SACRAMENTO MEDICAL FOUNDATION | Blood Centers

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March 23, 2000

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

Re: **Docket Number 99N-4783**

Dear Sir:

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Thank you for the opportunity to comment on Docket Number 99N-4783 entitled, **"Administrative Practices and Procedures; Good Guidance Practices,"** as published in the February 14, 2000 Federal Register. I believe the proposed rule is a useful clarification of the use of guidance documents and, further, that the agency has effectively used plain language in this statement which makes the document clear and easy to understand.

While the 1997 GGP document provided a careful definition of "guidance," and described the legal effect of guidance documents, I think it appropriate that these be reinforced and reissued in the Proposed Rule. I especially appreciate *"that guidance documents are not treated as binding requirements on you or on FDA."* Further, it is noted that *"guidance documents themselves do not create rights or responsibilities under the law, and guidance documents are not legally binding on you or on the agency,"* with which I heartily agree. I agree that guidance documents often deal with *"highly controversial issues,"* so this is an appropriate communication vehicle from the agency, i.e., the use of guidance documents. As in the 1997 GGP document, there should be, in all guidance documents, *"a statement of non-binding effect; the absence of any language implying that the document is mandatory; and other standard information...and whether a document is draft or final."* As noted, it would be appropriate to include from the 1997 GGP document *"an opportunity to raise an issue regarding whether FDA staff have followed GGPs."*

In Section C, entitled, **Legal Effect of Guidance Documents,** there appears to be an inconsistency. In the first paragraph, it states that, *"they* [guidance documents] *do not legally bind you or the agency."* However, in the second paragraph, it states that, *"Proposed [Article] 10.115(d) further provides that you may choose to use an approach other than the one set forth in a guidance document."* It further goes on to state that, *"if you would like to choose an alternate approach, FDA is willing to discuss that approach with you to ensure that it complies with all relevant laws and regulations."* If a guidance document is not binding, it's not clear why one would have to discuss with the FDA an alternate approach. For

99N-4783

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example, one alternate approach would be not to accept the guidance in the guidance document. Does this mean that one would have to notify and discuss this with the FDA? Would we have to obtain FDA approval of our alternative to guidance? This seems illogical and even inconsistent to have to discuss with the FDA an alternate approach to a guidance document, if the guidance document is not legally binding in the first place!

I appreciate and support that, as noted on **page 7325**, in the second full paragraph on this page, that one *"may submit comments on any guidance document (Level 1 or Level 2, draft or final) at any time."* I further appreciate that *"the FDA will review all of the comments that it receives and will revise guidance documents in response to your comments when appropriate."* I further support the proposition later on in [Article] 10.115(h) that *"comments will be available to the public in accordance with FDA's regulations at* [Article] *10.20(j)."* As noted, I heartily endorse that *"such comments will be available at the Dockets Management Branch, and, when feasible, on the Internet."* The latter would be even more useful and available than the former.

As noted in the last paragraph on **page 7325**, and carried over to **page 7326**, I support the statement that the *"FDA will direct its employees to continue educating the public about the non-binding effects of guidance."* Under Section G., labeled **Dispute Resolution**, I think it quite appropriate that *"if you believe that someone at FDA did not follow the procedures in [Article] 10.115(o) or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the Center or Office that issued the guidance document."*

In Section VI, **Comments Received by the Agency, 2.**, I would disagree with the agency's interpretation of the exception and believe it should not only interpret it *"so narrowly,"* but that there should be a real, or demonstrated, *"public health emergency,"* for its waiver of the requirement for prior public participation. The *"public health emergency"* should be present and not just theoretical; further, the agency should detail the data supporting the *"emergency."*

On **page 7327, 4.**, a comment noted that there should be written notice from the FDA when *"it determines to deviate from a guidance document, and state the given reasons for such deviation."* Since we are being asked for written

justification for an alternate approach to a guidance document, it seems equally incumbent upon the FDA that it *"should provide the requester with written notice stating the reasons for such* [FDA] *deviations."*

Again, thank you for the opportunity to comment on the Proposed Rule Regarding Good Guidance Practices. I trust that, in the revisions to the Code of Federal Regulations, that Article 10.115 will be responsive to the points that I have raised, especially the need to discuss with the FDA an alternative approach to a guidance document which is not one which establishes or *"legally enforces rights or responsibilities."* This is especially true, since, as noted in the Code wording, *"they [guidance documents] do not legally bind the public or FDA."*

Sincerely,

Paul V. Holland, M.D.
Medical Director/Chief Executive Officer

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Return Service Requested

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