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Joan Claybrook, President

June 5, 1996

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm 1-23
Rockville, MD 20857

RE: Guidance Documents; The Food and Drug Administration's Development and Use [Docket No. 95P-0110]

I. Introduction

On behalf of Public Citizen's Health Research Group, we offer the following comments on the Food and Drug Administration's development and use of guidance documents.

In summary, we believe that guidance documents have been abused by both the FDA and the drug and device industries as vehicles that convey FDA policies without the enforceability that accompanies regulations. As a result, industry has ignored matters that are critical to public health. Guidance documents should be no more than their name implies--resources to guide reviewers and applicants in understanding specific statutory and regulatory requirements. They should never be used to establish rights or responsibilities. All policies, standards, and requirements should be promulgated as regulations and should be communicated to the public through the Federal Register.

II. Background

According to the FDA's own estimate, there are well over a thousand guidance documents in current distribution[1]. Some of these documents contain information that the regulated industry uses to clarify requirements imposed by Congress or promulgated by FDA. Others assist FDA employees by providing specific review and enforcement approaches. For the most part, these types of guidance documents are useful and appropriate.

Numerous examples of these types of guidances exist. A small sampling of available documents includes: how to label a medical device, determination of significant versus non-significant risk device studies, instructions on determining when to submit a PMA supplement, and points to consider when reviewing an IDE.

But other types of guidance documents attempt to convey important FDA policies to the

[1]Federal Register 61(46), March 7, 1996, p. 9182.

regulated industry. Since these documents are not regulatory vehicles, they cannot be enforced and thus allow industry to avoid addressing critical issues. Two examples of these types of guidance documents were the publications that set forth guidance for including women and the elderly in the testing of new drugs. Since the FDA had no authority to enforce these guidelines, they were virtually ignored by the pharmaceutical industry resulting in considerable deficiencies in the knowledge of how certain products will affect those populations.

We urge the FDA to differentiate between explanations of existing policies, which are the appropriate use of guidance documents, and new policies, which should require promulgation of regulations.

III. Response to Specific Issues Raised in the Federal Register

A. Value of standardized nomenclature.

We agree that a more standardized nomenclature would improve the public's understanding of the available guidance documents, however we do not support the time or expense involved in renaming all existing documents. The FDA should define specific categories of documents and should use these classifications for all future publications. As documents are periodically updated over the next few years, they can receive the new nomenclature. Until that time, all documents should be indexed and categorized in a way that allows the public to identify and access all available information despite the generation of the nomenclature used.

B. How to communicate to FDA staff and to the public the principle that guidance is not binding.

The best way for the FDA communicate that guidance in not binding is for the Agency to ensure that guidance documents are not used to establish policies or requirements. If guidance documents are used only to explain existing regulations, it will be clear to both applicants and reviewers that there is no binding information in the documents.

In addition, the cover of each document should contain an advisory statement indicating that the guidance is not binding. For guidance documents that have not yet been revised to include this information, a sheet of paper containing the statement should be stapled to the cover of each document distributed.

C. Public input in guidance document development.

We believe the proposed three-tiered structure of public input into guidance document development is unnecessarily complicated. If guidance documents are used to explain the FDA's

interpretation of existing statutory and regulatory requirements, there should be no need for the public to want or need substantial opportunity to provide input. All users of guidance documents should be encouraged to provide informal feedback about the usefulness of the documents at any time. This feedback should be filed and used to update future editions of the material. If feedback on existing documents is routinely negative, the FDA should strongly consider rewriting and reissuing them.

We believe that a better use of public input is in the decision of which types of new guidance documents to develop. An annual Federal Register notice should solicit suggestions for areas in which the regulated industry feels it needs assistance. The FDA should consider these public comments in the development of new material for distribution.

D. Adequacy of current guidance document access systems.

Although the current systems allow the public to obtain documents through a number of different mechanisms, we believe that it is still too difficult to identify and obtain all necessary guidance documents. A significant part of this problem is the lack of a comprehensive index of all available guidance documents. The FDA should ensure that all guidance documents are listed in one comprehensive document, and this document should be available at every source from which guidance documents can be requested including the FDA home page on the World Wide Web. The document should be called "Index of FDA Guidance Documents." It is not necessary to publish the entire index in the Federal Register each year, but the FDA could publish an annual notification of the sources where the list could be obtained.

While the publication of a comprehensive index would greatly improve the public's awareness of guidance documents, full access to this information will be restricted until the document dissemination process has been improved. Guidance documents are currently available from so many different sources that it is difficult to know where to request certain information. Since most Centers distribute only some of the available guidance documents, it is very difficult to know whether or not all available information has been received.

This problem is compounded by the confusing and misleading instructions provided through the various systems. For example, when calling the CDRH Facts on Demand System, one option is to request a DSMA Facts index. This so-called index is nothing more than a sheet of paper telling you how to use the Facts on Demand System (something the user presumably knows how to do if she or he has succeeded in requesting the "index"). A second option in this system is to use the index to request a specific document. Needless to say this is a difficult task when no index has been provided. The Facts on Demand System also seems to have an usually large amount of "down" time. On one day recently, the recorded list of options included DSMA Facts, MQSA Facts, and MQSA Facts, when the third option should have been DUPSA Facts. On another day, the system never answered the phone, and today, while preparing these comments, we received a recorded message for over four hours saying to call back later.

The Electronic Docket/World Wide Web system is also not without problems. It does not yet contain a comprehensive listing of all documents, and there is no way to ascertain whether or not additional documents on a given topic exist.

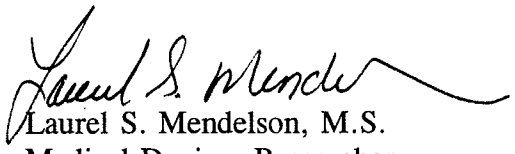
Both the Facts on Demand and the Internet are creative solutions to distributing documents. Once the systems have been updated to provide comprehensive, reliable information, they will be very valuable resources. The FDA would be wise to ensure that these systems are operating at their optimal levels as soon as possible.

Despite the accessibility of electronic communication, the FDA should not forget its commitment to American citizens. Thus individual consumers who do not have access to the latest technology must still be able to obtain information. For this reason, hard copies of the comprehensive index as well as each individual guidance document must be made available from at least one FDA source.

E. Public Awareness of appeals mechanisms.

We believe that the mechanisms currently in place are sufficient for appealing decisions relating to guidance documents. If these documents are used only to explain policy and not set policy, there should be little need or desire for appeal based on these documents.

Sincerely,



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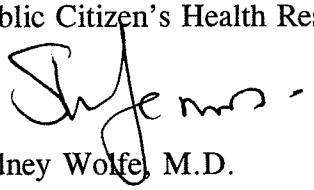

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