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May 18, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20857

Re: Docket Number 2007D-0021; Draft Guidance for Industry: Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members; February 2007

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide the following comments on the above cited draft guidance document. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for new cures.

General comments

PhRMA appreciates the predictability the guidance and timelines will provide. Public advisory committee meetings provide sponsors the opportunity to receive valuable feedback and information from FDA's external experts regarding product development. Sponsors devote a significant amount of time and resources to develop appropriate advisory committee briefing materials. Ample time to develop briefing materials and communication with FDA regarding the specific issues to be discussed at the meeting are crucial to ensuring quality materials. We believe specific comments below will strengthen the guidance in these areas. Furthermore, seeking judicial review of the Agency's determination with regard to disclosure of information should be seen as a last resort. Every effort should be made for the parties to seek understanding of issues and agree on disclosure before a suit needs to be filed. As described below, we recommend the Agency provide dispute resolution or an administrative appeal for Agency review of the issue before requiring a suit to be filed in a federal court to prevent disclosure of arguably confidential material.

Specific Comments and Recommendations

1. Lines 173 – 180 (Section III B). FDA differentiates between two types of advisory committee meetings – those for which briefing materials may contain information that, under certain circumstances, could be considered to be exempt from public disclosure under FOIA, and those for which briefing materials do not contain such information. FDA also describes timelines for disseminating briefing materials based on they type of meeting, i.e., the Agency "intends" to post briefing materials on the FDA Web site "at least" two full business days for the former type of meeting and "probably" will make briefing materials available on the FDA Web

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site "more than" two full business days before the latter type of meeting. More definitive statements regarding FDA activity are warranted in this section in that they will lead to greater predictability and a more efficient process. Furthermore, unless the Agency is willing to commit to a longer timeframe for posting materials that do not contain information that could be considered to be exempt from disclosure under FOIA, the distinction between the two posting timelines is slight and unnecessary, especially considering "no later than two business days" adequately describes both proposed timelines.

Recommendation: The guidance should be revised to state, "We will post all publicly available briefing materials on our Web site no later than two full business days before the first day of an advisory committee meeting."

2. Lines 263 – 264 (Section IV A). FDA states that for open advisory committee meetings that involve sponsor-prepared briefing materials, approximately 11 weeks before the meeting is scheduled to occur, FDA intends to notify a sponsor that an advisory committee will consider an issue that is directly relevant to the sponsor. For clarity, we suggest that the statement be consistent with the timeline in the Appendices (i.e., 55 days). Furthermore, as noted above, the development of appropriate advisory committee briefing materials requires a significant amount of time and resources on the part of a sponsor. As a result, sponsors need as much advance notice of an advisory committee meeting as possible. Notification less than 55 days prior to the meeting severely impacts the sponsor's ability to prepare briefing materials.

Recommendation: PhRMA recommends the guidance be revised to state, "For open advisory committee meetings that involve sponsor-prepared briefing materials, no later than 55 days before the meeting is scheduled to occur, FDA will notify a sponsor that an advisory committee will consider an issue that is directly relevant to the sponsor."

3. Lines 266 – 267 (Section IV A). The guidance states, "FDA will explain the meeting's focus to the sponsor and also may advise the sponsor about the information it may wish to include in its briefing materials." At the time a sponsor is notified of the meeting, it should also understand the specific issues to be discussed and the type of information that should be included in the briefing material. Ideally, draft questions for the advisory committee will be shared with the sponsor at this time. We believe sharing this type of information would enable sponsors to provide briefing materials that directly address the issues to be discussed during the meeting.

Recommendation: The guidance should be revised to state, "FDA will explain the meeting's focus to the sponsor and will advise the sponsor about the information it may wish to include in its briefing materials. FDA will make every effort to make available the draft questions for the committee at the time it informs a sponsor that an advisory committee will consider an issue that is directly relevant to the sponsor."

4. Line 278 – 280 (Section IV A). The guidance states that defamatory, irrelevant, or intemperate statements are inappropriate for inclusion in briefing materials. We question whether this statement is needed. From our perspective, briefing materials are developed to be fact-based and professional in tone. With regard to inclusion of irrelevant material, it is our experience that sponsors include information they believe to be needed based on the guidance provided by FDA about the issues that will be discussed at the advisory committee meeting. Unfortunately, oftentimes sponsors are not given sufficient details regarding the specific issues for discussion when the briefing documents are developed and the degree to which irrelevant material is included is generally directly related to the amount of detail provided to the sponsor.

We anticipate that to the extent sponsors are provided draft questions for the committee at the time they are notified of the advisory committee meeting (see above), irrelevant information will not be included in the briefing materials.

Recommendation: PhRMA recommends the statement be deleted.

5. Lines 348 – 353 (Section IV C). The draft guidance states that advisory committee members will receive complete copies of the briefing materials, including information that is exempt from disclosure under FOIA. Furthermore, the Agency will not include information exempt from disclosure under FOIA in the publicly available version of the briefing materials, and the Agency will notify the committee members that such exempt information may not be discussed during any open portion of the advisory committee meeting. In our view, it is appropriate to notify advisory committee members as described in the draft guidance. However, we believe the direction provided to advisory committee members should be strengthened.

Recommendation: Advisory committee members should be notified that they may not release exempt materials before, during, or after the advisory committee meeting and can only use the exempt materials for their work on the advisory committee. We recommend this section of the guidance be revised to reflect this standard.

6. Lines 428 – 430, 449 – 459, 493 – 496 (Sections IV E and IV F). The draft guidance describes four courses of action a sponsor might take after receiving FDA's final decision regarding information that is exempt from disclosure under FOIA. A sponsor that disagrees with FDA's determination has only one option – to seek judicial review to prevent the disclosure. FDA does not offer an opportunity for conflict resolution or administrative appeal in this situation. Due to resource issues and timeline constraints, seeking judicial review is not an optimal course of action for the sponsor or for FDA. This presents an untenable situation for a sponsor who is interested in protecting its perceived confidential commercial or trade secret information yet also recognizes the importance of fully participating in the scheduled advisory committee meeting. Therefore, we believe FDA should offer sponsors an opportunity to present its view in a formal dispute resolution or administrative appeal before seeking judicial review.

Recommendation: PhRMA recommends FDA amend the text in Option 4 to include an opportunity for conflict resolution or administrative appeal before seeking judicial review.

7. Lines 454 – 459 (Section IV E). In the draft guidance, if a sponsor chooses to seek judicial review to prevent FDA from releasing certain information in the briefing materials, the Agency will not release the information in dispute and may postpone the advisory committee meeting. The procedures that will be followed in the event a sponsor seeks judicial review need to be clarified in the guidance.

Recommendation: FDA should make it clear in the guidance that they will not release *any* briefing materials to the advisory committee or publicly in the event the advisory committee meeting is postponed. The guidance should also make clear that if FDA does not postpone the advisory committee meeting; only non-disputed materials will be released.

8. Lines 466 – 468 (Section IV E). The draft guidance states that during the open portion of the advisory committee meeting, the sponsor should not discuss any information that the FDA and the sponsor agree is exempt from disclosure under FOIA. This statement is an unreasonable restriction on the sponsor's right to use its own proprietary or confidential

information. It is appropriate and necessary to restrict the advisory committee's disclosure of confidential information included in the briefing materials, but a sponsor may decide during the meeting that certain information should be disclosed. If the sponsor decides to disclose or release certain information at that time, it is their sole right to do so.

Recommendation: This sentence in the guidance should be deleted.

9. Lines 478 – 483 (section IV F). With regard to FDA-prepared advisory committee briefing materials, the body of the guidance states that the Agency will send its briefing materials to the sponsor as described in the timelines. The only timeline including a commitment from FDA to share its briefing materials is Appendix A, which states that between 21 and 14 days before an advisory committee meeting, FDA will send a copy of its briefing materials, as prepared for public release, to the sponsor for review. We believe the final guidance needs to provide a greater commitment on the part of FDA with regard to the timeframe for sharing its briefing materials with the sponsor. Furthermore, the sponsor should be afforded ample opportunity to review the FDA's briefing materials and the proposed redactions, and to discuss and disagree with the Agency when necessary.

Recommendation: FDA's materials should be provided to the sponsor at the same time the sponsor's package is due to the Agency, i.e., 22 days before the advisory committee meeting. This commitment should be reflected in the appendix and the following sentence should be added to section IV F, "FDA will send a copy of its briefing materials to the sponsor for review no later than 22 days prior to the first day of the advisory committee meeting."

10. Appendix B. In Appendix B, FDA intends to notify the sponsor that they are taking an issue directly relevant to the sponsor to an advisory committee 55 business days before the meeting. The sponsor is expected to submit two versions of its briefing materials: a complete (unredacted) version and a redacted version only 13 business days later. This is an unrealistic timeframe to expect the sponsor to respond with two versions of the briefing material.

Recommendation: To help ensure quality briefing material and a productive advisory committee meeting, we recommend revising the timeline to provide the sponsor with at least 20 business days to develop briefing materials. Additional changes to the timeline are recommended to accommodate this change.

Sincerely,

