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

Guidance for Industry

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)

July 2025
Procedural

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Contains Nonbinding Recommendations

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

This guidance represents 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 proposed biosimilar, including interchangeable biosimilar, products[2] 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) (21 U.S.C. 355), biologics license applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)),[3] or submissions for devices under the FD&C Act.[4]

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

[2] In this guidance, the following terms are used to describe biological products licensed under section 351(k) of the PHS Act: (1) "biosimilar" or "biosimilar product" refers to a product that the FDA has determined to be biosimilar to the reference product (see sections 351(i)(2) and 351(k)(2) of the PHS Act) and (2) "interchangeable biosimilar" or "interchangeable product" refers to a biosimilar product that the FDA has determined to be interchangeable with the reference product (see sections 351(i)(3) and 351(k)(4) of the PHS Act).

[3] 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* (September 2023). 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 guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[4] For information on meetings for medical device submissions, see the draft guidance for industry *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program* (March 2024). When final, this guidance will represent the FDA's current thinking on this topic.

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., in-person, virtual (videoconference), teleconference, or written response only (WRO)).

This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings.[5]

This guidance finalizes the draft guidance of the same name issued in August 2023.

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 proposed biosimilar, including interchangeable biosimilar, 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 good meeting management practices 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), the FDA has committed to specific performance goals that include meeting management goals for formal meetings that occur between the FDA and requesters.[6]

[5] The guidance for industry *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* (November 2015) has been withdrawn.

[6] See BsUFA III goals letter titled "Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027," available on the FDA website at https://www.fda.gov/media/152279/download.

III. MEETING TYPES[7]

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

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 as it relates to the biosimilarity assessment. This meeting type does not involve substantive review of summary data or full study reports. Although the FDA encourages requesters to provide analytical data from at least one lot of the proposed biosimilar or interchangeable biosimilar product compared to the U.S.-licensed reference product, the data are not required as long as the requester provides sufficient information with the meeting request 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. The meeting request should include the following, as appropriate:

- Identification of reference product.
- The indications intended to be sought for licensure.
- A comparative analytical assessment plan, including preliminary identification of the critical quality attributes and planned characterization methods.
- If a requester seeks to use a non-U.S.-licensed comparator product during development, the proposed bridging strategy to justify the relevance of the data generated with the non-U.S.-licensed comparator product.
- A conceptual description of the planned clinical pharmacokinetics and/or pharmacodynamic study or studies, including proposed endpoints.
- A conceptual plan that includes initial considerations regarding the need for a comparative clinical study. If the requester plans to conduct a comparative clinical safety and efficacy study, this conceptual plan should include the patient population and proposed endpoints.
- Any guidance already received from other health authorities on product development.

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

- Identification to the FDA of the regulatory status in other jurisdictions.

Extensive analytical, nonclinical, and/or clinical data are not expected to be provided based on the expected stage of development of the proposed biosimilar, including interchangeable biosimilar, 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, including interchangeable biosimilar, product development program, a different meeting type should be requested. Requesting a BIA meeting is not a requirement prior to joining the BPD program.

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 in which (1) the requester seeks input on how to address the hold issues; or (2) 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* (April 2018).

- 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* (November 2017).[8]

- 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 2a Meeting

A BPD Type 2a meeting is a meeting focused on a narrow set of issues (e.g., often one but not more than two issues and associated questions) requiring input from no more than three

[8] We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

disciplines or review divisions. To request a BPD Type 2a meeting, requesters must first have had a BIA or another BPD meeting type with the FDA.[9] Examples of such discussion issues could include the following:

- Immunogenicity testing strategy following prior FDA recommendations or feedback.
- A request for feedback on an updated study design when the revisions are based on prior FDA feedback.
- Defined chemistry, manufacturing, and controls (CMC) postapproval commitments (e.g., related to analytical methods) discussing the approach in advance of conducting the study to ensure the approach is in line with the FDA's expectations.

D. BPD Type 2b Meeting

A BPD Type 2b[10] meeting is a meeting to discuss a specific issue (e.g., ranking of quality attributes, CMC issue such as control strategy, study design or endpoints, postapproval 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.

E. 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 (e.g., detailed and robust analytical similarity data or clinical study reports), FDA advice regarding similarity between the proposed biosimilar, including interchangeable biosimilar, product and the reference product, and FDA advice regarding the need for additional studies, including design and analysis.

- Examples of a BPD Type 3 meeting submission include the following:
  - Comprehensive analytical similarity data sufficient for the FDA to make a preliminary evaluation of analytical similarity. 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 studies.

[9] Section I.H. of the BsUFA III goals letter.

[10] A BPD Type 2b meeting under BsUFA III has the same scope as a BPD Type 2 meeting under BsUFA II; accordingly, the FDA considers a BPD Type 2b meeting to be broader in scope than a BPD Type 2a meeting.

- Examples of topics on which the requester can seek FDA advice as part of a BPD Type 3 meeting, in addition to a discussion of the in-depth data described above, include the following:

  - Proposal for any additional planned studies

  - Proposal for justification of extrapolation

F. BPD Type 4 Meeting

A BPD Type 4 meeting is a presubmission meeting to discuss the format and content of a complete original application under the Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs (also known as *the Program*)[11] or supplement submitted under 351(k) of the PHS Act for a proposed biosimilar, including interchangeable biosimilar, product. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including the following:

- Identification of those studies that the requester is relying on to support a demonstration of biosimilarity or interchangeability

- Discussion of any potential review issues identified based on the information provided

- Identification of the status of pediatric assessments to adequately address the Pediatric Research Equity Act (PREA)

- Acquainting FDA reviewers with the general information to be submitted in the marketing application (including technical information)

- Discussion of the best approach to the presentation and formatting of data in the marketing application

IV. BsUFA FEES ASSOCIATED WITH THE BPD PROGRAM

Under the BsUFA user fee provisions of the FD&C Act, BPD fees are assessed for products in the BPD program. BPD fees include the initial BPD fee, the annual BPD fee, and the reactivation fee. No fee is associated with a BIA meeting. For more information about BsUFA fees, including the assessment of BPD fees and the consequences for failure to pay any required BPD fees, refer to the guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2022* (July 2023).

[11] See BsUFA III goals letter.

V. MEETING FORMATS

There are four meeting formats: in-person, virtual (videoconference), teleconference, and WRO as follows:

1. **Face-to-Face**:

    a. **In-person**: Core attendees[12] from the FDA and the sponsor/applicant participate in person at the FDA; such meetings will be hybrid with a virtual component to allow non-core participants to join virtually. Because the intent is that the primary discussion occurs face-to-face in person, all sponsors and FDA individuals who are key to such discussions (i.e., "core" attendees) should participate, if feasible, in person. Individuals expected to have a more peripheral role (e.g., may be called on to comment on a single question) may participate virtually. If core sponsor personnel are suddenly unable to attend the in person meeting due to illness or unexpected travel issues, they can join the meeting virtually. If core sponsor personnel are not planning to attend in person, the meeting should be requested as a virtual face-to-face meeting.

    b. **Virtual (videoconference)**: Attendees participate from various remote locations via a **video and audio connection** (e.g., with core attendees' cameras on).

2. **Teleconference**: Attendees participate from various remote locations via an **audio only connection** (e.g., telephone, virtual meeting platform without cameras on).

3. **Written response only (WRO)**: WRO responses are sent to requesters in lieu of meetings conducted in one of the three formats described above. Requesters may request this meeting format only for BIA, BPD Type 2a, and BPD Type 2b 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, including interchangeable biosimilar product development.[13]

To promote efficient meeting management, requesters should 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

[12] FDA expects to have its core participants with primary speaking roles participate in person while others may join virtually (see https://www.fda.gov/industry/prescription-drug-user-fee-amendments/update-person-face-face-formal-meetings-fda).

[13] See the guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* (December 2017).

requests must be made in accordance with any applicable electronic submission requirements.[14] Meeting requests must be addressed to the appropriate review division or office to qualify for meeting management performance goals[15] and, if previously assigned, are expected to be submitted to the pre-investigational new drug application (pre-IND) file or application (e.g., investigational new drug application (IND), BLA). The FDA considers meeting requests sent by fax or email to be courtesy copies only and are not substitutes for formal submissions.

The requester should submit a meeting request for the development of a proposed biosimilar, including interchangeable biosimilar, product with multiple indications that span multiple review divisions to the division that has regulatory oversight of the reference product.

Requesters are not required to request meetings in sequential order (e.g., BIA, BPD Type 2a, BPD Type 2b, BPD Type 3, then BPD Type 4). However, to request a Type 2a meeting, requesters must first have had a BIA or another BPD meeting type with the FDA.[16] The meeting type requested depends on the stage of the development program and/or the advice sought. The FDA will grant one BIA meeting for the development program of a particular proposed biosimilar, including interchangeable biosimilar, product and, generally, one BPD Type 4 meeting for each application or supplement, as appropriate. The FDA will, as appropriate, grant as many BPD Type 2a, BPD Type 2b, and BPD Type 3 meetings as are requested and considered necessary to support the development and review of a proposed biosimilar, including interchangeable biosimilar, 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. Application number (if previously assigned).
2. Development-phase code name of product (if pre-licensure).
3. Proper name (if post-licensure).
4. Structure (if applicable).
5. Proper and proprietary names of the reference product.
6. Proposed indication(s) or context of product development.

[14] See section 745A(a) of the FD&C Act; see also the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014) and *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).

[15] BsUFA III goals letter.

[16] BsUFA III goals letter.

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.H., Meeting Management Goals, of the BsUFA III goals letter) to apply:

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

2. Proposed meeting format (i.e., in-person, virtual (videoconference), teleconference, or WRO).

3. Brief statement of the purpose of the meeting. This statement should include a brief background of the issues underlying the proposed 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. List of specific objectives or outcomes the requester expects from the meeting.

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

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

8. List of requested FDA attendees and/or discipline representative(s). Requests for attendance by FDA staff who are not otherwise essential to the application's review 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 a later meeting date is acceptable to the requester to accommodate the inclusion of nonessential FDA attendees.

9. Suggested dates and times (e.g., morning, 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 planned 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. Based on experience, the maximum number of questions that can be reasonably answered within the allotted meeting time is 10 questions (subquestions will be counted as separate questions). Therefore, a meeting request should include no more than 10 questions listed consecutively regardless of discipline, and should include fewer than 10 if the questions are more complex.

VII. ASSESSING AND RESPONDING TO MEETING REQUESTS

Although requesters must request a specific meeting type and format,[17] the FDA assesses each meeting request, including WRO requests for BIA, BPD Type 2a, and BPD Type 2b meetings, and determines whether the request should be granted, the appropriate meeting type, and the appropriate meeting format. The FDA honors requests for BPD Type 2b, BPD Type 3, and BPD Type 4 meetings except in the most unusual circumstances. However, the FDA may determine that a different type of meeting is more appropriate and may grant a different type of meeting than is requested.[18] Additionally, if the FDA determines that the WRO format is not appropriate for a requested WRO meeting or that the face-to-face (i.e., in-person, virtual (videoconference)) or teleconference meeting format is not appropriate for a requested face-to-face or teleconference meeting, the FDA will notify the requester that the meeting has been denied, as described in section VII.A., Meeting Denied. However, if an in-person, virtual (videoconference), or teleconference meeting format is requested for a BPD Type 2a meeting, but the FDA determines

[17] BsUFA III goals letter.

[18] If the FDA grants a meeting of a different type than requested, this may require the payment of a biosimilar biological product development fee as described in section 744H of the FD&C Act before the meeting will be conducted. If a biosimilar biological product development fee is required under section 744H, and the sponsor does not pay the fee within the timeframe required under section 744H, the meeting will be cancelled.

that a written response to the questions would be the most appropriate format, the FDA will notify the requester as described in section VII.B. Meeting Granted.

The meeting request must be accompanied by the meeting package for BIA, BPD Type 1, BPD Type 2a, BPD Type 2b, and BPD Type 3 meetings (see section VIII.C., Meeting Package Content, for additional information regarding the content of the meeting package).[19] 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 as described above, the FDA will consider the meeting request incomplete and will generally 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. These notifications include an explanation of the reason for the denial. Denials are based on 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, the FDA may deny a meeting request because it is premature for the stage of product development, is clearly unnecessary, or is not appropriate for the format requested (e.g., WRO versus in-person/virtual (videoconference)/teleconference for BIA, BPD Type 2a, or BPD Type 2b meetings) 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. The FDA will consider a subsequent request to schedule the meeting 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 in-person, virtual (videoconference), or teleconference meeting formats, these notifications include the date, time, conferencing arrangements and/or location of the meeting, and expected FDA participants. For BIA, BPD Type 2a, and BPD Type 2b WRO meetings, these notifications include the date the FDA intends to send the written response (see Table 3 for FDA WRO response timelines).

For the BPD Type 2a meeting, although the requester may request an in-person, virtual (videoconference), or teleconference meeting format, the FDA may determine that a written response to the requester's questions would be the most appropriate means for providing feedback and advice to the requester. When it is determined that the meeting request can be appropriately addressed through a written response, the FDA will notify the requester of the meeting format change in writing, and this notification will include the date the FDA intends to send the written response in the Agency's response to the meeting request (see Table 3 for FDA WRO response timelines). If the requester believes an in-person, virtual (videoconference), or teleconference BPD Type 2a meeting is valuable and warranted, then the requester may provide rationale in a follow-up correspondence explaining why that meeting format is valuable and

[19] BsUFA III goals letter.

warranted, and the FDA will reconsider this request. If the FDA agrees to grant the in-person, virtual (videoconference), or teleconference meeting format, the Agency will strive to schedule the meeting to occur within 60 calendar days of the FDA's receipt of the meeting request.

For in-person, virtual (videoconference), or teleconference meeting formats, the FDA schedules 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)
BIA	21 days
BPD 1	14 days
BPD 2a	21 days
BPD 2b	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)
BIA	75 days
BPD 1	30 days
BPD 2a	60 days
BPD 2b	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)
BIA	75 days
BPD 2a	60 days
BPD 2b	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 BIA, BPD Type 1, BPD Type 2a, BPD Type 2b, and BPD Type 3 meetings, the meeting request is considered incomplete, and the FDA generally will deny the meeting. For BPD Type 4 meetings, the background package must be received no later than 14 calendar days after the FDA's receipt of the meeting request.[20]

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

Requesters must submit a meeting package to the appropriate review division or office[21] and, if previously assigned, the meeting package is expected to be submitted to the relevant pre-IND file or application(s) (e.g., IND, BLA). Meeting packages are expected to be submitted via the appropriate center's document room (paper submission) or electronic gateway, as applicable. Submissions must be made in accordance with any applicable electronic submission requirements.[22]

Occasionally, to facilitate the meeting process, CDER staff may request, in addition to the electronic format, a limited number of meeting packages in paper format (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 details to meet the intended meeting objectives. For example, inclusion of raw data in addition to the derived conclusions may be appropriate in

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[20] BsUFA III goals letter.

[21] Id.

[22] See section 745A(a) of the FD&C Act; see also 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*.

some situations. Similarly, merely describing a result as *significant* does not provide the review division with enough information to give advice or identify important problems the requester may have missed. FDA guidances identify and address many issues related to biosimilar, including interchangeable biosimilar, product development, and requesters should consider these when planning, developing, and providing information needed to support a meeting with the FDA.[23] If a product development plan adopts an alternative approach from that recommended in FDA guidance, the alternative approach should be identified 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 data and information).

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. Application number (if previously assigned).
2. Development-phase code name of product (if pre-licensure).
3. Proper name (if post-licensure).
4. Structure (if applicable).
5. Proper and proprietary names of the reference product.
6. Proposed indication(s) or context of product development.
7. Dosage form, route of administration, dosing regimen (frequency and duration), strength, 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. List of planned attendees, including titles and affiliations, from the requester's organization, including consultants and interpreters (if applicable).

[23] See the FDA Biosimilars Industry Information and Guidance web page, available at https://www.fda.gov/drugs/biosimilars/industry-information-and-guidance.

12. Background section that includes the following:

    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. Status of product development (e.g., CMC; nonclinical; clinical, including any development outside the United States, as applicable).

13. Brief statement summarizing the purpose of the meeting.

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

15. 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 relevant committees within CDER or CBER, 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 in-person, virtual (videoconference), or teleconference meeting date for BPD Type 2b and BPD Type 3 meetings. For all other meeting types, the FDA intends to send the requester its preliminary responses to the questions no later than 2 calendar days before the in-person, virtual (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 meeting 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 is 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 the FDA may reschedule a meeting. 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 to the questions 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.

- 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 the FDA of a scheduled BPD meeting.[24] For more information on BPD fees, refer to the guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2022*. If the requester pays the required BPD fee after the meeting has been canceled because of nonpayment, the goal time frame for the FDA's response to a meeting request will be calculated from the date on which the FDA received the payment, not the date on which the requester originally submitted the meeting request.[25]

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

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

[25] BsUFA III goals letter.

considers a subsequent request to schedule a meeting to be a new request and the goal time frame for the FDA's response is 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).

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 then considers 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 to the requester's questions seem sufficient. If the FDA agrees that the meeting can be canceled, the reason for cancellation is documented and the preliminary responses represent the final responses and the official record.

- The FDA determines that the meeting package is inadequate or, for BPD Type 4 meetings, the meeting package is not received by the FDA within 14 calendar days of the meeting request. 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.

In general, presentations by requesters 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 FDA will not extend the length of a meeting 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 is 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

relevant discussion points, agreements, clarifications, and action items can be added to the meeting minutes.

At BPD Type 4 meetings for original applications reviewed under the Program, 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., PREA requirements, data standards) 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.

- In cases of a WRO, the WRO will serve as the meeting minutes.

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

1. 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.

2. The review division and the meeting chair will take the concerns under consideration, and the FDA will act in one of the following two ways:

- 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, the FDA will document changes in an addendum to the official minutes. The addendum will also document any remaining requester objections.

XIV. FOLLOW-UP OPPORTUNITY

For all meeting types, to ensure the sponsor's understanding of FDA feedback from meeting discussions or a WRO, sponsors may submit clarifying questions to the Agency. Only questions of a clarifying nature will be permitted (i.e., to confirm something in minutes or a WRO issued by the FDA) rather than raising new issues or new proposals.[26] The FDA intends to develop criteria and parameters for permissible requests, and the FDA may exercise discretion about whether requests are in scope.[27] The clarifying questions should be sent in writing as a "Request for Clarification" to the FDA within 20 calendar days following receipt of meeting minutes or a WRO. For questions that meet the criteria, the FDA will issue a response in writing within 20 calendar days of receipt of the clarifying questions. The FDA's response will reference the original meeting minutes or WRO.

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.

[26] BsUFA III goals letter.
[27] BsUFA III goals letter.

REFERENCES

Guidances for Industry

Draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (September 2023)

Draft guidance for industry *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program* (March 2024)

Draft guidance for review staff and industry *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* (September 2018)

Guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* (December 2017)

Guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the Division Level* (November 2017)

Guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2022* (July 2023)

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020)

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014)

Guidance for industry *Special Protocol Assessment* (April 2018)

Related Center for Biologics Evaluation and Research Standard Operating Policies and Procedures (SOPPs)[1]

SOPP 8101.1 *Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products* (March 2023)

[1] SOPPs can be found on the Biologics Procedures (SOPPs) web page at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-procedures-sopps.