



May 1, 2000

Dockets Management Branch  
Mail Code HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

5168 (M) MAY -1 P2:38

**Re: Docket No. 99N-4783: Administrative Practices and Procedures; Good Guidance Practices**

Dear Madam/Sir:

The Health Industry Manufacturers Association (HIMA) is pleased to submit comments on the Food and Drug Administration (FDA)'s proposed rule to codify its policies and procedures for the development, issuance, and use of guidance documents. HIMA is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture nearly 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and nearly 50 percent of the \$159 billion purchased annually around the world.

HIMA appreciates the opportunity to provide the following comments on the proposed rule.

**General Comments**

Since FDA published its "Good Guidance Practices" (GGPs) three years ago, both industry and the agency have gained experience with GGPs. HIMA commends the agency, especially the Center for Devices and Radiological Health (CDRH) for taking a leadership role in establishing GGPs as they have brought consistency to the ways in which FDA develops and uses guidance documents. HIMA also recognizes that FDA must expend considerable resources to develop guidance documents, to revise existing documents, and to train FDA personnel on the application of these documents. HIMA believes that the final rule, when published, should maximize the opportunities and options for early collaboration with industry in the development and revision of guidance documents. Using industry resources in the development of guidance documents would help to conserve the agency's resources and at the same time yield more meaningful documents.

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Currently, FDA lists thousands of guidance documents on its web site. HIMA recognizes the enormous task for FDA and industry to keep current with this large number of documents. HIMA is hopeful that as the centers develop internal procedures to implement the final regulation, they also review their current listings of documents and eliminate those that are obsolete, redundant, or no longer appropriate. When the final regulation becomes effective, it would be beneficial for the agency to have only those essential documents in effect and thus have a more manageable set of guidance documents.

### **Specific Comments**

#### **B. Definitions**

##### *Section 10.115 (b)*

##### *Definition of "guidance document"*

In this section FDA defines the types of matters that can be the subject of guidance documents such as the design, production, manufacturing, and testing of regulated products; the processing, content, and evaluation/approval of submissions; and inspection and enforcement policies. HIMA recommends that the agency include "labeling" and "promotion" of products on this list. Labeling should be added because it represents a significant part of the regulatory review process for both the agency and industry. Promotion should be added as it represents an area of focus for enforcement actions by the agency.

FDA recognizes that there are certain documents directed towards its own staff that would also provide guidance to industry. FDA considers those documents to be guidance documents. HIMA recommends that FDA provide examples of these staff documents to avoid confusion as to which documents might fall into this category. HIMA further requests that FDA uniformly title such documents as guidance documents or Compliance Policy Guides (CPGs), as appropriate. Currently, documents include a range of different identifying titles, such as, "Points To Consider," "Blue Book Memoranda," and "Review Criteria for Assessment." Identifying all guidance documents, with the exception of CPGs, as "Guidance Document" is more useful and would eliminate any confusion the affected industry may have as to which documents are indeed guidance documents.

##### *Section 10.115 (c)*

##### *Levels of guidance documents*

In this section of the proposed rule, FDA establishes two levels of guidance documents and section 10.115 (g) describes the different degrees of public participation each level is subject to before issuance. Level 1 documents are described as documents that provide initial interpretations of statutory or regulatory requirements or provide interpretations of complex scientific issues or highly controversial issues. Level 2 guidance documents are characterized as

documents describing current practices or minor changes in policy and therefore are less controversial in nature. However, there are times when guidance documents designated as Level 2, may in fact be very controversial in nature and FDA may be unaware of the controversy until it releases the document. For these types of circumstances, HIMA requests that FDA consider the immediate withdrawal of the document and re-assignment of the document to a Level 1 designation and its accompanying degree of public input. HIMA further recommends that the agency, as part of GGPs, establish a procedure to address these situations.

### **C. Legal Effect of Guidance Documents**

#### Section 10.115 (d)

##### *Legal effect of guidance documents*

HIMA supports and encourages FDA's willingness to discuss alternative approaches other than those set forth in guidance documents provided the alternative approach complies with relevant laws and regulations.

The proposed regulation states that FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence. Should this departure occur with the appropriate justification and the concurrence of the supervisor, it should be considered a one-time event. If the departure reoccurs, especially among multiple reviewers, and evolves to a permanent departure from the guidance document, then the agency should consider a potential revision of the guidance document and should determine potential ways in which the affected industry could provide input.

#### Section 10.115 (e)

##### *Other means to communicate new agency policy*

HIMA supports the agency's position that new information on an agency policy or regulatory approach should not be communicated in the form of speeches or comments made at meetings. In the past FDA has used internal resources as well as consulting its advisory panels in determining requirements to be imposed on industry. An example of this occurred regarding the improved longevity of pacemakers when implanted with steroid eluting high impedance leads. FDA has indicated that industry demonstrate a 6 month minimum improvement in device longevity. The imposition of this requirement represents agency policy that was not communicated to industry through the GGP process and as a result there was no public input on this matter. HIMA recommends that the agency specify that statements made at advisory panel meetings as a means to communicate new regulatory expectations to a public audience for the first time fall within the prohibited category of communicating agency policy and that GGPs must be followed in these instances.

#### **D. Public Participation in the Development and Issuance of Guidance Documents**

Section 10.115(f)(1-4) identifies industry's options for participating in the development and issuance of guidance documents; and section 10.115(g) identifies FDA's procedures for developing and issuing guidance documents. While 10.115(g) specifically allows FDA to determine the process for seeking early input from individuals/groups outside FDA (e.g. meetings), industry's opportunity to influence the development of guidance under 10.115(f) appears limited to content as opposed to process recommendations. HIMA requests that the final regulation provide a means by which industry could make recommendations as to which collaborative approach would be most appropriate when a specific guidance document is under consideration for development.

##### *Section 10.115 (f)*

##### *How the public can participate in development and issuance of guidance documents*

##### *(f) (1) (6) Providing input into the development of guidance documents*

While there are many tools by which the agency could solicit input into the development of guidance documents, HIMA believes that the most effective method is one in which FDA and industry work together to develop a guidance document. It is important for FDA and industry to establish a dialogue prior to, during, and after guidance document development. This dialogue is important so that industry and FDA can come to a common understanding of the intent behind the words contained in the document. Engaging in a dialogue has the benefits of resolving misunderstandings in a timely manner and reducing the level of frustration experienced by both parties. Active dialogue between FDA and industry will result in the development of meaningful documents that are useful to both parties.

There are many examples where FDA and industry have engaged in discussions to come to a common understanding of a particular issue. The "Most Frequently Asked Questions About FDA's Current Draft CPG of Research and Investigational Use In Vitro Diagnostic Devices," published by HIMA (Mar. 11, 1999) is one such example. In this case, both parties came to the table with different perspectives focusing on different issues related to the same topic. After working through the differing perspectives, the two parties developed a document that addressed each of their concerns.

Another example where FDA and industry worked together to develop a meaningful guidance document is the work product of CDRH's Product Development Protocol (PDP) reengineering team. Throughout the process, FDA engaged industry. As the team developed documents describing various components of the PDP, industry was asked to provide input into each draft document. This effort resulted in a guidance document that had considered the perspectives of the stakeholders. For the development of useful, meaningful guidance documents, more discussions such as those described above must occur.

Although HIMA believes that the most effective way for gaining public input into the development of guidance documents is one in which the agency and the industry work cooperatively to develop the document, FDA may consider other methods as appropriate for the particular guidance document topic under consideration. These methods could include public meetings, (including FDA workshops and conferences), FDA-hosted meetings with specific industry groups, industry-hosted meetings with FDA, meetings convened by a neutral third party, written communications (email or other correspondence), and teleconferencing or video-conferencing. However, the most interactive techniques are clearly preferred throughout the process beginning before the development of the first draft to the final version and for revisions thereafter.

(f) (2) Submission of drafts of guidance documents

HIMA commends the agency for encouraging stakeholders to submit draft guidance documents because these draft documents can be a useful starting point for the agency in developing guidance. Because so much effort can go into developing the first draft, FDA can save a significant amount of time and resources by using the draft developed by the affected stakeholders.

However, drafting a guidance document is considerable work for the participating individuals/companies and often requires senior management commitment. Industry has often had the experience of expending considerable effort in drafting a proposed guidance document to which they never get any real response from FDA. Therefore, HIMA requests that the agency include a provision within the final regulation that requires FDA to respond to draft guidance documents proposed by stakeholders and in the response, relate what elements were or were not acceptable in the draft and what changes would render the draft acceptable to the agency.

(f) (3) Suggestions for revisions of guidance documents

Although this section of the proposed rule allows the public to suggest specific guidance documents for revision, it does not contain a provision to allow public requests for deletion of guidance documents which are no longer useful due to changes in the law, scientific technology, or patient treatment. Therefore, HIMA requests that FDA include such a provision in the final regulation.

(f) (4) Annual publication of guidance document agenda

As FDA identifies the topics for the guidance document agenda, HIMA recommends that the GGPs outline the criteria and process that is to be followed in determining if a new guidance document is necessary. HIMA also recommends that the Guidance Development Agenda provide the agency's classification of the planned guidance document (i.e. Level 1 or Level 2). Providing this information would allow industry to comment on the appropriateness of the classification and to plan for interactive involvement in the development of Level 1 documents.

FDA proposes to publish a Guidance Development Agenda only once per year, instead of twice as is currently done. HIMA believes that the agency's agenda for guidance document development topics changes quickly enough to merit a semi-annual publication. For example, FDA's rule-making agendas are published twice a year because of the changing policy development that evolves in a six-month period. Because the agency's thinking evolves more quickly than just annually, HIMA recommends that the agency continue to publish this list semi-annually.

If the agency considers it a burden to publish the Guidance Document Agenda in the Federal Register twice each year, then HIMA suggests that FDA, at a minimum, post the agenda on its web site semi-annually. That way, the administrative burden is essentially conducting an internal e-mail survey of the relevant FDA offices asking them to list their potential topics, and then electronically posting those topics on the web site.

Section 10.115 (g)

*Agency procedures for developing and issuing guidance documents*

(g) (5) FDA's response to comments

In this section, FDA states that based on comments, it will revise guidance documents "when appropriate." The agency, therefore, has the authority to determine what comments and changes are adopted in the final released version of the guidance, and as such, can allow for some comments to be submitted and not addressed and thereby remain open issues. Because FDA does not commit to responding to written comments in the proposed rule, HIMA requests that, in the final regulation, the agency establish a requirement that it respond to written comments. HIMA believes that the agency could accomplish this by providing general responses to comments grouped by topic rather than providing detailed written responses to each and every comment.

FDA and the regulated industry could derive significant benefits if the agency were to respond to comments. First, the responses to comments will serve as important drafting history. Members of the regulated community routinely refer to the agency's responses to comments made in the context of rule-making to better understand the rules. FDA's responses to comments on guidance documents could show the basis for the agency's thinking and how the agency deals with specific issues that are raised by members of the public, just as they do for rule-making.

Second, responses show that the agency is paying attention to the public comments and has considered the comments. This encourages stakeholders to submit future comments.

Third, responding to comments has the benefit of convincing the public that the agency has legitimate positions, and thus increases the likely acceptance of the rules as fair, and enhances compliance with the rules by the regulated community.

*Section 10.115 (h)*

*How the public can submit comments*

This section of the proposed rule requires those who choose to submit comments on guidance documents to do so by sending hard copies only to the FDA's Dockets Management Branch. HIMA recommends that FDA also establish a mechanism by which comments could be sent to the Dockets Management Branch by e-mail, and at the same time copy by email the office that is developing the guidance. This is logistically the most efficient way, and it would encourage participation by many people who now are routinely communicating on-line instead of using the traditional mail.

**E. FDA's Internal Procedures**

*Section 10.115 (i)*

*Standard elements in a guidance document*

HIMA recommends that FDA also include as a standard element an explanation as to why the agency believes a guidance document is necessary for a particular topic. This additional information will enable industry to better understand FDA's reason for issuing the guidance document.

HIMA also recommends that, where appropriate, FDA should reference the recommendations of the Global Harmonization Task Force (GHTF) and international standards in guidance documents. By recognizing the GHTF initiative in GGP's, the agency will validate its commitment to harmonization and will advance the effort toward achieving a common methodology in the creation and implementation of global guidance documents.

*Section 10.115 (j)*

*Center and office procedures for approval of guidance documents*

HIMA requests that the agency further define how all guidance documents designated as "draft" are to be viewed by the agency and industry during this interim period leading to the formal release of the final guidance document. Understanding that the draft stage is a necessary part of the process, HIMA recommends that FDA include provisions in the GGP's that outline how such draft documents are to be interpreted in the event that the "release" of the final version is delayed for a prolonged period. An example of this delay is witnessed by the adaptation of the "*Modifications To Devices Subject to Premarket Approval - The PMA Supplement Decision Making Process*" draft guidance. This draft was issued on 8/6/98 and the final document has still not been released. This particular guidance is very useful to industry in administering changes to existing medical devices and has a direct impact on the number of submissions filed with the agency. Release of this particular guidance can have a material impact on reducing the number of submissions received by the agency.

To address this issue HIMA requests that the agency's internal procedures consider 3 stages for a new guidance document:

- draft
- approvable
- approved.

The approvable stage would represent a period after the first draft stage in which FDA has responded to the comments and republished the guidance and would allow the FDA and the public to continue to work through any unresolved issues regarding the guidance. The approved stage would represent the current practice of releasing the final version once all the issues are resolved.

During the approvable stage, the public (industry) could recognize and apply the portions of the guidance that are agreed to and represent a period for industry to transition towards full implementation of the guidance. In terms of establishing time limits to each of the draft and approvable stages, neither of these stages should last longer than 1 year.

In this section of the proposed rule, the agency states that each Center will develop procedures that identify an appropriate level of approval for its guidance documents. Although the proposed rule does not define which level of approval is necessary, the agency's 1997 guidance document on GGP's established a minimum level of approval authority for each level of guidance document, for new legal interpretations and for significant changes in policy. FDA states that it did not include minimum levels of approval authority in the proposed rule because it believes these are internal procedures inappropriate for inclusion in a regulation. HIMA, however, views a minimum level of approval authority as a means of defining the significance of a guidance document and therefore, recommends that the agency define these in the final regulation.

Finally, HIMA recommends that any internal procedures developed by each Center to implement this regulation, fall into the category of FDA documents directed to its own staff that also provide guidance to the regulated industry and therefore are guidance documents and should be made available to the public.

*Section 10.115 (k)*

*Procedures for FDA review and revision of existing guidance documents*

HIMA agrees that the agency should periodically review existing guidance documents to determine whether they need to be changed or withdrawn. Many documents are outdated or are redundant as they discuss the same subject.

To reduce the number of guidance documents subject to review and revision HIMA recommends that FDA consolidate several of its guidance documents. This can be accomplished by combining:

- documents addressing identical topics,
- documents covering one topic which applies to several premarketing application types, and
- documents containing identical premarketing application elements for similar product lines.

Benefits to the agency that can be derived from this process include resource savings by reducing the number of documents FDA employees need to keep current and train; greater consistency when revising documents because similar subject matters are contained in one document rather than several; and a document system which is easier to manage and keep current. The following examples represent areas where some documents can be combined.

*Examples of Documents Addressing Identical Topics:*

- 510(k) Additional Information Procedures #K93-1 (blue book memo), 7/23/93
- Guidance on the Center for Devices and Radiological Health's  
Pre-market Notification Review Program #K86-3 (blue book memo), 6/30/86
- 510(k) Refuse to Accept Procedures #K94-1 (blue book memo), 5/20/94
- Center for Devices and Radiological Health's Pre-market Notification  
[510(k)] Refuse to Accept Policy (with updated checklist 3/14/95) 6/30/93
- PMA Refuse to File Procedures #P94-1 (blue book memo) 5/20/94
- CDRHs PMA Refuse to Accept/Accept/File 6/30/93
- PMA/510(k) Expedited Review #G94-2 (blue book memo) 5/20/94
- PMA/510(k) Expedited Review - Guidance for Industry and CDRH  
Staff, 3/20/98

*Example of Documents Containing One Topic With Multiple Applications:*

- Center for Devices and Radiological Health's Investigational Device  
Exemption (IDE) Refuse to Accept Policy, 6/30/93
- 510(k) Refuse to Accept Procedures #K94-1 (blue book memo),  
5/20/94
- CDRHs PMA Refuse to Accept/Accept/File, 6/30/93

*Example of Elements Applying to Similar Products:*

- Guidance In Vitro Diagnostic Potassium Test System 1107, 7/6/98
- Guidance In Vitro Diagnostic Sodium Test System 1109, 7/6/98
- Guidance In Vitro Diagnostic Urea Nitrogen Test System 1110, 7/6/98
- Guidance In Vitro Diagnostic Glucose Test System 1105, 7/6/98

*Section 10.115 (l)*

*Procedures for consistent application of GGP's*

FDA states that it will monitor the development and issuance of guidance documents to ensure that GGP's are followed. HIMA recommends that as CDRH develops its specific procedures for monitoring the consistent application of GGP's, it consider using the newly appointed CDRH ombudsman to perform this function.

**F. Public Access to Guidance Documents**

*Section 10.115 (m)*

*Public Access to copies of guidance documents*

HIMA commends the agency on the effective use of its Internet web site to communicate with the public. Industry recognizes the progress the agency has made in using the Internet as a resource to make guidance documents, both draft and final, available to the public. Use of the Internet as a medium for communicating guidance, policy, and regulation has significantly enhanced the retrieval of information in a timely manner and in various formats to suit the needs of the regulated industry.

Therefore, HIMA recommends that FDA use its web site, to the fullest extent possible, as the major vehicle for providing copies of guidance documents to the public. Furthermore, HIMA recommends that the agency use its web site for posting the comprehensive list of guidance documents, quarterly updates, and the list of the agency's guidance document development agenda.

*Section 10.115 (n)*

*Procedures for publishing lists of available guidance documents*

FDA's guidance document lists will include the name of the document, issuance and revision dates and information on how to obtain copies of the document. HIMA recommends that the agency consider the inclusion of a brief statement describing the document because titles sometimes do not clearly identify the full scope of the document.

## **G. Dispute Resolution**

### Section 10.115 (o)

#### *Handling complaints regarding use and development of guidance documents*

Section 10.115 (o) identifies an appeals mechanism for cases in which the procedural requirements of the GGP's have not been followed. However, the proposed GGP regulation does not identify an appeals process for situations where someone disagrees with the substance of the guidance. Therefore, HIMA suggests that FDA cross-reference the normal appeals process for agency decisions (21 CFR § 10.75). Also, HIMA requests that CDRH establish procedures by which the CDRH Ombudsman could become involved in disputes regarding the use, development, and the content of guidance documents originating within CDRH.

HIMA further recommends that FDA define review time periods for appeals in the final regulation as this will provide more definition and clarity to FDA and industry regarding the appeals process. This is especially needed for product premarketing applications. Delays in the appeals review process cause product submission review cycles to increase and can be extremely costly, including delaying patients' ability to obtain medically necessary treatment or access to new technologies.

Finally HIMA requests that FDA post on its guidance document web site, for each Center and Office, the supervisor and higher supervisor titles, addresses and telephone numbers. Also, post the name, address, and telephone number of the Chief Mediator and Ombudsman and the CDRH Ombudsman on the electronic guidance document web site. This additional information will add more clarity to the appeals process, making it easier for the public to understand and access.

## **H. Conforming Changes**

### Section 10.90 (b)

#### *Replace the word guidelines with guidance documents*

In this section of the proposed rule, the agency proposes to eliminate the category called "guidelines," and with it, their binding effect. HIMA supports the elimination of the category "guidelines" as FDA no longer appears to develop this type of document. However, HIMA believes that matters that would have been appropriate for the "guideline" designation in the past should have a Level One Guidance Document designation under the GGP's. In addition, because existing guidelines may lose their binding effect under this proposal, HIMA requests that FDA clarify whether or not it intends to abide by the requirements of those guidelines, especially in cases where companies still use and rely upon them.

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HIMA appreciates the opportunity to comment on FDA's proposed regulations codifying its policies and procedures for the development, issuance, and use of guidance documents. HIMA also supports the comments submitted by the Indiana Medical Device Manufacturers Council. HIMA looks forward to working cooperatively with FDA as it implements the GGP's.

Respectfully submitted,

A handwritten signature in cursive script that reads "Janet Trunzo".

Janet Trunzo  
Associate Vice President  
Technology & Regulatory Affairs

jt:ts