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COMMENT ON FEDERAL REGISTER PROPOSED RULE, "ADMINISTRATIVE PRACTICES AND PROCEDURES; GOOD GUIDANCE PRACTICES" Federal Register, February 14, 2000 page 7321

1. The proposed rule does not specifically comment on or explain the status of advisory opinions (21 CFR 10.85) under these revised administrative practices. Will FDA comment on the effect this proposed rule will have on advisory opinion requests and the status of advisory opinions?

1.a. Are advisory opinions "guidance" that would fall under the purview of GGP's (good guidance practices)?

2. Will FDA publish a listing and make all advisory opinions available on the internet?

3. FDA states that FDA is always open to comments on guidance documents, as well as suggestions for guidance documents (page 7325 of this FEDERAL REGISTER proposed rule). In this spirit, does FDA have a mechanism for receiving and evaluating suggestions or ideas for novel or more efficient administrative procedures agency wide? If not, will FDA develop such a mechanism?

For example, a suggestion I would offer is that FDA create a database of companies (subdivided by location), and that all letters issued to a company (including IND review, Product review, Compliance letters {including court orders}, general correspondence, etcetera) be scanned and saved in this database. Such letters would be available to all FDA reviewers, inspectors, etcetera. Such a database would do more to assure quality and consistency of Agency action as a practical matter than any other action FDA could take. Does FDA have procedures for receiving and evaluating such proposals?

4. I note a recent incident involving bovine derived materials obtained from European countries, which is apparently a problem because USDA published a rule in 1998 expanding the number of European countries

99N-4783

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banned as a source of bovine derived materials. I was aware of FDA's letters to manufacturers as published in the FEDERAL REGISTER of August 29, 1994, as well as FDA's guidance document on this topic (solely because of their publication in the FEDERAL REGISTER).

I was unaware of other letters (other than by CVM) issued by FDA's CDER or CBER on this important topic. I became aware that supposedly another letter was issued to manufacturers from FDA on May 9, 1996, concerning the issue of BSE and CJD (Creutzfeldt-Jakob Disease) - I say supposedly because I am unable to independently verify or obtain a copy of such a letter. I am unable to find this letter in either the FDA or CBER websites using the search engines associated with these sites (using the search criteria of "bovine spongiform encephalopathy" or "May 9, 1996"). Does the May 9, 1996 letter from FDA regarding bovine sourced materials exist? If it does, I would suggest that FDA post such letters on the internet if they contain information that contains important FDA and public health policy implications.

4.a. Does FDA assure that broadly disseminated letters issued to all or a significant grouping of manufacturers, sponsors, or applicants is posted on the internet, or made available to FDA employees? Would FDA comment on whether FDA has internal written procedures with regard to distribution of letters or advisories to FDA employees in all Centers? (Rhetorical question - how often does FDA's own internal QA group audit such systems?)

5. With regard to 21 CFR 10.115(m), I have written to FDA before suggesting that the September 29, 1978 preamble to the cGMP's be posted on the internet. As this document was written prior to the use of the internet, it has not been available on the website run by the Office of the Federal Register. However, as this is an extremely important document that explains FDA rationale with regard to cGMP's (current Good Manufacturing Practices), and is invaluable guidance, an effort should be made to widely distribute it. I have talked to field inspectors who are unaware of this document, and have no access to obtaining a copy.

6. On page 7327 of the proposed rule, comment number 9 suggested that the agency not make policy through informal mechanisms such as speeches or statements at meeting.

FDA's response agreed with the premise. However, as an employee of FDA, I note that there no longer appears to be written procedures to assure that this does not happen. For example, in CBER there used to be an SOP, "Clearance of CBER Regulatory and Policy Documents" (#A-1-93 May 24, 1993) that had a specific mechanism for the review and clearance of speeches, statements, and articles. However, I no longer see this SOP posted on CBER's web site. In my view, if FDA is serious about assuring that non-written policy is not made, it will update and enforce an internal written procedure on the subject.

In addition, the posting on the FDA web site of all speeches would do much to assure consistency and correctness of public statements made by FDA employees. It would be a good QA tool, showing where differences of opinion do exist so that matters can be addressed and resolved.

Finally, I note that the aforementioned SOP states that such speeches and talks would be saved for future reference. If that were to be rigorously implemented across FDA, that would be very helpful . FDA employees are constantly asked to give presentations. Having to come up with de-novo presentations on subjects at the last minute is not efficient or effective (incomplete or wrong presentations help no one). By being able to access previously reviewed and approved presentations, consistency and more efficient utilization or resources would be achieved.

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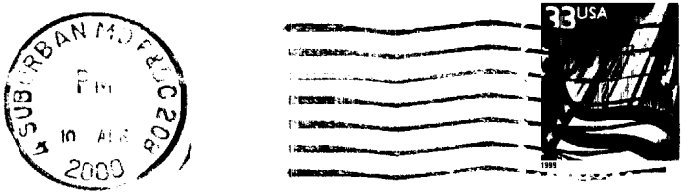

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