Biotechnology Industry Organization

June 9, 2015

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

**Re: Docket No. FDA–1999-D-1315: Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Draft Guidance for Industry; Availability**

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the revised draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of Prescription Drug User Fee Act (PDUFA) Products."

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

BIO commends FDA on the revised Draft Guidance, as it will provide additional clarity for Sponsors requiring formal meetings with the Agency. BIO believes that effective communication between the Sponsor and FDA can help to expedite drug development, and that clear guidance on when a specific type of meeting is appropriate creates a more predictable and transparent drug development and review process.

In particular, BIO appreciates that the guidance clarifies:

- The 14 calendar day window for a meeting date beyond the 30 days from the date request receipt of a Type A meeting (or 60 days for Type B, or 75 days for Type C).

- The inclusion of Breakthrough Therapy development and certain post-action meetings, Risk Evaluation and Mitigation Strategies (REMS) meetings, and post-marketing requirement meetings within Type B meetings.

- The additional flexibility provided by allowing a Sponsor/Applicant to request the Written Response meeting format for pre-IND and Type C meetings.

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Additionally, there are a number aspects of the Draft Guidance for which BIO offers further considerations or requests for clarification and/or revision:

- BIO suggests that timeline nomenclature (e.g., "30 days" versus "one month") be standardized throughout the document.

- When a Written Response is determined to be the most appropriate type of response by the Agency, BIO suggests that the Agency include a general explanation for why a meeting is not necessary. This information will be helpful for requestors to understand which situations will warrant a face-to-face meeting, a teleconference, or a videoconference.

- Regarding Chemistry, Manufacturing, and Controls (CMC), in some cases FDA has requested meetings during review, but has not provided background information on what is planned to be discussed. It would be helpful to the Sponsor if FDA would provide background materials or topics for discussion prior to such meetings. (For example, whether the issue pertains to drug substance or drug product.) This would allow the Sponsor to prepare accordingly and identify the appropriate subject matter experts to attend such meetings.

- While live meeting minutes are a useful tool, there is some concern that they will detract from the more substantive discussion. BIO recommends the guidance specify that time allotted for meeting minutes should be accounted for, in addition to the time allotted for discussion.

- For combination products, BIO encourages the Agency to specifically list the Center for Devices and Radiological Health (CDRH) as an expert who should participate in meetings.

BIO has included specific line-by-line comments in the following chart. BIO appreciates this opportunity to comment on this Draft Guidance and we would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Managing Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

**SPECIFIC COMMENTS**

| SECTION | ISSUE | PROPOSED CHANGE |
|---|---|---|
| **III. INTRODUCTION** | | |
| *A. TYPE A MEETING* | | |
| Lines 105-106 | Is there a situation where a Type A meeting can be requested after the 3 months from the action date? | BIO recommends that FDA define the difference in requirements/expectations between post-action meetings that would be granted within 3 months versus after the 3 months. Specifically, what kind of FDA regulatory actions other than approval would constitute a post-action meeting within 3 months vs. post 3 months? The same example of "issuance of complete response letter" provided under both Type A and Type B may not be sufficiently clear to sponsors. |
| Lines 110-112 | "Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request. If a request is for a meeting date that is beyond 30 days from the date of the request receipt, the meeting date should be within 14 calendar days of the requested date." | BIO suggests clarify that a briefing package should be included with the meeting request: "Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request**, including a briefing package**. If a request is for a meeting date that is beyond 30 days from the date of the request receipt, the meeting date should be within 14 calendar days of the requested date." |
| *B. TYPE B MEETINGS* | | |
| Lines 122-125 | "In both scenarios, the FDA intends to notify the requester of the date it intends to send the written response within the specified time frame for assessing the meeting request (i.e., within 21 days for a Type B meeting request)." | BIO proposes the following statement should be added to the end of this section to clarify the time frame of when the written responses will be received:<br><br>"In both scenarios, the FDA intends to notify the requester of the date it intends to send the written response within the specified time frame for assessing the meeting request (i.e., within 21 days for a Type B meeting request). **The written response should be transmitted to the** |

| SECTION | ISSUE | PROPOSED CHANGE |
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| | | **requester within 60 days of FDA receipt of the meeting request.**"<br><br>Additionally, BIO requests that FDA provider greater clarity on whether pre-IND meeting questions to FDA could accompany the submission of the IND application. |
| Line 127 | "Pre-emergency use authorization meetings" | BIO requests that FDA provide more information on these types of meetings. |
| Lines 155-161 | "Generally, with the exception of products granted breakthrough therapy designation status, we will not grant more than one of each of the Type B meetings for each potential application (e.g., investigational new drug application (IND), new drug application (NDA), biologics license application (BLA)) or combination of closely related products developed by the same requester (e.g., same active ingredient but different dosage forms being developed concurrently), but we can do so when it would be beneficial to hold separate meetings to discuss unrelated issues." | Typically there are separate Type B meetings for CMC (EOP2 and Pre-BLA). BIP recommends clarifying with examples of what meeting may qualify as unrelated issues:<br><br>"Generally, with the exception of products granted breakthrough therapy designation status, we will not grant more than one of each of the Type B meetings for each potential application (e.g., investigational new drug application (IND), new drug application (NDA), biologics license application (BLA)) or combination of closely related products developed by the same requester (e.g., same active ingredient but different dosage forms being developed concurrently), but we can do so when it would be beneficial to hold separate meetings to discuss unrelated issues **(e.g., CMC, clinical)**." |
| Lines 156-157 | Throughout this section, it mentions that EOP1 and EOP2 meetings are also Type B meetings. However, lines 156-157 states that "...we will not grant more than one of each of the Type B meetings for each potential application..." | Since generally no new application is needed at EOP1 and EOP2, BIO requests that this be clarified. |
| *C. TYPE C MEETINGS* | | |

| SECTION | ISSUE | PROPOSED CHANGE |
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| Lines 179-180 | "The written response should be transmitted within 75 days of FDA receipt of the meeting request." | BIO suggest clarifying that the written responses should be transmitted to the "requestor:" "The written response should be transmitted **to the requestor** within 75 days of FDA receipt of the meeting request." |
| **VII. MEETING PACKAGE CONTENT AND SUBMISSION** | | |
| Lines 448-449 | "A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question." | BIO suggests updating with another option for deleting the "brief summary," as an appropriate link to document may help with the Dossier being more succinct and avoid duplicate text: "A list of the final questions for discussion grouped by discipline and with **either** a brief summary for each question to explain the need or context for the question **or appropriate link to the core briefing document.**" |
| **XI. RESOLUTION OF DISPUTE ABOUT MINUTES** | | |
| **Lines** | "The addendum will also document any continued requester objections." | BIO recommends that a statement should be added to the end of this section to clarify an expected time frame for receipt of the Agency's position:<br><br>"The addendum will also document any continued requester objections. **The FDA will communicate their decision to the requester within 30 days of the initial correspondence.**" |