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Dockets Management Branch (HFD-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane,
Rockville, MD 20857

Ref: **Docket No. 01D-0086 – Guidance for Industry:**
"Disclosing Information Provided to Advisory Committee in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research" Draft Guidance.

Abbott Laboratories is pleased to have the opportunity to provide comments on the "Disclosing Information Provided to Advisory Committee in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research" Draft Guidance - published in the Federal Register on March 21, 2001.

We thank the Agency for your consideration of our comments. Should you have any question, please contact Ivone Takenaka, Ph.D. (Corporate Regulatory Affairs – Policy & Information Coordinator) at 847-935-9011 or by FAX at 847-938-3106.

Sincerely,

RPuhl for DLSporn

Douglas L. Sporn

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COMMENTS TO FDA
Draft Guidance For Industry on
"Disclosing Information Provided To Advisory Committee In Connection With Open Advisory Committee Meetings Related To The Testing Or Approval Of Biologic Products And Convened By The Center For Biologics Evaluation And Research".
Docket No. 01D-0086

Abbott Laboratories is pleased to provide the following comments:

General Comments:

Abbott would like to know whether there would be a process in place if the sponsor and the agency disagree on what should be redacted. Please describe the process.

In addition, we are concerned with the proposed time frames for submission of material to the advisory committee (Section V). With new products it is difficult to submit the information either 19 or 45 days prior to the committee meeting because changes often occur right up to the panel meeting. The guidance document does not describe how these situations will be addressed. We suggest addressing this item and exploring mechanisms to reduce the cycle time, such as, the use of closed session panel review of confidential information.

Specific Comments:

- **Section IV.A.** FDA has stated that sponsors are encouraged to submit an electronic version of the advisory committee package. Please provide further guidance on the format and preferred software program that electronic versions should be provided in.

- **Section IV.B.3.** We suggest deleting the requirement to justify why provided information is necessary to the advisory committee when requesting an exemption from public disclosure. Because the meeting topic relates to product testing or approval, sponsors are interested in providing the advisory committee with relevant information to make a decision. Sponsors are not interested in providing extraneous information. To require a detailed justification increases the amount of paperwork drafted by the sponsor and reviewed by the Agency.

- **Section IV.C.** In the section describing material ordinarily subject to disclosure, the Agency states it will make an exception when the "sponsor demonstrates [disclosure] will cause competitive harm." This requirement is beyond the requirements of the Federal Administrative Procedure Act (APA). Under the APA, an agency may not release "trade secrets and commercial or financial information obtained from a person as privileged or confidential." The APA does not require the higher burden "demonstrating [disclosure] will cause competitive harm." Therefore, we request deletion of this item.

- **Section V.A.** We request that FDA specify the number of copies of the advisory committee background package that should be submitted by the sponsor.

- **Section V.A.3.** Under this section, the sponsors' fully releasable submission is sent to the Access Litigation and Freedom of Information (ALFOI) staff for redaction review. Since the submission has already been designated "fully releasable" by the sponsor, we question the need for an ALFOI redaction review. Elimination of this step could be used to condense the time frame.

- **Sections V.A.6 and B.11.** The draft guidance proposes that SACS will send to the sponsor 14 business days prior to the advisory committee meeting by overnight mail a copy of the redacted version of the CBER review package. The sponsor would receive this package 13 days prior to the meeting, with the expectation that discussions on that package would be finalized by the COB 9 days prior to the meeting. This allows the sponsor only 3 full business days to review and comment on the redacted CBER package. Depending on the size of the CBER package, a 3-day review by the sponsor may not be feasible. It is requested that the final guidance is written to allow the sponsor 5 full business days to review and comment on the CBER package prior to finalizing the content with the CBER review.

- **Section V.A.10.** We request that FDA define what constitutes a "reasonable" number of hard copies for distribution to the committee and public.

- **Section V.C.** We understand that there may be instances where an application is under priority review and, in order to satisfy the agency's statutory obligations under FACA and the FOIA, allowances must be made for missing the PDUFA performance goal of acting on the priority application within 6 months of receipt. However, in those circumstances, the PDUFA performance goal should only be extended to account for the time allowed for the sponsor's advisory committee submissions and CBER review (i.e. 19 days for a fully releasable sponsor submission or 45 days for a sponsor submission that contains material designated by the sponsor as exempt from disclosure). Therefore, we recommend that the final guidance be written to define this allowed exemption from the PDUFA performance goal as such.

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