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

RE: Medical Devices; "Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings;" Draft Guidance for Industry and FDA Staff [Docket 01D-0297]

Dear Sir or Madam:

Abbott Laboratories submits the following comments in response to the Agency's request for comments on the draft guidance "Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings," published in the Federal Register on July 18, 2001 at 66 FR 37483.

We appreciate the opportunity to comment on FDA's draft guidance document. We begin our comments with some substantive concerns regarding the release of certain information. We follow with procedural suggestions to further increase the usefulness of the guidance document. By outlining the procedures associated with compiling information for advisory panel meetings, we feel the document will be extremely useful to industry, the public, and FDA. However, we have some suggestions to make the process even more efficient.

Release of Information

According to the guidance document, the following types of information are considered releasable prior to or at open public panel meetings: (1) pre-decisional/deliberative notes and (2) non-clinical laboratory and clinical protocols. For the following reasons, we respectfully disagree.

We are concerned with the Center's decision to make pre-decisional memoranda available to the public despite the Center's acknowledgement that such pre-decisional memoranda often qualifies for protection under the Freedom of Information Act (FOIA). Device regulations, 21 CFR § 814.9, specifically recognize the confidential nature of a premarket approval application (PMA).

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Pre-decisional memoranda contain information pertaining to the existence of the PMA and reviewer thoughts regarding the contents of the application, which is protected under 21 CFR § 814.9 and FOIA. The public release of such information prior to the panel meeting is premature and can negatively impact the sponsor and its pending application. Knowing that such material will be released to the public, reviewers may temper their discussion and memoranda. Such self-monitoring will impact advisory committees because they will not receive the benefit of candid reviewer comments. We recommend that CDRH not release pre-decisional memoranda to the public in connection with advisory panel meetings as such information qualifies for confidential protection under FOIA and the medical device regulations.

Clinical and non-clinical laboratory protocols are described as information generally considered available for public disclosure. We feel that as a general rule such material should be afforded protection under FOIA exemption § 552(b)(4). Study strategy is a company asset, provides a competitive advantage, and is specific to the company and its product. Therefore, such material should not be considered generally releasable.

Pre-decisional/deliberative notes and non-clinical laboratory and clinical protocols are protected information, which should not be released to the public as part of the advisory panel meeting process. We recommend CDRH modify its guidance document to provide confidential protection to these areas.

Procedural Suggestions to Further Increase the Usefulness of the Guidance Document

Establishing a clear procedure for panel meeting preparation is beneficial because it defines the types of information expected of the sponsor and the FDA. To further the usefulness of this document we have specific recommendations regarding the timeframes established in this guidance document, the flexibility needed to maximize the effectiveness of panel meetings, and the information provided from FDA to the sponsor.

In regard to timeframes, CDRH states it will notify a sponsor that a submission is going to the advisory committee approximately eight weeks prior to the panel meeting, which according to the established timeframes gives the sponsor one to two weeks to prepare its panel package. To allow the sponsor sufficient time to prepare its panel package we recommend CDRH give the sponsor more time either through an earlier notification or some type of "pre-notification" that the submission is a likely candidate for an upcoming panel meeting. At a minimum, we request the sponsor receive three to four weeks to prepare its panel package.

Flexibility in finalizing the sponsor's panel presentation and slides is requested. As this portion of the sponsor's panel package requires much preparation, we feel it is unrealistic to expect the sponsor to have the final presentation and slides available at the time the sponsor's package is submitted to the Agency.

Furthermore, we recommend allowing flexibility in addressing substantive changes to the sponsor's package. If substantive changes arise after the sponsor has submitted is panel package, the guidance document should allow the sponsor to update its package despite the established timeframes. Without such flexibility, the ability of the sponsor and Agency to present important, relevant information to the advisory committee is impacted.

Relying on 21 CFR § 14.35(d)(2), CDRH has adopted a strict rule on the acceptance of material after the timeframes specified in the document. Specifically, the guidance document states, "if a submission from a sponsor is not received by CDRH within the timeframes listed, it will not be

forwarded to the committee and will not be considered by the committee." We are concerned that such a policy will hamper the panel meeting process and limit the advisory committee from receiving information it feels is necessary to its decisions. As the preparation for a panel meeting is a very intense activity for a sponsor, there are many legitimate situations in which material will not be available within the specified timeframes. To disallow the presentation of such information to the panel will impact the panel's ability to consider all the information relevant to the decisions the panel is to make. Such an approach will impact the effectiveness of the advisory committee, and make the panel meeting process much less efficient for all parties. Furthermore, per 21 CFR § 14.35(d)(2), the individual advisory committee should have ultimate discretion in determining a cutoff date after which material will no longer be accepted. We recommend that the submission of such additional material be in a redacted addendum and provided to the panel at least three weeks prior to the meeting.

In the process of addressing public disclosure, CDRH should not overlook the impact such a process will have on the ability of sponsors to adequately prepare for panel meetings and the information needed by the panel to make informed decisions. For these reasons, we recommend CDRH adopt a more flexible approach to the timeframes presented in the guidance document.

Finally, we request that CDRH incorporate mechanisms to make information available to sponsors earlier in the process, thus allowing sponsors to better prepare for panel meetings. Specifically, we request that CDRH make panel questions and FDA internal documentation available to the sponsor seven weeks prior to the panel meeting, rather than providing an index three to four weeks and discussion one week prior to the panel meeting. The availability of such information earlier in the process will allow sponsors to better prepare for panel meetings and provide for more efficient proceedings.

By strengthening the confidential protections afforded to sponsors, providing greater flexibility of proposed timeframes, and advising sponsors of panel questions and FDA internal documentation earlier in the process, we believe the guidance document will improve the efficiency of CDRH panel meetings, while addressing the release of information to the public. Thank you for your consideration of these comments. Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

for:

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