March 27, 2018

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

Re: Docket No. FDA–2017-D-6530: FDA Draft Guidance, Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products.

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments in response to the FDA's Draft Guidance entitled *Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products (Guidance).*

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 recognizes the importance of good meeting management practices and acknowledges on behalf of industry that dissemination of these practices contributes to fostering a more robust system of dialogue and communication with FDA. BIO appreciates that FDA has issued the revised Guidance to reflect many of the meetings management enhancements agreed-upon under PDUFA VI. The biopharmaceutical industry values the opportunity for scientific dialogue with the Agency and believes the PDUFA meeting structure effectively promotes biomedical innovation. Formal face-to-face meetings are a central mechanism for aligning on complex scientific matters throughout drug development and are complemented by other channels of timely, interactive communication, including written-responses, teleconferences, and email. We envision this Guidance, once additional points of clarification are made, to be a reliable tool for Sponsors to engage in more productive discussions with the Agency. BIO's general comments on the Guidance are set forth below, followed by specific areas where we request clarification (beginning on page three):

- **Surrogate Endpoint/Biomarker Type C Meeting**: We are pleased that the Guidance formally implements the new Type C meetings to facilitate early consultation between review divisions and Sponsors on the use of a biomarker as a new surrogate endpoint for the development of a product that has never been previously used as the primary basis for product approval in the proposed context of use. This represents an important new opportunity for sponsors and FDA to continue to advance the science of biomarkers and facilitate more routine use in drug development, both through traditional and accelerated approval. BIO encourages FDA and sponsors to embrace this new meeting type. Further, we suggest that FDA

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should independently track this meeting type separate from other Type C meetings as part of its annual PDUFA Performance Report, so that the Agency and other stakeholders are able to track metrics of the Type C meetings for consultation around biomarkers versus other Type C meetings.

- **Background Package Contents**: Combination products and companion diagnostics are increasingly common in drug development and this necessitates closer coordination between CDER/CBER and CDRH. We are pleased that the Guidance lays out considerations for preparing the background package in a way that can help to expedite these cross-center consultations, including human factors, engineering studies, and combination product constituent parts. CDRH staff attendance and active participation in meetings helps to encourage appropriate coordination across medical products centers and alignment on key review timelines. Early pediatric study planning is also an imperative in drug development and BIO agrees that this topic should be highlighted in the background package and formal meetings, especially given changes to pediatric study requirements under the FDA Reauthorization Act of 2017.

- **Emerging Data Sources**: BIO believes that the PDUFA formal meeting framework provides the flexibility necessary to discuss emerging and innovative new data sources and evidence. With respect to data submitted as part of a background package, we suggest that FDA explicitly state that the Agency welcomes discussion of patient experience data, novel trials designs, and real-world evidence during the established formal PDUFA meetings.

- **Preliminary Responses to Sponsors**: A key process enhancement under PDUFA VI is the exchange of FDA's preliminary response either 2 or 5 days prior to the meeting depending on the meeting type. This earlier information exchange allows for more productive dialogue on key outstanding issues at the meeting, and in some instances, cancelling of the face-to-face meeting if all issues are resolved. We encourage FDA to closely track, monitor, and report data on preliminary response in the annual PDUFA Performance reports. While we commend FDA for providing preliminary comments prior to a meeting, we continue to encourage FDA to hold face-to-face meetings when the meeting requested (or FDA's written response) will involve discussions about emerging data sources such as patient experience data, novel trial designs, and real-world evidence.

- **Meetings Timelines**: With the implementation of the new Type B (EOP) meetings, the timelines for requesting meetings, scheduling submitting background packages, exchanging preliminary responses, and holding the meeting has become increasingly complex. While the charts in the guidance are helpful, we encourage FDA to include more detailed graphical timelines of the meetings process for all meeting types. For example, such a graphic may include timelines regarding when the FDA will review a submitted request, when a Sponsor should expect to receive a response to the submitted meeting request, when the background package should be submitted, and the meeting is expected to be scheduled, and other relevant timelines, all in relation to when an initial meeting request is submitted.

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BIO appreciates this opportunity to submit comments regarding FDA's Draft Guidance, Formal Meetings between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/
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SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
I. INTRODUCTION		
II. BACKGROUND		
III. Meeting Types		
Type A Meeting		
Type B Meeting		
Type B (EOP) Meeting		
Type C Meeting		
IV. Meeting Formats		
V. Meeting Requests		
Lines 171-198, 200-235, 292-294	The two lists included in the guidance document that outlining what sponsors "should" and "must" include when requesting meetings are confusing and would serve better if consolidated. Furthermore, additional information regarding denying requests based upon lack of required elements should clarified.	We suggest that FDA provide a single list of information to be provided in meeting requests and background packages, and delineate which items are required (i.e. must be included) and which materials can be included upon the Sponsor's discretion (i.e., should be included). The FDA should also clarify whether the "must list" may also be tied to the ability to deny requests that do not have substantive "required" elements.
Lines 197-198	In order to facilitate a timely submission of the Meeting Request, flexibility should be allowed in the amount of information required to accompany each of the draft questions.	BIO suggests that follow line edit: 11. A list of proposed questions, grouped by FDA discipline. For each question there should be a brief explanation of the context and purpose of the question. The context/purpose of the question(s) can also be integrated into the brief background on the purpose of the meeting and the issues underlying the agenda.
Lines 229-235	Changes are proposed to aid the Sponsor in determining the "nonessential" FDA attendees. It may not always be clear to the Sponsor which FDA staff members are not otherwise essential to the application's review.	BIO suggests the follow line edits: 7. A list of requested FDA attendees and/or discipline representative(s). Note that requests for attendance by FDA staff who are not otherwise essential to the application's

SECTION	ISSUE	PROPOSED CHANGE
		review may affect the ability to hold the meeting within the specified time frame of the meeting type being requested. Therefore, when attendance on the proposed dates is not possible by ~~nonessential~~ FDA staff determined by FDA to be nonessential, ~~is requested, the meeting request should provide a justification for such attendees and state~~ the Sponsor may be requested to indicate whether or not a later meeting date is acceptable ~~to the requester~~ to accommodate the nonessential FDA attendees.
VI. Assessing and Responding to Meeting Requests		
Meeting Denied		
Meeting Granted		
VII. Meeting Package		
Timing of Meeting Package Submission		
Where and How Many Copies of Meeting Packages to Send		
Meeting Package Content		
VIII. Preliminary Responses		
IX. Rescheduling and Canceling Meetings		
X. Meeting Conduct		
XI. Meeting Minutes		
Lines 582-607	The section on meeting minutes lacks some specificity.	BIO suggests that the FDA provide a confirmation of no changes for the record. We also suggest that the guidance explicitly state that changes documented in an addendum will be provided to the requester and that the FDA will provide a timeline of 30 days for responses both for cases where there are and there are not changes.
References		
Appendix: Summary of Meeting Management Procedural Goals		