



April 27, 2007

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane RM 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members
[Docket No. 2007D-0021]

Dear Sir/Madam:

We offer the following comments as you finalize this guidance document.

Line 165 states that information submitted to the advisory committee from individuals or organizations who are not sponsors is not considered to be briefing materials with the implication that those materials will not be available for public view prior to the advisory committee meeting. We urge the Agency to reconsider this provision, as those materials may be relevant to the preparatory activities of the sponsor.

Line 177 (as well as several additional references throughout the document) states that, for FDA briefing materials which do not contain information exempt from public disclosure, FDA will probably (emphasis added) make the briefing materials available on their website more than two full business days before the committee meeting is scheduled to occur. This language is vague and provides no outer bounds. We recommend revising it to state that the agency will post the information no later than 2 days prior to the meeting, and will attempt to provide it earlier when feasible.

Line 185 begins an explanation of the distinction that may result in materials being posted early. However the narrative regarding whether materials which are fully releasable without redaction vs. whether they were subject to disclosure under FOIA is not clear. The two examples did not seem to illustrate the point. We request that the agency clarify how those two categories differ from each other.

Line 266 states that, when FDA notifies a sponsor of an impending meeting, they may (emphasis added) advise the sponsor about the information it may wish to include in its briefing materials. We urge the agency to formalize a step in the process in which the Agency informs the sponsor about the scope and objective of the planned meeting in writing.

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Line 454 refers to a judicial review in federal court in the event of disagreement between the Agency and sponsors regarding the releasability of particular information contained within the briefing document. We urge the Agency to consider a step prior to that in which the concerns of the sponsor could be escalated within FDA for resolution similar to other processes in place for PDUFA products.

In addition, the Appendix A states that FDA will send a copy of their briefing materials intended for the public to the sponsor for review. We request that the guidance document indicate that the sponsor will receive an unredacted copy of the applicable portions of the briefing document.

We also request that the document specify that the Agency materials will be posted at approximately the same time as the sponsor's material to provide for a complete presentation to the viewing public.

Thank you for the opportunity to comment on this draft guidance.

Sincerely,



Kathleen Grim
Executive Director
Regulatory Compliance