

COALITION FOR BLOOD SAFETY

American Association of Blood Banks - America's Blood Centers -
American Blood Resources Association

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April 27, 2000

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

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

To Whom It May Concern:

The Coalition for Blood Safety (CFBS), formerly known as the Coalition for Regulatory Reform (CFRR), appreciates the opportunity to submit written comments on the Food and Drug Administration's (FDA) proposed rule, Administrative Practices and Procedures: Good Guidance Practices. CFBS is composed of the American Association of Blood Banks (AABB), including the American Red Cross (ARC) and the Armed Services Blood Program, America's Blood Centers (ABC), and the American Blood Resources Association (ABRA). CFBS was formed in 1994 after the Food and Drug Administration (FDA) invited the blood banking industry to develop and explore ideas with FDA for a more efficient regulatory system for blood and plasma products. The coalition represents the entire spectrum of blood and plasma collection and transfusion interests.

The agency requested comments on how effectively it has used plain language and whether this has made the document "more clear and easy to understand." The CFBS appreciates the agency's effort to improve clarity and finds the language in this document easier to understand and interpret. The definitions are particularly helpful. However, while it may be useful to formulate questions and then answer them, inclusion of the questions in the body of the rule is not necessary and adds another level of complexity to the numbering system. The answers provide the necessary information, and with little modification, can stand alone. Questions, which have been answered, could be used in the background information but should not appear in the actual regulation.

The agency requested comments on the effectiveness of the procedures described in the 1997 GGP document. CFBS believes that the agency has improved greatly in obtaining public input into the development of guidances. In the past two years, CBER has held numerous public workshops seeking public input, and has carefully considered public comments submitted in

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response to draft guidances. We particularly note the impact of public input on HCV lookback guidance. CFBS appreciates these efforts and encourages their expansion and continuation. It is essential that the agency obtain early and frequent input from the public and industry and reach consensus on proposed new guidances.

We are particularly concerned about one aspect of CBER interpretation of the Administrative Practices and Procedures Act that appears to be contrary to the intent stated in Good Guidance Practices. Section 10.115(g)(1)(i) specifically states that “FDA may seek or accept early input from individuals or groups outside the agency. For example, FDA may do this by participating in or holding public meetings and workshops.” CFBS has been told repeatedly that CBER interprets the Administrative Practices and Procedures Act to mean that they are unable to meet with us or any other group to discuss the potential content of a guidance document or development of a policy until after the draft guidance is published for comment. It appears that this is not true at CDRH, where, for example, a recent guidance announcement indicated that the draft guidance had been developed with input from some but not all industry before being published for comment. The concern expressed by CBER staff that CBER cannot meet exclusively with one segment of industry because it must meet with the entire industry can be easily overcome in the case of the blood industry because there is one group, the CFBS, that was specifically formed for this purpose and represents all aspects of blood and plasma collection and transfusion. Moreover, the CFBS has established the ability to work successfully with CBER. In the one instance in which we were permitted to assist in developing the draft guidance for “Submission of Chemistry and Manufacturing Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of Form FDA 356h Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use” the draft guidance was well received and did not require significant changes to be finalized. We request that the agency adopt uniform policies for all Centers and that early meetings be encouraged, prior to publishing an actual draft guidance.

Section 10.115(g)(1)(3)(b) states that after FDA prepares a draft of a level 1 guidance document, FDA may also present the draft guidance document to an advisory committee for review. It is not uncommon, particularly at the Blood Products Advisory Committee, to have proposals for new or revised guidances that are first seen by the blood bank industry during the committee meeting. While the advisory committee meetings provide an opportunity for public comment, it is nearly impossible to provide a reasoned response, particularly with regard to providing data to the advisory committee, if we do not see the content until the day of the advisory committee meeting. We recognize that advisory committee recommendations are not binding on FDA, but such recommendations do have significant impact. It is inappropriate to discuss proposed guidance with advisory committees without informing industry of the proposed content. We request that proposed guidance to be presented to an advisory committee also be required to be available to the public with sufficient time to formulate comment for the advisory committee meeting.

We agree with the definitions of level 1 and 2 guidance. The standard policy of the agency should be to publish level 1 as draft guidances for comment. There are very few circumstances that should permit the agency to decide that prior public participation is not feasible or appropriate and require implementation in the initial document. If the agency determines that

there are public health reasons for immediate implementation, it should clearly define the public health threat.

Further, the agency should require an explanation of why it incorporated or declined to incorporate comments to the draft guidance into the final guidance. Although each comment does not need to be addressed, as is required in rulemaking, explanations should be provided in answer to comments when several similar or identical comments are received, and must be discussed if the majority of the comments disagree with a particular provision.

We support the requirement to make guidances readily available. Posting them on the Internet has proven to be a satisfactory method of accomplishing this, and we commend the agency for this approach. We agree that it is important to maintain a mechanism to obtain a hard copy as well.

The agency also requested comments on the proposed change to update the comprehensive Federal Register list of all current guidance documents on an annual rather than a quarterly basis and that new guidances be added to the Federal Register within 30 days. We believe that this change would be acceptable, provided each FDA center maintains a current list that is updated each time a new guidance is published.

In Section 10.115 (d)(1) the proposed rule states that guidance documents do not legally bind you or the agency. We believe that this and other explanations of legal effect are misleading and should be clarified. Section 10.115(d)(2) indicates that you may choose another approach other than the one set forth in a guidance document and that FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations. In fact, this second stipulation implies a legal obligation to follow the guidance's content, just that the choice of how it is done may be negotiable. For example, in the blood bank industry, many of the guidances address donor suitability. While you may be able state a new donor question using different language, you clearly cannot choose to ignore that criteria in determining donor suitability. In effect, the guidance is binding. Whether the language in the guidance uses the term required or recommended is immaterial. Likewise, section 10.115(d)(3) states that guidance documents represent the agency's current thinking and that FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence. This section also implies that guidance documents are the standard of practice.

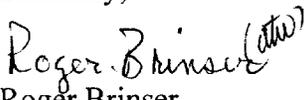
There is no discussion of determining criteria for deciding whether issuing a guidance or a regulation would be more appropriate. While we appreciate delineation of the processes required by GGP, we are concerned that guidance may be issued where regulation would be more appropriate, simply because the GGP is a simpler process.

Finally, we note that several recommendations from CBER to the blood industry were published in older documents that were identified as memos. We request that these memos be reviewed and reissued/designated either as guidance documents or promulgated as regulations if that is more appropriate.

CFBS also requests that the agency coordinate efforts among Centers to develop and issue guidance. The standard elements to appear in all guidance, as required by this proposed rule, should assist us in identifying and utilizing guidance documents. CBER has made improvements in this area by publishing a list of CDRH guidance that will be utilized by CBER. However, this coordination must be strengthened and improved, so that expectations of each Center are similar and guidance for one Center is not contradictory to that of another Center. This is especially important in the blood industry since it is regulated by all three Centers.

Once again, CFBS appreciates the opportunity to comment on FDA's proposed rule Administrative Practices and Procedures: Good Guidance Practices. We believe that the most important factor in successful guidances is early and continual communication between the agency and its stakeholders and look forward to such dialogue with the agency. Should you have any questions concerning our comments, please feel free to contact Kay R. Gregory, MS, MT(ASCP)SBB, AABB Director, Regulatory Affairs at (301) 215-6522 or by e-mail to kayg@aabb.org

Sincerely,


Roger Brinser
Chair, Coalition For Blood Safety

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