AstraZeneca

Date: APR 2 7 2007

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

Re: Docket Number 2007D-0021
Response to FDA Call for Comments
Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members

Dear Sir or Madam:

Reference is made to the February 28, 2007 Federal Register notice announcing the request for comments on Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members.

AstraZeneca has reviewed this draft guidance and our comments are attached.

Please direct any questions or requests for additional information to me, or in my absence, to Cathie Schumaker, Executive Director FDA Liaison, at 301-770-4479.

Sincerely,

Lynley K Thinnes

Lynley K Thinnes, Director
Regulatory Affairs
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LKT
Enclosure

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Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members		
Section	**Page or Line Number**	**Comment or proposed replacement text**
III. B	175 and 179	Current guidance wording states no definitive commitment to posting publicly available version of advisory committee information, see line 175: "we intend to post publicly" and line 179: "will probably make materials available on the FDA website. We suggest that stronger wording be included showing the commitment for making the public version of AC briefing materials available on the FDA website.
III. B	Lines 202-215	For AC meetings that last more than one day and address more than one topic for a drug, suggest briefing materials for **all** days of the AC meeting should be available on the website at the same time (at least 2 full business days prior to the beginning of the Advisory Committee meeting) as the materials apply to the same. Suggested revision (additions in bold/cap): For meetings that last more than one day, we ~~intend to~~ **WILL** post the publicly available version of the briefing materials **FOR ALL MEETING DAYS** on our Web site at least two full business days before the **MEETING** ~~topic to which the materials pertain will be discuss~~ed.
IV. A	Line 264	Line 264 states 11 weeks notice but the Appendix states 55 business days. Recommend that these be consistent with line 264 revised to say Approximately 55 business days before the meeting is scheduled to occur.
IV. D	Line 372-379	For the review of advisory material it would be helpful to add actual timeframes for review and when to expect contact with Sponsor or appropriate follow up.
IV. E	Lines 428-429	Suggest that the sponsor can provide additional information to the briefing materials to allow for new information pertinent to the briefing materials with appropriate justification. Suggested revision (additions in bold/cap): Once we have notified the sponsor of our final decision, no new documents or information may be added to the briefing materials, **UNLESS THE SPONSER PROVIDES JUSTIFIABLE REASONS FOR THE CONSIDERATION OF ADDITIONAL INFORMATION**
Appendix A	Line 602	Suggest that the Advisory Committee timeline include FDA action to notify sponsor within a pre-defined timeframe of the intention to request briefing materials for an advisory committee meeting