Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Neel Patel at 301-796-0970 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2018
Procedural

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Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides recommendations to industry on formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This guidance does not apply to meetings associated with the development of products intended for submission in, or with the review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act), biologics license applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act), or submissions for devices under the FD&C Act.[2] For the purposes of this guidance, *formal meeting* includes any meeting that is requested by a sponsor or applicant (hereafter referred to as *requester(s)*) following the procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference/videoconference, or written response only (WRO)).

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] For information on meetings for new drug applications and 351(a) BLAs, see the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs or Biologics guidance web pages at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm and https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

This guidance discusses the principles of good meeting management practices (GMMPs) and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings.[3]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The GMMPs in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately.

As part of the reauthorization of the Biosimilar User Fee Act (BsUFA),[4] the FDA has committed to specific performance goals that include meeting management goals for formal meetings that occur between the FDA and requesters.[5]

III. MEETING TYPES[6]

There are five types of formal meetings that occur between requesters and FDA staff to discuss development and review of a biosimilar or interchangeable product: Biosimilar Initial Advisory (BIA), Biosimilar Biological Product Development (BPD) Type 1, BPD Type 2, BPD Type 3, and BPD Type 4.

[3] The previous guidance for industry *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* published November 18, 2015, has been withdrawn.

[4] The Biosimilar User Fee Act of 2012 (BsUFA I) added sections 744G and 744H to the FD&C Act, authorizing FDA to collect user fees for a 5-year period from persons that develop biosimilar biological products. BsUFA was reauthorized for a 5-year period in 2017 under Title IV of the FDA Reauthorization Act of 2017 (BsUFA II), enacted on August 18, 2017.

[5] See the BsUFA II goals letter titled "BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022" available on the FDA website at https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.

[6] The meeting types and goal dates are described in the BsUFA II goals letter and apply to formal meetings between FDA staff and requesters of BsUFA meetings; they do not apply to meetings with CDER Office of Generic Drugs, CDER Office of Compliance, or CDER Office of Prescription Drug Promotion.

Requesters are not required to request meetings in sequential order (i.e., BIA, BPD Type 2, BPD Type 3, then BPD Type 4). The meeting type requested depends on the stage of the development program and/or the advice being sought. Although the FDA would, in general, grant one BIA meeting and one BPD Type 4 meeting for a particular biosimilar or interchangeable product, requesters can request, as appropriate, as many BPD Type 2 and Type 3 meetings as needed to support the development and review of a biosimilar or interchangeable product.

A. BIA Meeting

A BIA meeting is an initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the PHS Act may be feasible for a particular product, and if so, general advice on the expected content of the development program. This meeting type does not include any meeting that involves substantive review of summary data or full study reports. However, preliminary comparative analytical similarity data from at least one lot of the proposed biosimilar or interchangeable product compared to the U.S.-licensed reference product should be provided in the meeting package. The analytical similarity data should be sufficient to enable the FDA to make a preliminary determination as to whether licensure under section 351(k) of the PHS Act may be feasible for a particular product and to provide meaningful advice. A general overview of the development program, including synopses of results and findings from all completed studies and information about planned studies, also should be provided.

Extensive analytical, nonclinical, and/or clinical data are not expected to be provided based on the expected stage of development of the proposed biosimilar or interchangeable product. If the requester is seeking targeted advice on the adequacy of any comparative data or extensive advice for any aspect of a planned or ongoing biosimilar or interchangeable development program, a different meeting type should be requested.

B. BPD Type 1 Meeting

A BPD Type 1 meeting is a meeting that is necessary for an otherwise stalled development program to proceed or a meeting to address an important safety issue. Examples of a BPD Type 1 meeting include the following:

- Meetings to discuss clinical holds: (1) in which the requester seeks input on how to address the hold issues; or (2) in which a response to hold issues has been submitted, and reviewed by the FDA, but the FDA and the requester agree that the development is stalled and a new path forward should be discussed.

- Meetings that are requested after receipt of an FDA nonagreement Special Protocol Assessment letter in response to protocols submitted under the special protocol assessment procedures as described in the guidance for industry *Special Protocol Assessment*.[7]

[7] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

- Meetings to discuss an important safety issue, when such an issue is identified and the FDA and requester agree that the issue should be discussed.

- Dispute resolution meetings as described in 21 CFR 10.75 and 312.48 and in the guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the Division Level.*

- Post-action meetings requested after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).

- Meetings requested within 30 days of FDA issuance of a refuse-to-file letter to discuss whether the FDA should file the application.

C. BPD Type 2 Meeting

A BPD Type 2 meeting is a meeting to discuss a specific issue (e.g., ranking of quality attributes; chemistry, manufacturing, and controls such as control strategy; study design or endpoints; post-approval changes) or questions for which the FDA will provide targeted advice regarding an ongoing development program. This meeting type may include substantive review of summary data but does not include review of full study reports.

D. BPD Type 3 Meeting

A BPD Type 3 meeting is an in-depth data review and advice meeting regarding an ongoing development program. This meeting type includes substantive review of full study reports or an extensive data package (e.g., detailed and robust analytical similarity data), FDA advice regarding the similarity between the proposed biosimilar or interchangeable product and the reference product based on a comprehensive data package, and FDA advice regarding the need for additional studies, including design and analysis, based on a comprehensive data package.

- Examples of a BPD Type 3 meeting submission include the following:

  – Comprehensive analytical similarity data that permit the FDA to make a preliminary evaluation of analytical similarity during development. The level of analytical data provided should be similar to what the requester intends to submit in a 351(k) BLA (e.g., full study reports and/or datasets that support the full study reports).

  – Full study report(s) for a clinical study or clinical studies.

- Based on the data and/or datasets and results reported in the full study reports, the FDA encourages the requester to provide an update on the development plan of the proposed biosimilar or interchangeable product. Examples of topics the requester can address as part of a BPD Type 3 meeting in addition to the in-depth data submitted include the following:

  – Proposal for any planned additional studies

155
156 – Proposal for extrapolation
157
158 **E. BPD Type 4 Meeting**
159
160 A BPD Type 4 meeting is a presubmission meeting to discuss the format and content of a
161 complete application for an original biosimilar or interchangeable product application or
162 supplement submitted under 351(k) of the PHS Act. The purpose of this meeting is to discuss
163 the format and content of the planned submission and other items, including the following:
164
165 • Identification of those studies that the sponsor is relying on to support a demonstration of
166 biosimilarity or interchangeability
167
168 • Discussion of any potential review issues identified based on the information provided
169
170 • Identification of the status of ongoing or needed studies to adequately address the
171 Pediatric Research Equity Act
172
173 • Acquainting FDA reviewers with the general information to be submitted in the
174 marketing application (including technical information)
175
176 • Discussion of the best approach to the presentation and formatting of data in the
177 marketing application
178
179
180 **IV. BSUFA FEES ASSOCIATED WITH THE BPD PROGRAM**
181
182 Under the BsUFA user fee provisions of the FD&C Act, BPD fees are assessed for products in
183 the BPD program. BPD fees include the initial BPD fee, the annual BPD fee, and the
184 reactivation fee. No fee is associated with a BIA meeting. For more information about BsUFA
185 fees, including the assessment of BPD fees and the consequences for failure to pay any required
186 BPD fees, refer to the draft guidance for industry *Assessing User Fees Under the Biosimilar*
187 *User Fee Amendments of 2017*.[8]
188
189
190 **V. MEETING FORMATS**
191
192 There are three formats for formal meetings: face to face, teleconference/videoconference, and
193 WRO as follows:
194
195 1. **Face to face —** Traditional face-to-face meetings are those in which the majority of
196 attendees participate in person at the FDA.
197

[8] When finalized, this guidance will represent the FDA's current thinking on this topic.

2. **Teleconference/Videoconference —** Teleconferences/videoconferences are meetings in which the attendees participate from various remote locations via an audio (e.g., telephone) and/or video connection.

3. **Written response only (WRO) —** WRO responses are sent to requesters in lieu of meetings conducted in one of the other two formats described above. Requesters may request this meeting format for BIA and BPD Type 2 meetings.

VI. MEETING REQUESTS

To make the most efficient use of FDA resources, before seeking a meeting, requesters should consult the information publicly available from the FDA that relates to biosimilar or interchangeable product development.[9]

To promote efficient meeting management, requesters should try to anticipate future needs and, to the extent practical, combine related product development issues into the fewest possible meetings.

To request a meeting, submit a written request to the FDA via the respective center's document room (paper submissions) or via the electronic gateway, as appropriate. Written meeting requests must be made in accordance with any applicable electronic submission requirements.[10] Requests should be addressed to the appropriate review division or office and, if previously assigned, submitted to the pre-investigational new drug application (pre-IND) file or application (e.g., investigational new drug application (IND), BLA). Meeting requests sent by fax or email are considered courtesy copies only and are not a substitute for a formal submission.

A meeting request for the development of a proposed biosimilar or interchangeable product with multiple indications that span multiple review divisions should be submitted to the division that has regulatory oversight of the reference product.

The meeting request should include adequate information for the FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

The meeting request should include the following information:

1. The application number (if previously assigned).

2. The development-phase code name of product (if pre-licensure).

[9] See the guidance for industry *Best Practices for Communication Between IND Sponsors and FDA During Drug Development.*

[10] See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.

3. The proper name (if post-licensure).

4. The structure (if applicable).

5. The reference product proper and proprietary names.

6. The proposed indication(s) or context of product development.

7. Pediatric study plans, if applicable.

8. Human factors engineering plan, if applicable.

9. Combination product information (e.g., constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable.

The meeting request must include the following information for the performance goals described in section I.I., Meeting Management Goals, of the commitment letter to apply:[11]

1. The meeting type being requested (i.e., BIA meeting, BPD Type 1, 2, 3, or 4 meeting). The rationale for requesting the meeting type should also be included.

2. The proposed format of the meeting (i.e., face to face, teleconference/videoconference or WRO).

3. A brief statement of the purpose of the meeting. This statement should include a brief background of the issues underlying the agenda. It also can include a brief summary of completed or planned studies or data that the requester intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in overall development plans. Although the statement should not provide the details of study designs or completed studies, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.

4. A list of the specific objectives or outcomes the requester expects from the meeting.

5. A proposed agenda, including estimated times needed for discussion of each agenda item.

6. A list of questions, grouped by FDA discipline. For each question there should be a brief explanation of the context and purpose of the question.

7. A list of planned attendees from the requester's organization, which should include their names and titles. The list should also include the names, titles, and affiliations of consultants and interpreters, if applicable.

8. 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 review

[11] See BsUFA II goals letter.

may affect the ability to hold the meeting within the specified time frame of the meeting type being requested. Therefore, when attendance by nonessential FDA staff is requested, the meeting request should provide a justification for such attendees and state whether or not a later meeting date is acceptable to the requester to accommodate the nonessential FDA attendees.

9. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate scheduling time frame of the meeting type being requested (see Table 2 in section VII.B., Meeting Granted). Dates and times when the requester is not available should also be included.

When submitting a meeting request, the requester should define the specific areas of input needed from the FDA. A well-written meeting request that includes the above components can help the FDA understand and assess the utility and timing of the meeting related to product development or review. The list of requester attendees and the list of requested FDA attendees can be useful in providing or preparing for the input needed at the meeting. However, during the time between the request and the meeting, the planned attendees can change. If there are changes, an updated list of attendees with their titles and affiliations should be provided to the appropriate FDA contact at least 1 week before the meeting.

The objectives and agenda provide overall context for the meeting topics, but it is the list of questions that is most critical to understanding the kind of information or input needed by the requester and to focus the discussion should the meeting be granted. Each question should be precise and include a brief explanation of the context and purpose of the question. The questions submitted within a single meeting request should be limited to those that can be reasonably answered within the allotted meeting time, taking into consideration the complexity of the questions submitted. Similar considerations regarding the complexity of questions submitted within a WRO should be applied.

VII. ASSESSING AND RESPONDING TO MEETING REQUESTS

Although requesters should request a specific meeting type and format, the FDA assesses each meeting request, including WRO requests for BIA and BPD Type 2 meetings, and determines whether or not the request should be granted, the appropriate meeting type, and the appropriate meeting format. Requests for BPD Type 2, 3, and 4 meetings will be honored except in the most unusual circumstances. However, if the FDA determines that WRO format is not appropriate for a requested WRO meeting or that in-person format (i.e., face to face or teleconference/videoconference) is not appropriate for a requested in-person meeting, we will notify the requester that the meeting has been denied, as described in section VII.A., Meeting Denied.

The meeting request should be accompanied by the meeting package (see section VIII.C., Meeting Package Content, for additional information regarding the content of the meeting package). This ensures that the FDA has adequate information to assess the potential utility of the meeting and prepare for the meeting. If the meeting package is not submitted to the review

division with the meeting request, the FDA will consider the meeting request incomplete and generally will deny the meeting request.

A. Meeting Denied

If a meeting request is denied, the FDA will notify the requester in writing according to the timelines described in Table 1. The notification will include an explanation of the reason for the denial. Denials will be based on a substantive reason, not merely on the absence of a minor element of the meeting request or a minor element of the meeting package. For example, a meeting request can be denied because it is premature for the stage of product development, is clearly unnecessary, or is not appropriate for the format requested (e.g., face to face/videoconference/teleconference versus WRO) or the meeting package does not provide an adequate basis for the meeting discussion.

The FDA may also deny requests for meetings that do not have substantive information related to the elements described in section VI., Meeting Requests. A subsequent request to schedule the meeting will be considered as a new request (i.e., a request that is assigned a new set of time frames described below in section VII. B., Meeting Granted).

B. Meeting Granted

If a meeting request is granted, the FDA will notify the requester in writing according to the timelines described in Table 1. For face-to-face and teleconference/videoconference meetings, the notification will include the date, time, conferencing arrangements and/or location of the meeting, and expected FDA participants. For BIA and BPD Type 2 WRO meetings, the notification will include the date the FDA intends to send the written response (see Table 3 for FDA WRO response timelines).

For face-to-face and teleconference/videoconference meetings, the FDA will schedule the meeting on the next available date at which all expected FDA staff are available to attend; however, the meeting should be scheduled consistent with the type of meeting requested (see Table 2 for FDA meeting scheduling time frames). If the requested date for any meeting type is greater than the specified time frame, the meeting date should be within 14 calendar days of the requested date.

Table 1: FDA Meeting Request Response Timelines

Meeting Type	Response Time (calendar days from receipt of meeting request and meeting package)
BIA	21 days
BPD 1	14 days
BPD 2	21 days
BPD 3	21 days
BPD 4	21 days

Table 2: FDA Meeting Scheduling Time Frames

Meeting Type	Meeting Scheduling (calendar days from receipt of meeting request and meeting package)
BIA	75 days
BPD 1	30 days
BPD 2	90 days
BPD 3	120 days
BPD 4	60 days

Table 3: FDA WRO Response Timelines

Meeting Type	WRO Response Time (calendar days from receipt of WRO meeting request and meeting package)
BIA	75 days
BPD 2	90 days

VIII. MEETING PACKAGE

Premeeting preparation is critical for achieving a productive discussion or exchange of information. Preparing the meeting background package should help the requester focus on describing its principal areas of interest. The meeting package should provide information relevant to the discussion topics and enable the FDA to prepare adequately for the meeting.

A. Timing of Meeting Package Submission

As discussed in section VII., Assessing and Responding to Meeting Requests, if the meeting package is not submitted with the meeting request for each meeting type, the meeting request will be considered incomplete and the FDA generally will deny the meeting.

B. Where and How Many Copies of Meeting Packages to Send

Requesters should submit an archival meeting package to the appropriate review division or office or, if previously assigned, to the relevant pre-IND file or application(s) (e.g., IND, BLA) via the appropriate center's document room (paper submission) or via the electronic gateway, as applicable. Submissions must be made in accordance with any applicable electronic submission requirements.[12]

[12] See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.

To facilitate the meeting process, CDER strongly suggests that copies of meeting packages provided in electronic format also be provided in paper (desk copies). The number of desk copies of a meeting package will vary based on the meeting. The CDER project manager will advise on the number of desk copies needed for the meeting attendees. CBER neither requests nor accepts paper copies (desk copies) of meeting packages that have been submitted in electronic format.

C. Meeting Package Content

The meeting package should provide information relevant to the product, stage of development, and meeting type requested (see section III., Meeting Types), in addition to any supplementary information needed to develop responses to issues raised by the requester or review division. The meeting package should contain sufficient detail to meet the intended meeting objectives. For example, inclusion of raw data in addition to the derived conclusions may be appropriate in some situations. Similarly, merely describing a result as *significant* does not provide the review division with enough information to give good advice or identify important problems the requester may have missed. FDA guidances identify and address many issues related to biosimilar or interchangeable product development and should be considered when planning, developing, and providing information needed to support a meeting with the FDA.[13] If a product development plan deviates from current guidances, or from current practices, the deviation should be recognized and explained. Known or expected difficult design and evidence issues should be raised for discussion (e.g., selection of study populations, doses, or endpoints different from those studied for the reference product's licensure; extrapolation of indications).

To facilitate FDA review, the meeting package content should be organized according to the proposed agenda. The meeting package should be a sequentially paginated document with a table of contents, appropriate indices, appendices, and cross references. It should be tabbed or bookmarked to enhance reviewers' navigation across different sections within the package, both in preparation for and during the meeting. Meeting packages generally should include the following information in the order listed below:

1. The application number (if previously assigned).

2. The development-phase code name of product (if pre-licensure).

3. The proper name (if post-licensure).

4. The structure (if applicable).

5. The reference product proprietary and proper names.

6. The proposed indication(s) or context of product development.

[13] See the FDA Biosimilars guidance web page, available at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm.

7. The dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s).

8. Pediatric study plans, if applicable.

9. Human factors engineering plan, if applicable.

10. Combination product information (e.g., constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable.

11. A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the requester's organization, including consultants and interpreters, if applicable.

12. A background section that includes the following:

    a. A brief history of the development program and relevant communications with the FDA before the meeting

    b. Substantive changes in product development plans (e.g., manufacturing changes, new study population or endpoint), when applicable

    c. The current status of product development (e.g., chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable)

13. A brief statement summarizing the purpose of the meeting.

14. A proposed agenda, including estimated times needed for discussion of each agenda item.

15. A list of questions for discussion grouped by FDA discipline and with a brief summary for each question to explain the need or context for the question. Questions regarding combination product issues should be grouped together.

16. Data to support discussion organized by FDA discipline and question. The level of detail of the data should be appropriate to the meeting type requested and the stage of product development.

IX. PRELIMINARY RESPONSES

Communications before the meeting between requesters and the FDA, including preliminary responses, can serve as a foundation for discussion or as the final meeting responses. Nevertheless, preliminary responses should not be construed as *final* unless there is agreement between the requester and the FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the requester is satisfied with the FDA's preliminary

responses), or a particular question is considered resolved allowing time for discussion of the other questions during the meeting. Preliminary responses communicated by the FDA are not intended to generate the submission of new information or new questions. If a requester nonetheless provides new data or a revised or new proposal, the FDA may not be able to provide comments on the new information, and the requester may need to submit a new meeting request for the FDA to provide feedback on the new information.

The FDA holds internal meetings, including meetings with the CDER or CBER Biosimilar Review Committee, to discuss the content of meeting packages and to gain internal alignment on the preliminary responses. The FDA will send the requester its preliminary responses to the questions in the meeting package no later than 5 calendar days before the face-to-face, videoconference, or teleconference meeting date for BPD Type 2 and BPD Type 3 meetings. For all other meeting types, the FDA intends to send the requester its preliminary responses no later than 2 calendar days before the face-to-face, videoconference, or teleconference meeting.

X. RESCHEDULING MEETINGS

Occasionally, circumstances arise that necessitate the rescheduling of a meeting. If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A new meeting request should not be submitted. Requesters and the FDA should take reasonable steps to avoid rescheduling meetings. For example, if an attendee becomes unavailable, a substitute can be identified, or comments on the topic that the attendee would have addressed can be forwarded to the requester following the meeting. It will be at the discretion of the review division whether the meeting should be rescheduled depending on the specific circumstances.

The following situations are examples of when a meeting may be rescheduled by FDA. This list includes representative examples and is not intended to be an exhaustive list.

- The review team determines that additional information is needed to address the requester's questions or other important issues, and it is possible to identify the additional information needed and arrange for its timely submission.

- Essential attendees are no longer available for the scheduled date and time because of an unexpected or unavoidable conflict or an emergency situation.

- Before preliminary responses are sent by the FDA, the requester sends the FDA additional questions or data that are intended for discussion at the meeting and require additional review time.

- It is determined that attendance by additional FDA personnel not originally anticipated or requested is critical and their unavailability precludes holding the meeting on the original date.

XI. CANCELING MEETINGS

Failure to pay required BPD fees for a product, within the required time frame, may result in the cancellation by FDA of a previously scheduled BPD meeting.[14] For more information on BPD fees, refer to the draft guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2017*.[15] If the requester pays the required BPD fee after the meeting has been canceled because of nonpayment, the goal time frame for FDA's response to a meeting request will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.[16]

Occasionally, other circumstances arise that necessitate the cancellation of a meeting. If a meeting is canceled for reasons other than nonpayment of a required BPD fee, the FDA will consider a subsequent request to schedule a meeting to be a new request and the goal time frame for FDA's response will be calculated from the date of the subsequent request. Requesters and the FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no longer necessary). Cancellation will be at the discretion of the review division and will depend on the specific circumstances.

The following situations are examples of when a meeting may be canceled. This list includes representative examples and is not intended to be an exhaustive list.

- The requester determines that preliminary responses to its questions are sufficient for its needs and additional discussion is not necessary (see section IX., Preliminary Responses). In this case, the requester should contact the FDA regulatory project manager to request cancellation of the meeting. The FDA will consider whether it agrees that the meeting should be canceled. Some meetings can be valuable because of the discussion they generate and the opportunity for the division to ask about relevant matters, even if the preliminary responses seem sufficient to answer the requester's questions. If the FDA agrees that the meeting can be canceled, the reason for cancellation will be documented and the preliminary responses will represent the final responses and the official record.

- The FDA determines that the meeting package is inadequate. Meetings are scheduled on the condition that the requester has submitted appropriate information to support the discussion. Adequate planning by the requester should avoid this problem.

XII. MEETING CONDUCT

Meetings will be chaired by an FDA staff member and begin with introductions and an overview of the agenda. Attendees should not make audio or visual recordings of discussions at meetings described in this guidance.

[14] See section 744H(a)(1)(E)(i) of the FD&C Act.

[15] When finalized, this guidance will represent the FDA's current thinking on this topic.

[16] See BsUFA II goals letter.

Presentations by requesters generally are not needed because the information necessary for review and discussion should be part of the meeting package. If a requester plans to make a presentation, the presentation should be discussed ahead of time with the FDA project manager to determine if a presentation is warranted and to ensure that the FDA has the presentation materials ahead of the meeting, if possible. All presentations should be kept brief to maximize the time available for discussion. The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of content, distinct from clarifications or explanations of previous data, that was not included in the original meeting package submitted for review, FDA staff may not be able to provide commentary.

Either a representative of the FDA or the requester should summarize the important discussion points, agreements, clarifications, and action items. Summation can be done at the end of the meeting or after the discussion of each question. Generally, the requester will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and action items. FDA staff can add or further clarify any important points not covered in the summary and these items can be added to the meeting minutes.

At BPD Type 4 meetings for original applications reviewed under the BsUFA Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs (also known as *the Program*),[17] the requester and the FDA should also summarize agreements regarding the content of a complete application and any agreements reached on delayed submission of certain minor application components.

XIII. MEETING MINUTES

Because the FDA's minutes are the official records of meetings, the FDA's documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference. The FDA will issue the official, finalized minutes to the requester within 30 calendar days after the meeting.

The following are general considerations regarding meeting minutes:

- FDA minutes will outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted format. This information does not need to be in great detail. The minutes are not intended to represent a transcript of the meeting.

- FDA project managers will use established templates to ensure that all important meeting information is captured.

- The FDA may communicate additional information in the final minutes that was not explicitly communicated during the meeting (e.g., pediatric requirements, data standards)

[17] See BsUFA II goals letter.

or that provides further explanation of discussion topics. The FDA's final minutes will distinguish this additional information from the discussion that occurred during the meeting.

The following steps should be taken when a requester disagrees that the minutes are an accurate account of the meeting:

- The requester should contact the FDA project manager and describe the concern

- If, after contacting the FDA project manager, the requester still disagrees with the content of the minutes, the requester should submit a description of the specific disagreements either:

  – To the application; or

  – If there is no application, in a letter to the division director, with a copy to the FDA project manager

- The review division and the office director, if the office director was present at the meeting, will take the concerns under consideration

  – If the minutes are deemed to accurately and sufficiently reflect the meeting discussion, the FDA project manager will convey this decision to the requester and the minutes will stand as the official documentation of the meeting.

  – If the FDA deems it necessary, changes will be documented in an addendum to the official minutes. The addendum will also document any remaining requester objections.

To request information on additional issues that were not addressed at the meeting, the requester should submit a new meeting request or a submission containing specific questions for FDA feedback.

REFERENCES

Related guidances[1]

Draft guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2017*[2]

Guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development*

Guidance for review staff and industry *Good Review Management Principles and Practices for PDUFA Products*

Related CBER SOPPs[3]

SOPP 8101.1: *Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products*

SOPP 8404.1: *Procedures for Filing an Application When the Applicant Protests a Refusal to File Action (File Over Protest)*

Other guidances

Draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*[4]

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act*

[1] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs or Biologics guidance web pages at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm and https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[2] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs or Biologics guidance web pages at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm and https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[3] SOPPs can be found on the Biologics Procedures (SOPPs) web page at https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm.

[4] When final, this guidance will represent the FDA's current thinking on this topic.

679 Guidance for industry *Special Protocol Assessment*
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681 Guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the*
682 *Division Level*
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