



February 23, 2000

1710 '00 FEB 29 P1:39

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

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

Dear Ms. Barclay and Policy Staff:

Thank you for providing the opportunity to comment on the referenced draft. The purpose of this letter is to focus on a single area of the Proposed Rule and suggest enhanced language.

Gen-Probe Incorporated Comment:

A key area of the existing 21 CFR 10.90b has been removed in favor of increased (supervised) flexibility at the FDA. The specific section of concern is located at 10.90(b)(1)(i) in the existing regulation and reads as follows:

“A person may rely on a guideline with the assurance that it is acceptable to the FDA, or may follow different procedures or standards.”

Gen-Probe’s comment is that so much planning goes into finalizing a Guidance that it should be a reliable reflection of FDA’s current thinking. When that thinking changes, a Guidance update in draft form should be publicized within 30 days. The February 14, 2000, proposal removes the regulatory assurance that guidance documents may be relied upon to document the agency’s thinking.

Also removed from the current regulation completely is 10.90(b)(2), which reads:

“A guideline represents the formal position of the FDA on a matter and, except as provided in paragraph (b)(3) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with a guideline issued under this section that has not been amended or revoked.”

99N-4783

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Gen-Probe Incorporated's proposal is a compromise between the strict requirement of the paragraph above, the government's need for greater flexibility, and industry's need to rely on published and final guidance documents.

Gen-Probe Incorporated Proposal:

These reproposed sections document that published guidances will be acceptable for use if followed. The reproposal also preserves FDA flexibility, but in a more limited and structured fashion.

Rewrite two sections of the proposed Regulation as follows:

10.115(d)(3) – “Although guidance documents do not legally bind the FDA, they represent the agency's current thinking. You may rely on a guidance with the assurance that it is acceptable to the FDA, or you may follow different procedures or standards. When the agency's current thinking changes, FDA employees may depart from guidance documents only with appropriate, documented justification, documented supervisory concurrence, and by issuing a “draft” update to the public within 30 days of the decision that the current guidance is no longer sufficient to represent the Agency's thinking.”

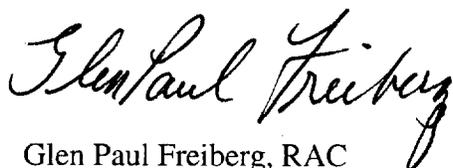
The proposed section below documents that the published guidances will be promptly updated and announced to the public if the guidance no longer represents the agency's thinking.

10.115(k)(1) – “When the agency determines that a guidance, or portion of a guidance, no longer represents current agency thinking on a topic, a draft update will be published for comment within 30 days of the decision. Submissions accepted for filing prior to an updated announcement will not fall under the changed guidance.”

Existing (k) (1) and (2) become (2) and (3) respectively.

This completes Gen-Probe Incorporated comments on this first draft of the updated regulation. Should you wish to contact me, my direct phone is (619) 410-8703 and my email address is GlenF@Gen-Probe.com.

Sincerely,



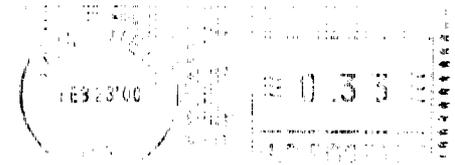
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c: AMDM, HIMA



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