on the development of particular guidance documents from individual nongovernmental groups such as consumer groups, trade associations, patient groups, and public interest groups. The agency may participate in meetings with these various parties to obtain each party's views on priorities for developing guidance documents. The agency may also hold meetings and workshops to obtain input from each interested party on the development or revision of guidance documents in a particular FDA subject area.

Comments submitted for Level 1 documents will be submitted to the public docket and will be available to the public for review. The agency will review all comments, but in issuing a final guidance, need not specifically address every comment. The agency will make changes to a guidance document in response to comments as appropriate.

For Level 2 guidance, the agency will provide an opportunity for public comment upon issuance. Unless otherwise indicated, the guidance will be implemented upon issuance. The agency will make changes to Level 2 guidance if comments indicate that such changes are appropriate. Comments submitted for Level 2 guidance documents will be sent directly to the issuing Center or Office. Each guidance will identify the Center or Office to which such comments should be sent. The Center or Office will review all comments and will make changes to the guidance in response to such comments, as appropriate.

For all guidance documents—Levels 1 and 2—comments will be accepted at any time. Guidance will be revised in response to comments, as appropriate. These comments will be submitted to the issuing Center or Office identified in the guidance document.

Public Notification of Proposed/New Guidance Documents. In the March 7 Notice, the agency solicited comment regarding what approach would best ensure that the public is kept apprised of new guidance document developments. Comments responding to the question regarding how best to notify the public and solicit input on proposed or new guidance suggested a variety of vehicles including the Federal Register, the world wide web (WWW), the trade press, trade associations/organizations, public workshops, and grassroots meetings.

In an effort to ensure that notice is provided both electronically and by hard copy, the agency will be providing notice both in the Federal Register and on the FDA WWW home page. FDA has established a home page on the WWW at ''http://www.fda.gov''. Each of the Centers and the Office of Regulatory Affairs also have established home pages, which are linked to the FDA home page. These Center and Office home pages can be accessed directly or by going through the FDA home page. Guidance document notices and/or drafts will be posted on the FDA home page or will be accessible from there.

The availability of all new guidance documents, both Levels 1 and 2, will be posted on the appropriate FDA WWW home page as each guidance is issued. Notices of availability of Level 1 guidance documents will appear in the Federal Register when each new guidance is issued. If several new Level 1 guidance documents are being issued at the same time, a single Federal Register notice may be issued for all of those new documents. The agency will issue Federal Register notices of all new Level 2 guidance documents on a quarterly basis.

Proposing New Guidance. A number of comments on the March 7 Notice suggested that it is more important for the agency to ensure adequate public participation in the process that leads to the development of a guidance document than in the process following the agency's development of a draft guidance. These comments urged the agency to provide a mechanism for the public to recommend subjects for new guidance or drafts of proposed new

guidance documents. One comment suggested utilizing a ''Guidance Proposal Policy'' pursuant to which FDA employees or the public would propose topics for guidance and the proposals would be reviewed and approved/not approved by FDA management. Another comment suggested that a central location, such as a guidance document calendar, be designated for industry to propose new guidance development and to learn of new development activities. One comment suggested that the Centers and Offices solicit comments about the need for guidance through a Federal Register notice. Finally, one suggested that possible topics for development of guidance be published in the agency's annual regulatory agenda.

The agency agrees that it is important to provide for the public's involvement in the process that leads to the development of a draft guidance document. As part of its GGP's, therefore, the agency is instituting procedures for involving the public in decisions to develop or revise guidance documents and prioritize the development and revision of guidance documents. The agency will accomplish this in two ways. First, as a part of its GGP's, the agency will, on a semiannual basis, publish (in the Federal Register and on the FDA WWW home page), possible topics for guidance document development during the next year. At that time, FDA will solicit input from the public regarding these and additional ideas for new guidance documents or guidance document revisions or priorities. The purpose of publishing this ''guidance document agenda'' is to encourage the public to participate in the process that leads to the development of guidance documents. The agency will not be bound by the list of possible topics—i.e., it will not be required to issue every guidance document on the list and it will not be precluded from issuing guidance documents that are not included on the list.

The second way that the agency will involve the public in decisions to develop, revise, or prioritize guidance documents will be to include, as part of its GGP's, a ''Guidance Proposal Policy.'' The ''Guidance Proposal Policy'' will provide the public an opportunity to propose topics for new or revised guidance or to propose draft guidance documents. The guidance proposal policy not only provides the public a meaningful opportunity to participate in the prioritization and development of guidance documents, it also allows the agency to take advantage of outside expertise and resources.

Review and Revision of Guidance Documents. A number of comments to the March 7 Notice suggested that the agency establish periodic review of guidance documents at predetermined intervals and create mechanisms for the public and agency personnel to suggest earlier review. Several comments suggested that a policy should be adopted whereby if a guidance document cannot be reviewed and revised within a reasonable time (e.g., 3 years), it should be deemed obsolete. At least one comment objected to the sunset concept.

FDA agrees that it would be valuable to periodically review and, where appropriate, revise all guidance documents. As a practical matter, guidance documents are regularly used by FDA and thereby undergo an informal review process. The agency's current workload will not permit it to commit to formal strict review/revision deadlines without diverting resources from other tasks. The agency does not think it is in the public's best interest for guidance documents that have not been reviewed or revised within some certain period of time to be deemed obsolete. The result would be to eliminate many current, valuable guidance documents. The agency believes that the guidance proposal policy will help to keep the agency apprised of potentially outdated guidance documents. Thus, as part of its GGP's, the agency is recommending review of existing guidance regularly and when appropriate (e.g., when there are significant changes in the statute or regulations), but it is not adopting a policy whereby certain guidance documents automatically are deemed obsolete with the mere passage of time.

Other Quality Control Measures. A number of the comments suggested additional quality control measures to help improve the quality of guidance. For example, one suggested that the agency adopt a uniform sign-off policy whereby each guidance document has concurrence at least at the level of an Office director. Others suggested that FDA employ other standard elements such as clearly marking superseded and superseding documents, identifying the underlying statutory and regulatory requirements, including a glossary of terminology, cross-referencing other relevant agency publications, and incorporating the following information: Relevant dates (issuance, effective, implementation, review, withdrawal, expiration), status (under development, draft, final), tier, revision history, superseded/superseding documents, available appeals mechanisms, draft number, and a summary/description of the document.

FDA agrees that many of the above standard elements would help to ensure uniformity throughout the agency and to make the documents more useful to the public. The agency thinks that it is important to include the issuance date of a guidance, its status (e.g., draft), and, where applicable, the date of the document's last revisions. When a guidance document supersedes another document, it also is important to identify the document that the new guidance is superseding. In addition, superseded documents that remain available for historical purposes should be stamped or otherwise identified as superseded.

Finally, as part of GGP's, the agency is implementing a uniform sign-off policy that directs that, at a minimum, all Level 1 guidance documents receive the sign-off of an Office Director and Level 2 guidance receive the sign-off of a Division Director. The Office of the Chief Counsel (OCC) will review and sign off on Level 1 guidance documents that set forth new legal interpretations and any other guidance documents that the Office Directors (or other issuing officials) determine should have (OCC) review. The Office of Policy (OP) will review and sign off on Level 1 guidance documents that constitute significant changes in agency policy and any other guidance documents that the Office Directors (or other issuing officials) determine should have OP review.

V. Dissemination/Availability to Public

In the March 7 Notice, FDA solicited comment on how best to provide the public access to guidance documents. FDA's Centers and Offices currently use a variety of mechanisms to make guidance documents available to the public. Nevertheless, many of the comments stated that there is room for improvement in FDA's current access programs.

Guidance Document Lists. In the March 7 Notice, the agency expressed its intent to ensure that all current guidance documents are included on a list and that the public is aware that the list exists. FDA solicited comment on how best to make the list available—electronically, on the established FAX information systems, or in the Federal Register.

Most comments were in favor of one centralized system (with the individual Centers and Offices keeping copies as well); most agreed that the centralized system must include one electronic method and one hard copy method; some urged use of the Federal Register

because it is available electronically and by hard copy.

As part of its GGP's, FDA will make a comprehensive list of all guidance documents available on the FDA WWW home page and in the Federal Register. The WWW list will be updated continuously. The Federal Register list will be published annually and updated quarterly. The quarterly update will list all new guidance documents issued during that quarter and all guidance documents that have been withdrawn during that quarter. The list will include the name of each guidance document, the guidance's issuance/revision dates, and information on how to obtain copies of all of the guidance documents included on the list. The list will be organized by Center and Office and should group guidance documents by their intended users or the regulatory activities to which they apply.

Guidance Documents. In the March 7 Notice, the agency sought comment on the agency's current systems for providing access to the actual guidance documents. Specifically, the agency asked whether the current systems provide adequate access, whether it would be feasible to rely principally on the FAX systems and electronic methods—such as the WWW—or whether hard copies are necessary.

Comments submitted to the docket suggested that improvements could be made to FDA's current access systems. For example, some comments suggested that there were difficulties in using the FAX-ON-DEMAND systems. Others complained that the current systems were not kept up to date.

The Centers and Offices each will retain responsibility for maintaining a comprehensive, current set of their guidance documents and making those guidance documents available to the public. All guidance documents made available by the Centers and Offices should be included on the comprehensive list. To the extent feasible, guidance documents will be made available electronically (e.g., on the WWW). The Centers and Offices will make all guidance documents available in hard copy upon request.

VI. Appeals

In the March 7 Notice, FDA emphasized the importance of an effective appeals mechanism to ensure that there will be full and fair reconsideration and review of how guidance documents are being applied. The agency expressed its belief that an effective appeals process would protect against guidance documents being applied as binding requirements.

Comments submitted to the docket and presentations at the April 26 public meeting indicated that the issue of appeals may not be an appropriate way to address this issue. According to these comments, if the agency involves the public in the development of guidance and takes steps to ensure that its employees do not apply guidance as binding requirements, there would be fewer appeals relating to guidance documents. Nevertheless, a number of comments stated that the public is not sufficiently aware of the agency's current appeals processes and/or that the agency's current appeals processes are not adequate.

The agency agrees that improving the development and use of guidance documents should limit the need for appeals. Nevertheless, the agency believes that an effective appeals mechanism is needed for those times when someone believes the GGP's may not have been followed or the GGP's fail to achieve their purpose. The agency has appeals mechanisms in place. However, there is a lack of knowledge regarding their existence and a lack of clarity about how they work—both of which likely contribute to the criticism that they are inadequate. Accordingly, the agency is including, in its GGP's, a section that describes the appeals mechanisms relating to guidance.

As a general matter, a person with a dispute involving a guidance document can appeal a decision by going up the Center and Office chains of command, which are described in the GGP's. The Office of the Chief Mediator and Ombudsman (the Ombudsman) may be asked to become involved if the matter is not resolved by going up the chain of command, little progress is being made going up the chain of command, or a person does not know where to begin an appeal. The GGP's provide information regarding the Office of the Ombudsman and provide Center- and Office-specific information regarding telephone and/or mail contacts for questions on appeals.

The text of the GGP's document is set forth below.

Dated: February 18, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

Good Guidance Practices

I. Purpose

This ''Good Guidance Practices'' (GGP's) document sets forth FDA's general policies and procedures for developing, issuing, and using guidance documents. The purpose of this document is to help ensure that agency guidance documents are developed with adequate public participation, that guidance documents are readily available to the public, and that guidance documents are not applied as binding requirements. The agency wants to ensure uniformity in the development, issuance, and use of guidance documents.[1]

II. Definition

The purposes of guidance documents are to: (1) Provide assistance to the regulated industry by clarifying requirements that have been imposed by Congress or issued in regulations by FDA and by explaining how industry may comply with those statutory and regulatory requirements and (2) provide specific review and enforcement approaches to help ensure that FDA's employees implement the agency's mandate in an effective, fair, and consistent manner. Certain guidance documents provide information about what the agency considers to be the important characteristics of preclinical and clinical test procedures, manufacturing practices, and scientific protocols. Others explain FDA's views on how one may comply with the relevant statutes and regulations and how one may avoid enforcement actions.

The term ''guidance documents'' includes documents prepared for FDA staff, applicants/sponsors, and the public that: (1) Relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. ''Guidance documents'' do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

III. Legal Effect of Guidance Documents

Guidance documents do not themselves establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency. Rather, they explain how the agency believes the statutes and regulations apply to certain regulated activities. However, because a guidance document represents the agency's current thinking on the subject addressed in the document, FDA's decisionmakers will take steps to ensure that their staff do not deviate from the guidance document without appropriate justification and appropriate supervisory concurrence.

Alternative methods that comply with the relevant statute or regulations are acceptable. If a regulated company or person wishes or chooses to use an approach other than that set forth in a guidance document, FDA will, upon request, discuss with that company or person alternative methods of complying with the applicable statutes and regulations.

[1] This document represents the agency's current practices for developing, issuing, and using guidance documents. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Individual FDA Centers or Offices may have additional/more detailed procedures to implement the general principles set forth herein.

FDA encourages industry to discuss alternative approaches with the agency before implementing them to avoid unnecessary or wasteful expenditures of resources.

IV. Application of GGP'S

FDA staff involved in the development, issuance, and application of guidance documents are expected to adhere to these GGP's. Documents and other means of communication excluded from the definition of guidance should not be used to initially communicate new or different regulatory expectations not readily apparent from the applicable statute or regulations to a broad public audience. Whenever such regulatory expectations are first communicated to a broad public audience, these GGP's should be followed. This does not limit the agency's ability to respond to questions as to how an established policy applies to a specific situation or to questions about areas that may lack established policy. However, such questions may signal the need to develop guidance in that area.

V. Procedures for Developing Guidance Documents

FDA has adopted a two-level approach to the development of guidance documents. The procedures for developing a guidance document will depend on whether that guidance document is a ''Level 1'' guidance or a ''Level 2'' guidance. Level 1 guidance documents generally include guidances 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 include all other guidance documents.

Development of Level 1 Guidance Documents. For Level 1 guidance documents, the agency will solicit public input prior to implementation, unless: (1) There are public health reasons for immediate implementation; (2) there is a new statutory requirement, executive order, or court order that requires immediate implementation and guidance is needed to help effect such implementation; or (3) the guidance is presenting a less burdensome policy that is consistent with public health. In the latter situations, the agency will solicit public input upon issuance/implementation.

For Level 1 guidance, the agency will, at a minimum, solicit public input by (1) issuing a notice of availability of a draft of the guidance in the Federal Register and indicating its availability on the appropriate FDA world wide web (WWW) home page [2], and (2) posting the draft on the appropriate FDA WWW home page or making the draft otherwise available. The notice of availability will provide information regarding how to obtain a copy of the draft guidance; hard copies of the draft will be available upon request. The agency may use one Federal Register notice of availability to solicit public input on several different draft guidance documents. For Level 1 guidance documents, the agency also may hold a public workshop to discuss a draft and/or present a draft to an advisory panel when, for example, there are highly controversial or unusually complex new scientific issues.

Because the agency recognizes that it is important to solicit input prior to its decision to issue a guidance and also, perhaps, during the development of a draft of a Level 1 guidance, the agency is implementing various practices to obtain input at the earliest stages of Level 1 guidance document development. For example, these GGP's provide that the public will have an opportunity to comment on and suggest areas for guidance development or revision and to submit draft guidances for possible adoption by the agency. (See the ''Guidance Document Agenda'' and ''Guidance Proposal Policy'' set forth below.)

In addition, FDA may solicit or accept early input on the need for new or revised guidance or assistance in the development of particular guidance documents from individual nongovernmental groups such as consumer groups, trade associations, patient groups, and public interest groups. The agency may participate in meetings with these various parties to obtain each party's views on priorities for developing guidance documents. The agency may also hold meetings and workshops to obtain input from each interested party on the development or revision of guidance documents in a particular FDA subject area.

Comments submitted on draft Level 1 guidance documents will be submitted to the docket identified in the Federal Register notice and on the appropriate FDA WWW home page. All comments will be available to the public for review. The agency will review all comments, but in issuing the guidance, need not specifically address every comment. The agency will make changes to the guidance document in response to comments, as appropriate.

Development of Level 2 Guidance Documents. For Level 2 guidance, the agency will provide an opportunity for public comment upon issuance. Unless otherwise indicated, the guidance will be implemented upon issuance.[3] The availability of new Level 2 guidance documents should be posted on the appropriate FDA WWW home page as each guidance is issued. Each quarter, the agency will publish a list in the Federal Register of all new Level 2 guidance documents.

Comments submitted for Level 2 guidance documents will be sent directly to the issuing Center or Office. Each guidance will identify the Center or Office to which such comments should be sent. The Center or Office will review all comments. The agency will make changes to the guidance in response to comments, as appropriate.

Comments on Guidance Documents In Use. For all guidance documents—Levels 1 and 2—comments will be accepted at any time. Comments on the guidance documents in use should be submitted to the issuing Center or Office identified in the guidance. Guidance will be revised in response to such comments, as appropriate.

Sign-off Policy. All drafts of Level 1 guidance documents that are being made available for public comment will receive the sign-off of at least an Office Director in a Center or the Office of Regulatory Affairs equivalent. All final versions of Level 1 guidance documents will receive the sign-off of at least an Office Director in a Center or the Office of Regulatory Affairs equivalent. The Office of the Chief Counsel (OCC) will review and sign off on Level 1 guidance documents that set forth new legal interpretations and any other guidance documents that the Office Directors (or other issuing officials) determine should have OCC review. The Office of Policy (OP) will review and sign off on Level 1 guidance documents that constitute significant changes in agency policy and any other guidance documents that the Office Directors (or other issuing officials) determine should have OP review. All Level 2 guidance documents will receive the sign-off of an official at the Division Director level or higher. The agency employees with sign-off authority should ensure that these GGP's have been followed whenever a guidance document is issued. If GGP's were not followed, the person with sign-off authority should withdraw the guidance document and reissue it in accordance with GGP's.

Guidance Document Agenda. On a semiannual basis, the agency will publish in the Federal Register and on the FDA WWW home page possible topics for guidance document development or revision during the next year. At that time, the agency will specifically solicit input from the public regarding these and additional ideas for new guidance documents or guidance document revisions or priorities. The agency is not bound by the list of possible topics—i.e., it is not required to issue every guidance document on the list and it is not precluded from issuing guidance documents that are not included on the list.

''Guidance Proposal Policy.'' If a member of the public wishes to propose one or more topics for new guidance or guidance revisions or to propose one or more draft guidance documents for adoption by FDA, that person should submit the proposal to the Centers or Offices with responsibility for overseeing the regulatory activity to which the guidance document would apply. The submission should include a statement regarding why new or revised guidance is necessary.

If the Center or Office agrees that the proposed topic should be covered by a guidance document, it will develop a guidance document in accordance with these GGP's. If the Office or Center agrees that a guidance document should be updated/revised, it will develop a revision in accordance with these GGP's. If the submitter

[2] FDA has established a home page on the WWW at ''http://www.fda.gov''. Each of the Centers and the Office of Regulatory Affairs also have established home pages, which are linked to the FDA home page. These Center- or Office-specific home pages can be accessed directly or through the FDA home page. Guidance document notices and/or drafts will be posted on the FDA home page or will be accessible from there.

[3] The agency may, at the discretion of the issuing Office, solicit comment before implementing a Level 2 guidance document.

has proposed a draft of the guidance document that the agency agrees can form the basis for a guidance document, the agency will follow the GGP's for issuing and implementing a guidance document based on that proposed draft.

Review and Revision of Guidance Documents. The agency intends to review existing guidance documents on a regular basis. As part of the ''Guidance Proposal Policy,'' members of the public may request review or revision of a particular guidance document on the basis that it is no longer current. Such requests should be accompanied by an explanation of why the guidance is out of date and how it should be revised. The agency will review such requests to determine if the guidance document at issue needs to be updated/revised. The Agency will, when appropriate, update or revise that guidance document in accordance with these GGP's. In addition, when significant changes are made to the statute or regulations, the agency will, on its own initiative, review and, as appropriate, revise guidance documents relating to that changed statute or regulation.

VI. Standard Elements

Nomenclature. All guidance documents will include: (1) The umbrella term ''guidance,'' (2) information that identifies the Center or Office producing the document, and (3) the regulatory activity to which and/or the persons to whom the document applies. In practice, the majority of guidance documents issued in the future will be called ''compliance guidance,'' ''guidance for industry,'' or ''guidance for FDA reviewers/staff.''

Statement of Nonbinding Effect. All guidance documents will include language such as the following:

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, regulations, or both.

Absence of Mandatory Language. Because guidance documents are not binding, mandatory words such as ''shall,'' ''must,'' ''require'' and ''requirement'' are inappropriate unless they are being used to describe or discuss a statutory or regulatory requirement. Before a new guidance is issued, it should be reviewed to ensure that mandatory language has not been used.

Other Standard Elements. Each guidance document will include the dates of issuance and latest revision. Documents that are being made available for comment should include a ''draft'' notation. When a guidance supersedes another guidance document, the new guidance document will identify the document that it is superseding. Superseded documents that remain available for historical purposes should be stamped or otherwise identified as superseded. All guidance documents should include a cover sheet that is modeled after the samples attached to this document.

The agency will update existing guidance documents (to include these standard elements) as they are revised.

VII. FDA Implementation of GGP's

Education. All current and new FDA employees involved in the development, issuance, or application of guidance documents will be provided a copy of and directed to review the agency's GGP's. The Centers and Offices will conduct additional training of employees involved in the development and use of guidance documents that will describe in more detail how to develop and use guidance documents under these GGP's. This training will emphasize the principles set forth in section III., above, regarding the legal effect of guidance documents.

The agency also will educate the public about the legal effect of guidance. These GGP's and the statement of the nonbinding effect of guidance that will be included in every future guidance document and on the comprehensive list of guidance documents (discussed in section VIII. below) should help to educate the public about the legal effect of guidance. FDA staff should take the opportunity to state and explain the legal effect of guidance when speaking to the public about guidance documents.

Monitoring. FDA will monitor agency employees' use of guidance documents. As part of this process, the Centers and Offices will monitor the development and issuance of guidance documents to ensure that these GGP's are being followed. In addition, they will spot-check the use of guidance documents to ensure that they are not being applied as binding requirements. Finally, the Centers and Offices will spot-check the use of documents and communications that are not defined as guidance, such as warning letters and speeches, to ensure that these documents are not being used to initially express a new regulatory expectation to a broad public audience.

Three years after these GGP's have been implemented, the agency will convene a working group to review whether these GGP's have been successful in achieving the agency's goal in issuing them. The working group will determine whether the GGP's are ensuring: (1) Appropriate public participation in the development of guidance, (2) that guidance documents are readily available to the public, and (3) that guidance documents are not being applied as binding requirements. The working group will review the results of the Center and Office monitoring efforts as well as the number and results of appeals relating to the development and/or use of guidance documents.

VIII. Dissemination/Availability to Public

Lists of Guidance Documents. A comprehensive list of all current guidance documents will be maintained on the FDA WWW home page. New guidance documents should be added to the list within 30 days of issuance. The agency will publish the comprehensive list in the Federal Register annually. Each quarter, the agency will publish a Federal Register notice that lists all guidance documents that were issued during that quarter and all guidance documents that have been withdrawn.

The guidance document lists will include the name of each guidance document, the document's issuance/revision dates, and information on how to obtain copies of the document. The lists will be organized by Center and Office and should group guidance documents by their intended users and/or the regulatory activities to which they apply. The list also will include (properly identified) draft documents being made available for public comment.

Guidance Documents. The Centers and Offices each will retain responsibility for maintaining a comprehensive set of their guidance documents and making those guidance documents available to the public. All guidance documents made available by a Center or Office should be included on the comprehensive list. To the extent feasible, guidance documents will be made available electronically (e.g., on the WWW). The Centers and Offices will make all guidance documents available in hard copy, upon request.

IX. Appeals

These GGP's should improve the agency's development and use of guidance documents. Nevertheless, an effective appeals mechanism is needed for those times when the GGP's may not have been followed or the GGP's fail to achieve their purpose. FDA intends to provide an opportunity for appeal to a person who believes that GGP's were not followed in issuing a particular guidance document or who believes that a guidance document has been treated as a binding requirement.

As a general matter, a person with a dispute involving a guidance document should begin with the supervisor of the person issuing or applying the guidance document. If the issue cannot be resolved at that level, the matter should be brought to the next level. This process would continue on up the chain of command.[4] If a matter is unresolved at the level of the Center Director, or if little progress is being made going through the chain of command, the Office of the Chief Mediator and Ombudsman (the Ombudsman) may be asked to become involved.[5] The Office of the Ombudsman can be reached at 301–827–3390.

The chains of command for such appeals generally are as follows:

Center for Drug Evaluation and Research (CDER)

-Reviewer/Project Manager
-Branch Chief/Team Leader/Supervisory Project Manager
-Division Director
-Office Director

[4] This general agency-wide process for appealing decisions is described in FDA's regulations (21 CFR 10.75).

[5] The Ombudsman reports directly to and acts on behalf of the FDA Commissioner in investigating and resolving issues and problems that affect products under FDA's jurisdiction. The office was created to investigate industry complaints about FDA's regulatory processes, identify deficiencies in those processes, respond to problems affecting a product under FDA's jurisdiction, and ensure that FDA policy is fairly and evenly applied throughout the agency. The Ombudsman also mediates disputes or issues between FDA and the regulated industry that have not been resolved through other means.

-Deputy Center Director
-Center Director

In addition, CDER has its own Ombudsman in the Office of the Center Director (301–594–5443) to help assist with appeals and dispute resolution. Additional information about this office can be found on the CDER home page at ''http://www.fda.gov/cder''.

Center for Biologics Evaluation and Research (CBER)

-Reviewer/Consumer Safety Officer
-Branch Chief/Laboratory Chief
-Division Director
-Office Director
-Associate Director
-Deputy Center Director
-Center Director

In addition, CBER has its own Ombudsman in the Office of the Center Director (301–827–0379) who handles appeals and dispute resolution.

Center for Veterinary Medicine (CVM)

-Reviewer
-Division Director
-Office Director
-Deputy Center Director
-Center Director

In addition, CVM has procedures in place to handle appeals of written decisions on issues involving science or policy. These procedures, which may apply to certain guidance document appeals, are outlined in a staff manual guide (#1240.3130). For additional assistance regarding the appeals process in CVM, persons can contact the Associate Director for Policy at 301–827–0139.

Center for Devices and Radiological Health (CDRH)

-Reviewer/Consumer Safety Officer
-Branch Chief/Team Leader
-Division Director
-Office Director
-Deputy Center Director
-Center Director

Questions related to the CDRH appeals process may be answered by the Division of Small Manufacturer's Assistance at 800–638–2041 or 301–443–6597. Questions may also be faxed to 301–443–8818.

Center for Food Safety and Applied Nutrition (CFSAN)

-Reviewer/Consumer Safety Officer
-Division Director
-Office Director
-Deputy Center Director
-Center Director

In CFSAN, the Industry Activities staff at 202–205–5251 is the contact point for appeals and will direct inquiries relating to appeals of guidance documents to the appropriate CFSAN office.

Office of Regulatory Affairs (ORA)

-Field Investigator/Field Inspector
-Supervisor/Team Leader
-Branch Chief
-District Director
-Regional Director

The Regional Directors report to the Associate Commissioner for Regulatory Affairs.

In addition, FDA's District Offices and resident posts nationwide have a variety of small business representatives, public affairs specialists, and others who can respond to questions from outside the agency regarding appeals. A listing of FDA's offices is found in the blue pages of local telephone directories and on FDA's home page at ''http://www.fda.gov''. Questions related to an appeal of guidance documents in ORA may be answered by the Division of Compliance Policy, which can be reached at 301–827–0420.

If it is unclear which Center or Office produced a guidance document or a person does not know where to begin an appeal, the Office of the Ombudsman handles jurisdictional questions and is available to refer those outside the agency to the appropriate place.

In summary, appeals regarding guidance documents can be made either by going up the chain of command, using specific Center or Office procedures, or going directly to the Office of the Ombudsman.

BILLING CODE 4160–01–F

Sample Cover Sheet for
Draft Guidance Documents

Guidance for Industry

FDA Approval of New Uses for Product XX

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Draft released for comment on: _____.

Comments and suggestions regarding this draft document should be submitted by _____, 1997, to _____. For questions regarding this draft document, contact _____.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for XX
Date

Sample Cover Sheet for
Final Guidance Documents

Guidance for Industry

FDA Approval of New Uses for Product XX

U.S. Department of Health and Human Services
Food and Drug Administration
Center for XX
Date

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