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

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for the Center for Biologics Evaluation and Research (CBER) staff for scheduling and conducting regulatory meetings between individuals in CBER and representatives of the regulated industry (including sponsors/applicants of user fee related products) and/or individual sponsor-investigators to address issues relating to product development.

II. Scope

A. This SOPP applies to meetings for Investigational New Drugs (INDs), Abbreviated/New Drug Applications (A/NDAs), Biologics License Applications (BLAs), and their respective pre-submissions, amendments, and supplements.

B. This SOPP applies to products covered by the Biosimilar User Fee Act (BsUFA), the Generic Drug User Fee Act (GDUFA), and the Prescription Drug User Fee Act (PDUFA).

C. This SOPP does not apply to device submissions covered by the Medical Device User Fee Act (MDUFA).

III. Background

A. Meetings with industry and sponsor-investigators are a forum for the Agency to provide guidance to representatives of the regulated industry (including sponsors/applicants of

user fee related products) and/or individual sponsor-investigators during product development and facility design, and to facilitate their compliance with the regulations governing development and post-approval marketing of products.

B. While meetings are usually requested by sponsors or applicants or individual sponsor-investigators, CBER will occasionally suggest that a meeting be scheduled.

C. The conduct of these meetings and additional information is further described in the appropriate appendix of this SOPP and the following guidance documents:

1. *Draft Guidance for Industry: Formal Meetings between the FDA and Sponsors or Applicants of PDUFA Products*

2. *Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products*

IV. Definitions

A. General

1. **Formal Meeting** – For purposes of this SOPP, formal meeting includes any meeting requested by a sponsor or applicant (i.e., the requester) following the procedures provided in this SOPP and the appropriate guidance documents.

2. **Meeting format** – Includes the following four types:

- **In person face-to-face** – Core attendees 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. If core sponsor/applicant personnel are not planning to attend in person, the meeting should be requested as a virtual face-to-face meeting.

- **Virtual face-to-face** (video conference) – Attendees participate remotely via virtual meeting platforms that allow for both audio and visual communication (e.g., MS Teams) with core attendees' cameras on.

- **Teleconference** – Attendees participate from various remote locations via audio only connection, without cameras on.

- **Written Response Only (WRO)** – Written responses are sent in lieu of an in-person or virtual meeting, or a teleconference.

B. BsUFA meetings

1. **Biosimilar Initial Advisory (BIA) Meeting** - An initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. **Note:** Such term does not include any meeting that involves substantive review of summary data or full study reports.

2. **Biosimilar Product Development (BPD) Type 1 Meeting** - A meeting which is necessary for an otherwise stalled drug development program to proceed (e.g., meeting to discuss clinical holds, dispute resolution meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

3. **BPD Type 2a Meeting** - 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 disciplines or review divisions. Note: To request a Type 2a meeting, sponsors must first have had a BIA or other BPD meeting with the Agency.

4. **BPD Type 2b Meeting** - A meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA will provide targeted advice regarding an ongoing biosimilar biological product development program. **Note:** Such term may include substantive review of summary data but does not include review of full study reports.

5. **BPD Type 3 Meeting** - An in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. **Note:** Such term includes substantive review of full study reports, FDA advice regarding the similarity between the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

6. **BPD Type 4 Meeting** - A pre-submission meeting to discuss the format and content of a complete application for an original biosimilar biological product application under the Program or supplement submitted under 351(k) of the PHS Act. **Note:** Please refer to the BsUFA Meeting appendix of this SOPP for additional information on BPD Type 4 Meetings.

C. GDUFA meetings

1. **Pre-Submission Meeting** - A meeting in which an applicant has an opportunity to discuss and explain the format and content of an ANDA to be submitted. **Note:** Although the proposed content of the ANDA will be discussed, pre-submission meetings will not include substantive review of summary data or full study reports.

2. **Product Development Meetings** - A meeting involving a scientific exchange to discuss specific issues (e.g., a proposed study design, alternative approach, or additional study expectations) or questions, in which FDA will provide targeted advice regarding an ongoing ANDA development program.

D. PDUFA meetings

1. **Type A Meeting** - A meeting which is necessary for an otherwise stalled drug development program to proceed (a “critical path” meeting) or to address an important safety issue. Post-action meetings requested within 3 months after an FDA regulatory action other than approval (i.e., issuance of a complete response letter) will generally be considered Type A meetings.

2. **Type B Meeting** - Type B meetings include:

   - Pre-IND

- Pre-emergency use authorization
- Pre-BLA/NDA
- Post-action meetings requested 3 or more months after regulatory action other than an approval
- REMS or PMR meetings that occur outside the context of a marketing application
- Discussion of the overall development program for products granted breakthrough therapy or regenerative medicine and advance therapy designation (i.e., the initial comprehensive multidisciplinary meeting). **Note**: Subsequent meetings for breakthrough therapy designated products will be considered either Type B or possibly Type A meetings if the meeting request meets the criteria for a Type A meeting.

3. **Type B (EOP) Meeting -** A meeting reserved for certain End-of-Phase 1 meetings (i.e., for products that will be considered for marketing approval under 21 CFR Part 312 Subpart E or 21 CFR Part 314 Subpart H or similar products) and End of Phase 2/Pre-Phase 3 meetings (21 CFR 312.47).

4. **Type C Meeting -** Any meeting other than a Type A, Type B, Type B (EOP), INTERACT, or Type D meeting regarding the development and review of a product. **Note:** Type C meetings include meetings to discuss early consultation on the use of new surrogate endpoints.

5. **Type D Meeting** - A meeting focused on a narrow set of issues (should be limited to no more than 2 focused topics) and should not require input from more than 3 disciplines or Divisions.

6. **INTERACT** (Initial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs) Meeting – A meeting intended for novel products and development programs that present unique challenges in early development. They are intended to facilitate IND-enabling efforts where the sponsor is facing a novel, challenging issue that might otherwise delay progress of the product towards entry into the clinic in the absence of this early FDA input. Typically, the issue is early in a development program - prior to when a pre-IND meeting might be requested or before submission of an IND. The sponsor needs to have selected a specific investigational product or a product-derivation strategy to evaluate in a clinical study before requesting an INTERACT meeting.

V. Policy

A. General

1. CBER will refer all inquiries regarding meetings to the applicable guidance documents listed in the reference section, applicable ICH Guidance, and this SOPP. The requester is expected to have reviewed all relevant documents in preparation for submitting the meeting request and meeting package. For product specific meeting information, please refer to the appropriate appendix of this SOPP.

2. In accordance with 21 CFR 10.65(e) and FDA policy, meetings with sponsors and applicants may not be electronically recorded. The official record of the meeting will be the FDA-generated meeting summary.

3. The Pediatric Research Equity Act of 2003 (PREA) (amendment to FD&C Act, section 505 and 351 of PHS Act) requires that before and during the investigational process of a new drug or biological product, FDA will discuss plans and timelines for pediatric studies or any planned request for waiver or deferral of pediatric studies with the sponsor or applicant at appropriate times.

   To assure that the statutory requirements are met in a timely manner, requesters should be advised (at the time the meeting is scheduled) that their pediatric development plan will be discussed, and where applicable, CBER will request this plan (or deferral or waiver request) be submitted after the meeting. The status will be recorded in the meeting minutes.

   a. See *Draft Guidance for Industry: How to Comply with the Pediatric Research Equity Act* and

   b. *Guidance for Industry: Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans* for additional information on pediatric requirements.

4. Requirements for electronic submissions

   a. Under Section 745A(a) of the FD&C Act, sponsors/applicants will be required to submit information electronically in the appropriate FDA-supported formats (Electronic Common Technical Document (eCTD)) for certain BLAs, NDAs, and Abbreviated New Drug Applications (ANDAs).

   b. Submissions that are not submitted electronically and electronic submissions that are not in a format that FDA can process, review, and archive will not be filed or received, unless exempted from these requirements.

   c. Please see the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format: Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications*, for complete eCTD requirements and exceptions under References.

5. Performance Goals:

   a. For products covered by user fees, the performance goals established in the most current user fee goal or commitment letter will be met.

   b. For products not covered by user fees, the procedures set forth in this document will be used; however, the performance goals will not apply. CBER will make every effort to respond to meeting requests and meet with sponsor/applicants of non-user fee products as expeditiously as possible.

B. Meeting Requests

1. Meeting requests will be evaluated promptly, and meetings will be scheduled and completed within the goal dates for the appropriate product type. If a request for a BsUFA meeting is received, contact the Associate Director for Review Management (ADRM)/Director of the Office of Regulatory Operations (ORO) prior to granting the meeting.

2. Requesters are encouraged to define in the meeting request the specific areas of input requested from CBER. The questions submitted to CBER 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 considered. In general, there should be no more than 10 questions listed consecutively inclusive of all disciplines. CBER requests that meeting requesters not submit sub-questions as they will be counted toward the overall number of questions.

    a. Note: Because Type D meetings are narrowly focused issues and disciplines, it is anticipated that only 3 to 5 questions would be submitted as discussed in the *Draft Guidance for Industry: Formal Meetings between the FDA and Sponsors or Applicants of PDUFA Products*.

3. Requesters may request a Written Response Only (WRO) to their questions rather than a face-to-face meeting or teleconference. Please note: for BsUFA, this only applies to BIA, BPD Type 2a and 2b meetings.

    a. In some cases, while the requester may request a face-to-face or teleconference meeting, CBER may determine that a written response to the requester's questions would be the most appropriate means for responding to the meeting request.

        i. For BsUFA products, this applies to BIA and BPD Type 2a meetings only.

        ii. For GDUFA products, this applies to Product Development Meetings only.

        iii. For PDUFA products this applies to pre-IND, Type C, Type D, and INTERACT meetings only. **Note:** Type C meetings for early consultation on the use of new surrogate endpoints will not be converted by CBER to a WRO. Refer to Appendix D for additional information regarding CBER's considerations for granting meetings and issuing WROs.

        iv. If the sponsor believes a face-to-face Pre-IND (PDUFA) or Type 2a (BsUFA) meeting is warranted, then the sponsor may provide a rationale explaining why a face-to-face meeting is valuable and warranted. CBER will convert, where possible, a WRO to a face-to-face meeting, for requests that include novel approaches to clinical development and/or where precedents are not well established.

    b. While it is CBER's preference to hold formal meetings, given the importance of these interactions in advancing public health, there are times when CBER needs to convert select meetings to WRO. Primarily CBER converts formal meetings to WRO to utilize resources efficiently and in accordance with PDUFA (and other user fee acts).

c. If CBER makes the determination to send WRO after review of the meeting package, CBER shall notify the requester of the change in meeting format and the date CBER intends to send a response (will not be later than the scheduled meeting) no later than 5 business days prior to the scheduled meeting. The requester will be notified by telephone or other rapid means of communication followed by a written confirmation using regulatory template *T 820.08: Meeting Rescheduled/Change in Format* template.

4. Meeting requests will be evaluated promptly to ensure that the correct meeting type, e.g., type B, type C, is requested according to the guidance. In some cases, CBER may disagree with the meeting type requested and that another meeting type is more appropriate depending on the nature of the request and questions. In these cases, meetings that fit the criteria for a different meeting type will be converted to the new meeting type. The requestor will be notified in writing with the *T 820.03: Respond to Meeting Request-Granted* if the meeting type has been changed.

5. To be considered a complete request, and one that qualifies for the user fee performance goals, the submission should be in writing and include the information based on the product type outlined in the appropriate appendix of this SOPP.

6. PDUFA Meetings:

a. For Type C meeting requests to discuss facility/establishment issues prior to submission of the application, the Office of Compliance and Biologics Quality (OCBQ), Division of Manufacturing and Product Quality (DMPQ) will process the request.

b. Separate meetings for manufacturing, clinical, and/or establishment issues could be suggested by CBER if the proposed agenda includes extensive discussion of more than one of these topics. CBER may choose to combine agendas if the objectives can be met in one session.

c. Generally, except for products granted breakthrough therapy or regenerative medicine advanced therapy (RMAT) designation status, only one of each of the Type B meetings for each potential application will be granted, but CBER can do so when it would be beneficial to hold separate meetings to discuss unrelated issues.

7. Pre-BLA/NDA meetings:

a. The purpose of the meeting is to discuss the planned content of the application with the appropriate CBER review division. Applicants are strongly encouraged to request this meeting.

b. The pre-BLA/NDA meeting should be requested sufficiently in advance of the planned submission of the application to allow for meaningful response to CBER feedback and should generally occur not less than 2 months prior to the planned submission of the application. Thus, the meeting request should be submitted at least 4 months prior to application submission.

c. The applicant and CBER may agree to a Formal Communication Plan as an alternative approach to the timing and nature of interactions and information exchange between the applicant and CBER during the BLA/NDA review. Refer to *R 910.05: Formal Communication Plan for Interactions and Information Exchange between the Applicant and FDA during Review of an Original BLA or NME NDA* for additional information.

C. Scheduling the meeting

1. If the requested date for any meeting type is greater than the specified timeframe in the most recent goals letter, the meeting date should be within 14 calendar days of the requested date.

2. Regulatory template *T 820.03: Respond to Meeting Request-Granted* will be used to confirm the logistics of the meeting once scheduled.

3. Refer to the regulatory reference *R 910.02: Attendee Table for BLA/NDA Meetings* for required CBER attendees.

D. Meeting packages

1. Meeting packages are prepared by the requester and submitted to CBER according to the schedule in the appropriate appendix of this SOPP based on the product type (i.e., BsUFA, GDUFA, or PDUFA). See the appropriate appendix for additional information on the content of meeting packages.

2. The meeting package provides summary information relevant to the product and supplementary information needed to develop responses to issues raised by the requester.

3. It's critical that the entire meeting package content support the intended meeting objectives and be organized according to the proposed agenda.

E. Reasons a meeting may not be held

1. The request for a meeting may be **denied** by CBER. Denials are based on substantive reasons. If a meeting request is denied, the requester will be given a reason for the denial, conveyed using the regulatory template *T 820.07: Respond to Meeting Request- Denied*. Examples of reasons for denial are included below:

a. The meeting request is substantially incomplete based on the omission of one of more of the elements identified in the current user fee goal letter.

b. The meeting is premature for the stage of development.

c. A previous meeting for the same purpose has already been held and no substantially new information has become available.

d. The requested feedback is not appropriate for a meeting with CBER at this time and would be best provided through another Office, for example, the Office of

Combination Products. CBER will generally inform the requester of the correct office.

e. For Type A, Type C (Early consultations on the use of a new surrogate endpoint only), Type D and INTERACT meeting denials: A meeting package was not submitted with the meeting request.

f. The requested feedback is not appropriate for the requested meeting type. CBER will generally inform the sponsor/applicant if a different meeting type is more appropriate.

2. The meeting may be **rescheduled** by CBER, and a new date immediately identified. If the meeting is rescheduled, the requester will be notified by telephone or other rapid means of communication followed by a written confirmation. Regulatory template *T 820.08: Meeting Rescheduled/ Change in Meeting Format* will be used to confirm the logistics of the meeting once rescheduled. Examples of reasons for rescheduling a meeting include:

a. The requester asked to reschedule the meeting and a new date is immediately identified.

b. The requester experiences any delay in submitting the meeting package.

c. The package is too voluminous to review prior to the original meeting date.

d. The package includes an excessive number of questions (more than 10 in total, including sub-questions) that could not be addressed effectively in the meeting time allotted.

e. Additional consult reviewers or management input is needed but cannot be obtained prior to the original meeting date.

f. Required CBER attendees become unexpectedly unavailable and appropriate substitutes cannot be identified.

g. Additional information was received after receipt of the meeting package.

3. The meeting may be **canceled** by CBER. If the meeting is canceled, the requester will be notified by telephone or other rapid means of communication followed by a written confirmation. Regulatory template *T 820.09: Meeting Cancelation* will be used to confirm the meeting cancelation. Examples of reasons for canceling a meeting include:

a. The meeting package was not received by the User Fee goal date.

b. The meeting package is grossly inadequate to enable CBER to provide meaningful responses to the questions. Examples of this situation include questions that are either vague or premature for meeting type.

c. Requester is satisfied with the CBER preliminary meeting responses and cancels the meeting. If the requester wants to cancel the meeting, a written confirmation should be sent to CBER.

d. The requester asks to cancel the meeting for any other reason.

e. CBER made the decision to send Written Responses Only rather than hold the Face-to-Face meeting or teleconference after the meeting confirmation was sent to the requestor. Regulatory template *T 820.08: Meeting Rescheduled/Change in Meeting Format* will be used to notify the requester. **Note**: Conversion to a WRO from a Face-to-Face or teleconference is not considered a cancelation for purposes of reporting goals for user fee meetings.

F. Internal Meetings

1. An internal meeting prior to the formal meeting with a requester will be scheduled. The internal meeting is an opportunity for the FDA to formulate a consensus on its responses to the requester's questions and to identify additional issues or comments to share with the requester.

2. The internal meeting should include all persons invited to attend the meeting with the requester.

G. Preliminary Meeting Responses

1. CBER will send preliminary meeting responses to the requester's questions contained in the meeting package prior to the formal meeting according to the timelines in the appropriate appendix of this SOPP.

2. The preliminary meeting responses will be considered final if CBER and the requester agree that no further discussion is needed, and the meeting will be cancelled.

3. Regulatory template *T 820.04: Preliminary Meeting Responses* will be used to send the preliminary meeting responses to the requester.

4. Preliminary meeting responses will not be edited by CBER as part of the meeting summary if the sponsor or applicant meets with CBER.

a. For INTERACT meetings, preliminary responses will be annotated and re-sent within 30 calendar days if the advice provided changes because of the meeting.

H. Meeting with sponsor or applicant

1. Formal meetings are reserved for clarification and further discussion of CBER's responses and comments in the Preliminary Meeting Responses. CBER will not discuss new proposals or new data. CBER discourages presentation of information contained in the briefing package as this depletes time for discussion of the responses.

2. Pre-BLA/NDA Meetings

a. Although pre-BLA/NDA meetings are not required, CBER strongly encourages these meetings to discuss the proposed planned content of the application with the appropriate review division.

b. At the pre-BLA/NDA meeting, CBER and the applicant will agree on the content of a complete application for the proposed indication(s), including preliminary discussions on risk management actions.

c. For those products that qualify under the PDUFA Program, CBER and the applicant may also reach agreement on submission of a limited number of application components not later than 30 calendar days after the submission of the original application. Refer to the most recent PDUFA goals letter for additional information.

3. For virtual meetings:

a. CBER employees are required to turn on their cameras when participating in virtual meetings with sponsors/applicants and other external stakeholders unless excused or instructed otherwise.

b. Meeting organizers may require only participants with primary speaking roles to use their cameras while allowing other virtual participants to turn on cameras only when speaking or to participate for listening purposes.

4. For meetings with CBER at the White Oak campus:

a. In person FDA attendees should include key staff with a speaking role, including the RPM/meeting coordinator. Additional FDA staff should participate in the meeting virtually. Industry is also encouraged to adhere to this attendance policy.

b. The requester should provide a list of attendees to the RPM at least 5 business days before the meeting, identifying who will be attending in-person and virtual. If the attendee list changes before the meeting, the requester should contact the CBER meeting point of contact (usually the RPM).

c. If the attendee list includes a Foreign National (FN) visitor(s), additional processing and approval is required and therefore, the Foreign National Visitors Data Request form (T 810.05) should be submitted to the RPM at least 2 weeks before the meeting.

d. All visitors must present proper identification, such as a valid form of government photo ID or Lawful Permanent Resident (LPR) Card. For FN visitors, a valid passport is the only acceptable form of identification.

e. Participants should be reminded by the RPM to arrive at the White Oak campus with sufficient time to undergo security screening.

f. All visitors driving onto the White Oak campus are required to go through vehicle screening and to park in designated Visitor parking areas. Shuttle service is

provided from the shuttle shelters located on Northwest Loop Road. Hired drivers must drop off visitors at Building 1. Visitors may then use shuttle service to the appropriate building and go through security screening. Visitors will be informed as to which entrance should be used. An FDA employee will meet and escort visitors to the meeting room.

g. All visitors will be escorted by an FDA employee at all times and will not have access to offices, IT equipment, conversations, or paperwork involving sensitive information.

I. Meeting Summaries

1. CBER meeting summaries are the official record of the meeting and should be issued no later than 30 calendar days following the meeting. For INTERACT meetings, preliminary responses will be annotated and re-sent within 30 calendar days if the advice provided changes as a result of the meeting. In cases of a WRO, the WRO will serve as the meeting summary from FDA.

2. Meeting summaries reflect discussions that occurred during the meeting and are not a transcription of the entire conversation/discussion.

a. A section clearly identifiable as information not having been discussed during the meeting, e.g., 'Post-meeting comments,' should be included as necessary. Examples of this type of information include:

i. CBER responses to post-meeting Action Items offered to be provided in the minutes.

ii. Clarification of comments made by CBER during the meeting.

3. The meeting requester is responsible for notifying CBER of any significant differences in their understanding of the meeting outcomes (as reflected in the official CBER summary). **Note:** For clarification questions, sponsors may submit an official Request for Clarification (see section 5 below).

a. CBER will make every effort to resolve differences in the meeting summary and the understanding of the meeting outcomes identified by the requester. This does not include discussion of new or alternative questions from those that were addressed during the meeting. Requests for evaluation of an alternative approach represent a new meeting request or may be submitted directly to the requester's IND or application.

b. If, after discussions with the requester, CBER deems it necessary to effect a change to the official minutes, the changes will be documented in an addendum to the official minutes. The addendum will also document any continued requester objections.

4. Requester's meeting minutes

a. In accordance with 21 CFR 10.65(f), the requester, or other meeting participant, may prepare and submit to CBER a memorandum summarizing their

understanding of issues discussed at the meeting. This memorandum, if provided by the requester, will be included, along with CBER's summary, in the administrative record.

i. Drafts of meeting minutes prepared by the requester are not the official summary of the meeting.

ii. Minutes prepared by the requester may or may not be considered during the preparation of the official CBER meeting summary.

5. Request for Clarification

a. For all meeting types, to ensure the requester's understanding of FDA feedback from meeting discussions or a WRO, requesters may submit clarifying questions to the agency.

b. Only questions of a clarifying nature will be permitted, i.e., to confirm something in preliminary responses (if the formal meeting has been canceled), meeting summary, or a WRO issued by FDA, rather than raising new issues or new proposals. FDA may exercise discretion to determine whether requests are in-scope.

c. The clarifying questions should be sent in writing as a "Request for Clarification" to the FDA within 20 calendar days following receipt of the meeting summary or a WRO. The request for clarification should be submitted as an amendment to the original meeting.

d. For Requests for Clarification that meet criteria a-c above, FDA will issue a response in writing within 20 calendar days of receipt of the clarifying questions. FDA's response will reference the original meeting summary or WRO.

e. For Requests for Clarification that are received more than 20 days after issuance of the meeting summary or WRO, the request should still be answered as resources allow, but the 20-day window does not apply.

f. If the request contains more than clarifying questions, the sponsor/ applicant will be notified that the request can be resubmitted as a new meeting request. The request for clarification can be processed as an IND amendment or Product Correspondence if submitted to a marketing application.

g. To obtain clarification for a single meeting response, limited to one discipline, sponsors may submit a question to the agency through the RPM. FDA will strive to issue a response via email within 3 business days.

VI. Responsibilities

A. Chair – Coordinates and facilitates, with the RPM (if separate), internal and formal meetings with requesters as outlined in this SOPP. **Note:** The Cross Discipline Team Leader (CDTL) as referred to in the PDUFA Program is the same as the Chair within CBER.

B. Office Management – Supervisory chain, including Division Directors or designees, within a division that evaluates the meeting request and makes the decision on whether to hold the meeting; participates in the evaluation of the meeting package; participates in the meeting; and works with the Review Committee as necessary.

C. Regulatory Information Specialist (RIS) – Coordinates with the RPM to schedule and organize formal meetings with requesters.

D. Regulatory Project Manager (RPM) – Manages the overall meeting request. These responsibilities include reviewing assigned sections, ensuring the requested meeting and associated internal meetings are scheduled; ensuring regulatory and administrative actions are completed on time, including all notifications to requester are sent; performs quality control checks; ensures all communications are uploaded into the appropriate regulatory system; and ensures that the file is administratively complete.

E. Review Committee Member - Reviews meeting requests and packages, participates in internal and formal meetings, and provides comments for the internal discussion, preliminary meeting responses and/or written responses.

VII. Procedures

A. Processing a meeting request

1. Coordinate the meeting request. **[RPM, RIS]**

a. Act as the contact person between CBER and the outside requester. **[RPM]**

b. Notify and coordinate with other staff, as needed. **[RPM, RIS]**

c. Refer to regulatory job aid *JA 910.09: Pre-BLA/NDA Meeting* for additional information, as appropriate.

2. Ensure that the necessary information is entered into the appropriate regulatory system(s), as appropriate. **[RPM, RIS]**

3. Evaluate the initial request for completeness based upon the elements listed in the appropriate appendix of this SOPP. See regulatory job aid *JA 820.07: Evaluating the Meeting Request* for additional information. **[Office Management, Review Committee Members, RPM]**

4. Decide whether the meeting will be granted or denied. **[Division Director or designee]**

5. Notify the requester of CBER's decision. **[RPM, RIS]**

a. If there is agreement the meeting should be denied:

i. Notify the requester that the meeting request is denied using regulatory template *T 820.07: Respond to Meeting Request- Denied*. **[RPM]**

ii. Update the relevant regulatory system with the appropriate information. **[RPM, RIS]**

b. If there is agreement the meeting should proceed: **[RPM, RIS]**

i. Notify the requester using regulatory template *T 820.03: Respond to Meeting Request-Granted* within the appropriate timeframe.

ii. Ensure all appropriate persons are identified and invited to attend both the internal and formal meeting. Ensure that the information is added to the appropriate Office calendar.

iii. Update the relevant regulatory system with all appropriate information.

B. Internal meeting

1. Preparing for the meeting:

a. Receive and distribute meeting packages to the Review Committee and Office management. **[RPM, RIS]**

b. Evaluate whether all appropriate disciplines and participants, including Special Government Employees (SGEs), have been included (CBER internal meeting and formal meeting with requester). **[RPM, Chair]**

c. Evaluate the meeting package. **[Review Committee Members, Office Management as appropriate]**

d. Review the meeting package prior to the meeting. **[Meeting Attendees]**

i. Persons unable to attend the internal meeting are expected to submit comments for the preliminary meeting responses.

ii. If appropriate, an alternate may participate in the internal meeting and participate in the formal meeting.

e. Engage in communications among themselves to develop their preliminary meeting responses if additional collaboration prior to the internal meeting is needed. **[Review Committee Members, Office management]**

f. Draft responses to the requester's questions and submit them for committee review at least 24 hours prior to the internal meeting. **[Review Committee]**

2. Meeting (CBER internal)

a. Discuss issues that arise during the review of the meeting package in addition to the questions received by the requester. **[Review Committee]**

b. Ensure CBER responses to the internal meeting are discussed and resolved. **[RPM, Review Committee Members]**

c. Ensure specific assignments, including roles and responsibilities, are defined for FDA/CBER staff to follow during the formal meeting. A leader, virtual host (for face-to-face meetings) and meeting recorder should be designated, and reviewers should be aware of the questions they will address. **[Review Committee Members]**

d. Decide whether Written Responses Only (WRO) are to be sent (see Appendix D) and/or whether the formal meeting will be rescheduled or canceled if the meeting was originally confirmed as a teleconference or face-to-face meeting. **[Review Committee Members]**

i. Concur with decision to send WRO or preliminary meeting responses. **[Branch Chief]**

ii. Notify requester: **[RPM]**

a) Of change of meeting format and date when responses will be provided if CBER decided to send Written Responses Only (no later than date of scheduled meeting).

b) By telephone or other rapid means of communication no later than 5 business days prior to the scheduled meeting; send written confirmation using regulatory template *T 820.08: Meeting Rescheduled/Change in Meeting Format*.

3. Preparing CBER preliminary meeting responses or WRO:

a. Ensure comments for the preliminary meeting/WRO responses are forwarded to the RPM. **[Review Committee Members]**

b. Ensure preliminary meeting/WRO responses are circulated for comment. **[RPM]**

c. Review and comment on preliminary meeting/WRO responses prior to issuance to the requester. **[Review Committee Members] Note:** Persons who were unable to attend the internal meeting are responsible for reading and commenting on the preliminary meeting responses before issuance.

d. Finalize preliminary meeting/WRO responses, including routing through Review Committee as appropriate. **[RPM]**

C. Written Responses Only (WRO)

1. These procedures are followed when WRO are sent to the requester with no expectation of a formal meeting via teleconference or face-to-face:

a. Send Written Responses to the requester using the timeline in the appropriate appendix of this SOPP using regulatory template *T820.53: Written Responses Only.* **[RPM]**

b. Update information in appropriate regulatory systems. **[RPM, RIS]**

D. Preliminary Meeting Responses

1. These procedures are followed when preliminary meeting responses are sent to the requester before a formal meeting via teleconference or face-to-face.

   a. Send preliminary meeting responses to the requester before the formal meeting using regulatory template *T820.04: Preliminary Meeting Responses* according to the timeline in the appropriate appendix of this SOPP. **[RPM, RIS]**

   b. Include a request for a response to CBER confirming the requester's planned questions for further discussion at the formal meeting or request to cancel the formal meeting.

2. If the requester sent written confirmation of their decision to cancel the meeting:

   a. Notify FDA/CBER attendees of cancelation. **[RPM]**

   b. Notify requester of cancelation using regulatory template *T 820.09: Meeting Cancelation.* **[RPM]**

   c. Ensure all relevant regulatory systems are updated. **[RPM]**

3. If the requester wants to proceed with the formal meeting:

   a. Notify appropriate FDA/CBER attendees of the meeting status and possible changes to the meeting agenda. **[RPM]**

   b. Ensure all relevant systems are updated. **[RPM]**

E. Meeting Rescheduled

1. Notify requester by telephone or other rapid means of communication followed by a written confirmation using regulatory template *T820.08: Meeting Rescheduled/Change in Meeting Format.* **[RPM]**

2. Update all appropriate regulatory systems. **[RPM]**

3. Notify FDA/CBER attendees. **[RPM]**

F. Meeting Cancelation

1. Notify requester by telephone or other rapid means of communication followed by a written confirmation using regulatory template *T820.09: Meeting Cancelation.* **[RPM]**

2. Update all appropriate regulatory systems. **[RPM]**

3. Notify FDA/CBER attendees. **[RPM]**

G. In-person Face-to-Face Meeting with the Sponsor/Applicant:

1. Coordinate arrival of external (non-FDA) attendees: **[RPM, Assigned Industry Escort]**

a. Escort attendees while on White Oak campus.

b. Connect in-person attendees with virtual attendees via online meeting platform. **[RPM, Assigned Virtual Host]**

2. Conduct the meeting: **[Chair, RPM, Review Team]**

a. Ensure that new proposals or new data information are not discussed.

b. Summarize key outcomes, agreements, and disagreements along with action items.

3. Ensure that external (non-FDA) attendees are escorted out of buildings. **[RPM, Assigned Industry Escort]**

H. Virtual and Teleconference Meetings

1. For teleconferences, ensure that the requester has been provided with dial-in numbers only. For virtual face-to-face meetings, both the web link and dial-in numbers are provided. **[RPM] Note:** This information will have been provided in advance of the meeting.

2. Participate in meeting, best practices include muting when not speaking. **[Chair, RPM, Review Team]**

a. Ensure that new proposals or new data information are not discussed.

b. Summarize key outcomes, agreements, and disagreements along with action items.

I. Meeting Summary

1. Draft a meeting summary; ensure it is reviewed and finalized using regulatory template *T820.06: Meeting Summary*. For INTERACT meetings, make annotations to the preliminary responses if the advice provided changes because of the meeting discussion. Use regulatory template *T 820.04: Preliminary Meeting Responses* to send amended annotated response to the sponsor. **[RPM, Review Committee Members]**

2. Ensure all FDA meeting attendees and supervisors review and agree on the draft meeting summary (annotated responses for INTERACT) before finalizing. **[RPM]**

3. Ensure the finalized meeting summary (annotated responses for INTERACT) is transmitted to the requester within 30 calendar days of the formal meeting and is entered into the appropriate regulatory system. **[RPM, RIS]**

4. Coordinate the appropriate response (e.g., guidance on a course of action or arranging a teleconference) if there is a disagreement raised by the requester regarding items in the official minutes. **[RPM]**

a. If issues cannot be resolved, review the specific disagreements submitted by the requester to determine if the summary is accurate or needs to be revised. **[Office/Division Director or designee]**

b. Notify the requestor if the meeting summary has been deemed to accurately and sufficiently reflect the meeting discussion and that the summary will stand as the official documentation of the meeting. **[RPM]**

c. Document any changes to the official summary, after discussion with the requester, in an addendum to the official summary. The addendum will also document any continued objections raised by the requester. **RPM]**

d. Enter all communications in the appropriate regulatory system. **[RPM, RIS]**

J. Request for Clarification

1. Receive and evaluate the request for clarification from sponsor to ensure the request meets the criteria in policy above. **[RPM, Review Committee Members]**

a. If the request does not meet the criteria, the request should be processed as general correspondence, and the requester should be notified via email. Note, steps 2-5 will not apply. **[RPM, RIS]**

2. Distribute to the appropriate members of the review committee and management if the request meets the criteria. **[RPM, RIS]**

3. Draft a response to the request and ensure that it is reviewed and finalized. **[RPM, Review Committee Members]**

4. Ensure that the finalized response is transmitted to the requester via email within 20 calendar days of the request. Note, if the request for clarification was received after 20 days, the 20-day timeline for CBER does not apply. **[RPM, RIS]**

5. Enter all communications with the requester in the appropriate regulatory system. **[RPM, RIS]**

K. Single Discipline Clarification Request

1. Receive and evaluate the request for clarification from requester to ensure the request meets the criteria for single-discipline clarification in policy above. **[RPM, Review Committee Members]**

a. If the request requires input from multiple disciplines, notify the requester that the question is out of scope for the 3-day clarification period and that we will respond as resources permit. **[RPM]**

2. Coordinate with appropriate discipline reviewer to prepare and finalize the response. **[RPM]**

3. Strive to send the finalized response to the requester via email within 3 business days. **[RPM]**

4. Enter all communications in the appropriate regulatory system per the procedures in Job Aid *JA 820.13: Procedure for Requests for Clarification*. **[RPM, RIS]**

VIII. Appendix

A. BsUFA Meeting Information

B. GDUFA Meeting Information

C. PDUFA Meeting Information

D. CBER Considerations for Meeting Format and issuing Written Response Only (WRO) for PDUFA Meetings

IX. References

A. References below are CBER Internal:

1. DCC Procedure Guide 22: Procedure for Processing, Routing and Storing Electronic Submissions

2. Regulatory Job Aids:

   a. JA 820.07: Evaluating the Meeting Request

   b. JA 910.09: Pre-BLA/NDA Meeting

   c. JA 820.13: Procedure for Requests for Clarification

3. Regulatory References

   a. R 910.02: Attendee Table for BLA/NDA Meetings

   b. R 910.05: Formal Communication Plan for Interactions and Information Exchange between the Applicant and FDA during Review of an Original BLA or NME NDA

4. Regulatory Templates:

   a. T 820.03: Respond to Meeting Request-Granted

   b. T 820.04: Preliminary Meeting Responses

   c. T 820.06: Meeting Summary

   d. T 820.07: Respond to Meeting Request-Denied

   e. T 820.08: Meeting Rescheduled/Change in Meeting Format

   f. T 820.09: Meeting Cancelation

g. T 810.05: Foreign National Visitors Data Request

h. T 820.53: Written Response Only

B. References below can be found on the Internet:

1. Federal Food Drug and Cosmetic Act (FD&C Act)

2. Pediatric Research Equity Act of 2007 (PREA)

3. 21 Code of Federal Regulations

4. User Fee Information

a. Biosimilar User Fee Act (BsUFA)

b. Generic Drug User Fee Amendments (GDUFA)

c. Prescription Drug User Fee Act (PDUFA)

5. Guidance Documents:

a. Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products

b. Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products

c. Draft Guidance for Industry: How to Comply with the Pediatric Research Equity Act

d. Guidance for Industry: Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Initial Pediatric Study Plans

e. Guidance for Industry: Providing Regulatory Submissions in Electronic Format: Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications

f. Guidance for Industry: Special Protocol Assessment

g. Guidance for Industry and Review Staff: Good Review Practice: Formal Dispute Resolution: Sponsor Appeals above the Division Level

h. Draft Guidance for Industry, Investigators and Other Stakeholders: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

X. History

Written/ Revision	Approved	Approval Date	Version Number	Comment
Raza	Martha Monser Regulatory Review Document Lead RABOB/DROP /ORO	September 21, 2026	17	Revised title for T 820.04 and new T 820.53; separated preliminary meeting responses and WROs into own templates.
Raza	Sonday Kelly, MS, RAC, PMP Director DROP/ORO	Dec. 11, 2025	16	Added single discipline clarification process.
Raza	N/A	February 14, 2025	15	Technical Update: Replace ZOOM with MS Teams
Trayer	Sonday Kelly, MS, RAC, PMP Director DROP/ORO	July 17, 2024	14	Updated policy on converting meeting types and clarified what *Type* and *Category* are for meetings. Eliminated the word *priority*; Added Camera guidance; and removed PTS and CRMTS throughout.
Monser	Katie Rivers, MS Chief, RABOB/DROP /ORO	January 26, 2024	13	Removed outdated policy regarding Wi-Fi connections and language in appendix D regarding only certain meetings allowed face-to-face in accordance with FDA policy
Trayer	Sonday Kelly, MS, RAC, PMP Director DROP/ORO	November 22, 2023	12	New appendix D for CBER considerations on type of meeting granted and issuance of WRO, general updates throughout.
Trayer	Sonday Kelly, ORO/DROP Director (Acting)	March 3, 2023	11	Updates to address post-COVID return to in-person/hybrid meetings and changes for 2023 CBER reorganization.
Trayer/Ryan	Darlene Martin, MS, PMP ORO/DROP Director (Acting)	September 28, 2022	10	Updated for PDUFA VII, BsUFA III, and GDUFA III changes
Monser	N/A	February 27, 2022	9	Technical Update for changes due to 2022 CBER Reorganization, updated references as appropriate.

Written/ Revision	Approved	Approval Date	Version Number	Comment
Monser	N/A	December 11, 2020	8	Technical Update for retirement of EDR and replacement with CBER Connect/CER and replace database with system
Monser	Job Aid Coordinator (reviewed)	November 4, 2019	7	Technical Update to correct broken hyperlinks, update references and update to current format/font
Linda Dixon, BPS	Christopher Joneckis, PhD	September 26, 2017	6	Updated to include BsUFA II, GDUFA II and PDUFA VI procedures
Linda Dixon, Working Group	Robert, Yetter, PhD	Oct 5, 2012	5	Updated to include PDUFA V information and updated procedures
Leonard Wilson/ Lydia Falk	Robert, Yetter, PhD	May 4, 2007	4	Updated to include updating the status of PREA studies and Quality System implementation
Leonard Wilson	Robert Yetter, PhD	Dec 23, 2002	3	Updated mail code and appendix 1; added references to PDUFA 3
Robert Yetter, PhD	Robert Yetter, PhD	Aug 15, 2002	2	Added reminder for sponsors to use Special Protocol Assessment (SPA); added link as appendix; revised appendices numbering
RMCC	Rebecca Devine	Feb 11, 1999	1	Original Document

SOPP 8101.1 - Appendix A: BsUFA Meetings

I. BSUFA Meeting Examples and Additional Information

A. Biosimilar Initial Advisory Meeting

1. Additional information:

a. Preliminary comparative analytical similarity data from at least one lot of the proposed biosimilar biological product compared to the U.S. licensed reference product should be provided in the meeting package.

b. The analytical similarity data should be sufficient in 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.

c. 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.

d. Extensive analytical, nonclinical and/or clinical data are not expected to be provided based on the expected stage of development of the proposed biosimilar biological product.

e. May request a Written Response Only (WRO) to the questions rather than a Face-to-Face, or teleconference.

B. BPD Type 1 Meeting

1. Examples include:

a. Meetings to discuss clinical holds: (1) in which the sponsor or applicant 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 sponsor or applicant agree that the development is stalled and a new path forward should be discussed.

b. Special protocol assessment meetings that are requested after receipt of an FDA letter in response to protocols submitted under the special protocol assessment procedures as described in the BsUFA goals letter.

c. Meetings to discuss an important safety issue, when such an issue is identified and the FDA and sponsor or applicant agree that the issue should be discussed.

d. Dispute resolution meetings as described in 21 CFR 10.75 and 312. 48 and in the BsUFA goals letter.

C. BPD Type 2a Meeting

1. Examples include:

a. Defined CMC post-approval 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 Agency's expectations.

b. Immunogenicity testing strategy following prior FDA recommendations/feedback.

c. Feedback on revised study design when revisions are based on prior FDA feedback.

2. Additional Information"

a. In order to request a Type 2a meeting, sponsors must first have had a BIA or other BPD meeting with the Agency.

b. May request a Written Response Only (WRO) to the questions rather than a Face-to-Face or teleconference.

D. BPD Type 2b Meeting

1. Additional Information:

a. This meeting can include substantive review of summary data, but does not include review of full study reports.

b. May request a Written Response Only (WRO) to the questions rather than a Face-to-Face or teleconference.

E. BPD Type 3 Meeting

1. Additional Information:

a. 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 biological 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.

2. Examples of a meeting submission include:

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

b. Full study report(s) for a clinical study(ies).

F. BPD Type 4 Meeting

1. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including:

a. Identification of those studies that the sponsor is relying on to support a demonstration of biosimilarity or interchangeability,

b. Discussion of any potential review issues identified based on the information provided,

c. Identification of the status of ongoing or needed studies to adequately to address the Pediatric Research Equity Act (PREA),

d. Acquainting FDA reviewers with the general information to be submitted in the marketing application (including technical information), and

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

2. This meeting does not include substantive review of summary data or full study reports.

II. BSUFA Meeting Management Procedural Goals

A. As stipulated by statute, a sponsor or applicant must pay a biosimilar biological product development fee (BPD fee) to participate in the FDA's BPD program to receive a BPD Type 1, 2a, 2b, 3, or 4 meeting for a product.

B. The Center may determine that a different type of meeting (i.e., Biosimilar Initial Advisory or BPD Type 1-4) is more appropriate and it may grant a meeting of a different type than requested which may require an additional user fee payment. Refer to the latest BsUFA goals letter for additional information.

C. When a request for a BsUFA Meeting is received, contact the Associate Director for Review Management prior to granting the meeting.

Table 1: Summary of Meeting Management Procedural Goals

Meeting Type	FDA's Response to Request	FDA's Receipt of Meeting Package	FDA's Preliminary Responses to Requester (if applicable)	FDA's Scheduled Meeting Date (days from receipt of request) or WRO	FDA's Meeting Minutes to Requester (if applicable)
Biosimilar Initial Advisory	21 days	With meeting request	NA	75 calendar days from receipt of meeting request and background package [includes WRO request]	30 days after meeting NA - WRO
BPD Type 1	14 days	With meeting request	NA	30 calendar days from receipt of meeting request and background package	30 days after meeting
BPD Type 2a	21 days	With meeting request	NA	60 calendar days from receipt of meeting request and background package [includes WRO request]	30 days after meeting NA - WRO
BPD Type 2b	21 days	With meeting request	5 calendar days	90 calendar days from receipt of meeting request and background package [includes WRO request]	30 days after meeting NA - WRO
BPD Type 3	21 days	With meeting request	5 calendar days	120 calendar days from receipt of meeting request and background package	30 days after meeting
BPD Type 4	21 days	14 calendar days after receipt of	NA	60 calendar days from receipt of meeting request	30 days after meeting

Meeting Type	FDA's Response to Request	FDA's Receipt of Meeting Package	FDA's Preliminary Responses to Requester (if applicable)	FDA's Scheduled Meeting Date (days from receipt of request) or WRO	FDA's Meeting Minutes to Requester (if applicable)
		meeting request			

III. BSUFA Content of Meeting Requests

A. The product name

B. The application number (if applicable)

C. The proposed proper name (or proper name if post-licensure)

D. The structure (if applicable)

E. The reference product name

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

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

H. 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 sponsor or applicant 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 need not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.

I. A listing of the specific objectives/ outcomes the requester expects from the meeting;

J. A proposed agenda, including estimated times needed for discussion of each agenda item not to exceed the total allotted meeting time

K. A list of proposed questions (grouped by discipline). Each question should be precise and there should be a brief explanation of the context and purpose of the question;

L. A list of all individuals with their titles and affiliation who will attend the requested meeting from the sponsor's or applicant's organization, including consultants and interpreters.

M. A list of FDA staff, if known, or disciplines, asked to participate in the requested meeting. Note that 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 state whether a later meeting date is acceptable to the requester to accommodate the nonessential FDA attendees.

N. The sponsor's proposal for a Face-to-Face meeting (in-person or virtual only) or teleconference or for a Written Response (Biosimilar Initial Advisory, BPD Type 2a, and BPD Type 2b meetings only)

O. Suggested dates and times (e.g. morning or afternoon) for the meeting that are within or beyond the appropriate time frame of the meeting type being requested.

IV. BSUFA Content of Meeting packages

A. The meeting package should provide information relevant to the product, development stage and meeting type requested. Refer to *Section I: Meeting Examples and Additional Information* of this appendix for information on specific meeting types.

B. To facilitate FDA review, the meeting package content should be organized according to the proposed agenda.

1. The product name and application number (if applicable)

2. The proposed proper name (or proper name if post-licensure)

3. The structure (if applicable)

4. The reference product name

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

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

7. A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the sponsor or applicant organization, including consultants and interpreters

8. A background section that includes the following:

a. A brief history of the development program

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

9. A brief statement summarizing the purpose of the meeting

10. A proposed agenda

11. A list of questions for discussion grouped by discipline with a brief summary for each question to explain the need or context of the question

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

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SOPP 8101.1 - Appendix B: GDUFA Meetings

I. GDUFA Meeting Information

A. Scope

1. Mid-Cycle meetings for complex products are not included in this appendix. These meetings will be managed within the scope of the application review.

B. Product Development Meetings

1. Meeting may be requested, due to the following reasons:

a. Development of a Complex Product for which FDA has not issued product-specific guidance or

b. An alternative equivalence evaluation (i.e., change in study type, such as in vitro to clinical) for a Complex Product for which FDA has issued product-specific guidance

c. A controlled correspondence response would not adequately address the prospective applicant's questions and

i. **Controlled correspondence** – a correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry, requesting information on a specific element of generic drug product development

ii. Refer to *Guidance for Industry: Controlled Correspondence Related to Generic Drug Development* for additional information.

d. A Product Development Meeting would significantly improve ANDA review efficiency.

e. Unless FDA is providing a written response to satisfy the Product Development Meeting goal, FDA will provide preliminary written comments 5 calendar days before each Product Development Meeting.

2. The prospective applicant submits a complete meeting package, including a data package and specific proposals, with the meeting request.

C. Pre-Submission Meetings

1. FDA will grant a Pre-Submission Meeting, if the applicant was granted a Product Development Meeting for the same Complex Generic Product or FDA believes in that the Pre-Submission Meeting would improve assessment efficiency. If appropriate to the purpose of the meeting, FDA will provide preliminary written response 5 calendar days before each meeting.

II. GDUFA Meeting Management Procedural Goals

Table 1: Summary of Meeting Management Procedural Goals

Meeting Type	FDA's Response to Request (granting or denying of meeting request)	FDA's Receipt of Meeting Package	FDA's Preliminary Responses to Requester (Not applicable to Written Responses Only (WRO))	FDA's Meeting Conducted Date	FDA's Meeting Minutes to Requester (Not Applicable for WRO)
Product Development Meetings	14 days from receipt	With meeting request	5 calendar days before the meeting	Within 120 days of granting the request	30 days after the meeting
Pre-Submission Meetings	30 days from receipt	With meeting request	5 calendar days before the meeting	Within 60 days from receipt if granted	30 days after the meeting

III. GDUFA Content of Meeting Requests (meeting package is contained within the request)

A. The product name and application number, if already assigned;

B. Chemical name and structure (if appropriate). If chemical name and structure is not appropriate, please include a description of your product;

C. Proposed indication or context of product development;

D. Type of meeting being requested;

E. Dosage form, route of administration, and dosing regimen (frequency and duration);

F. Combination product information (e.g., constituent parts, intended device, intended packaging, planned human factors studies), if applicable;

G. A brief statement summarizing the purpose of the meeting and identifying the type of milestone meeting, if applicable;

1. Include a description of the types of studies or data that the requester plans to discuss at the meeting.

2. For new products, include a description and the developmental status of the product.

H. A listing of the specific objectives or outcomes that the requester expects;

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

J. A background section that includes the following:

1. A brief history of the development program and relevant communications with FDA prior to the meeting;

2. Substantive changes in product development plans (e.g. new indication, population, basis for a combination), when applicable;

3. The current status of product development.

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

L. A list of planned external non-FDA attendees. 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;

M. A list of requested participants or disciplines to be represented from the Center;

N. Requested format of meeting, e.g., face-to-face, teleconference or written format;

O. Suggested dates for the meeting;

P. Suggested duration of the meeting.

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SOPP 8101.1 - Appendix C: PDUFA Meetings

I. PDUFA Meeting Examples and Additional Information

A. Type A meetings:

1. Dispute resolution described in 21 CFR 10.75, 312.48, and 314.103 and in *Guidance for Industry Formal Dispute Resolution: Appeals above the Division Level.*

2. 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.

3. Special Protocol Assessment meetings 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 G*uidance for Industry: Special Protocol Assessment.*

4. Post-action meetings requested within 3 months after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).

5. Meetings requested within 30 days of FDA's issuance of a refuse to file letter. In order to file an application over protest, applicants must avail themselves of this meeting (21 CFR 314.101(a)(3)).

B. Type B meetings:

1. Pre-IND meeting:

a. Occur prior to the submission of an initial Investigational New Drug Application (IND) to discuss the format for the IND, the scope and design of planned initial IND studies, design of animal studies needed to support human clinical testing, product manufacturing and characterization issues, selection and rationale for use of digital health technologies (DHTs), and the development plan to address requirements for the Pediatric Research Equity Act (PREA) of 2003. (See 21 CFR 312.82).

2. Pre-emergency use authorization meetings.

3. Pre-new drug application (pre-NDA)/pre-biologics license application (pre-BLA) meetings (21 CFR 312.47):

a. To inform CBER of the general information that will be submitted in the marketing application, to discuss preliminary efficacy results derived from

studies conducted to support the BLA/ NDA and appropriate methods for final statistical analysis;

b. To discuss the proposed format for data in the planned marketing application, to identify the studies that the applicant will rely on as adequate and well-controlled;

c. To discuss the validation and verification of digital health technologies (DHT) used in clinical studies

d. Plans to assess pediatric safety and effectiveness;

4. Post-Action meetings requested 3 or more months after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).

5. Meetings regarding REMS or post marketing requirements that occur outside the context of the review of a marketing application.

6. Meetings held to discuss the overall development program for products granted breakthrough therapy or RMAT designation status. Subsequent meetings for breakthrough therapy or RMAT designated products will be considered either Type B or possibly Type A meetings if the meeting request meets the criteria for a Type A meeting.

C. Type B (EOP) Meetings:

1. Certain end-of-phase 1 meetings (i.e., for 21 CFR Part 312 Subpart E or 21 CFR Part 314 Subpart H or similar products).

2. End-of-phase 2 /pre-phase 3 meetings (21 CFR 312.47).

D. Type C meetings**:**

1. Any meeting other than a Type A, Type B, or Type B (EOP), Type D, or INTERACT meeting regarding the development and review of a product, including meetings to discuss early consultation on the use of new surrogate endpoints**.** Examples include:

a. Facility/establishment issues - discussion prior to submission of the application.

b. General development discussion of a product.

c. Cost recovery

E. Type D meetings:

1. A meeting focused on a narrow set of issues (e.g., often one, but typically not more than two issues and associated questions). Examples include:

a. A follow-up question that raises a new issue after a formal meeting (i.e., more than just a clarifying question about an FDA response from a prior meeting);

b. A narrow issue on which the sponsor is seeking Agency input with only a few associated questions;

c. A general question about an innovative development approach that does not require extensive, detailed advice.

2. Issues discussed should not require input from more than 3 disciplines or Divisions

3. Meetings can be converted to a Type B or C meeting if the scope of the meeting is broad or includes complex questions/issues that require input from more than 3 disciplines or Divisions. FDA will inform the sponsor that the Agency will be converting the meeting to the appropriate meeting type (Type B or C) and the sponsor can either withdraw their request or accept the FDA's meeting-type conversion without re-submitting a new meeting request.

4. If the sponsor has several issues or a complex single issue with multiple questions, a Type C meeting should be requested rather than requesting several Type D meetings

F. Initial Targeted Engagement for Regulatory Advice on CBER/CDER ProducTs (INTERACT)

1. Meetings for novel questions and unique challenges in early development (i.e., prior to filing of an IND) intended to facilitate IND-enabling efforts where the sponsor is facing a novel, challenging issue that might otherwise delay progress of the product towards entry into the clinic in the absence of this early FDA input.

2. The sponsor needs to have selected a specific investigational product or a product-derivation strategy to evaluate in a clinical study before requesting an INTERACT meeting.

3. These meetings are intended to provide FDA input on issues that a sponsor needs to address early in a development program prior to a pre-IND meeting

4. Questions and topics within the scope of an INTERACT meeting include:

a. Novel questions for all CBER products (i.e., questions where there is no existing guidance or other information in writing the company could reference from FDA).

b. Choice of appropriate preclinical models or necessary toxicology studies for novel drug platforms or drug candidates;

c. CMC issues or testing strategies aimed to demonstrate product safety, adequate to support first-in-human study;

d. Overall advice related to the design of proof-of-concept or other pilot safety/biodistribution studies necessary to support administration of an investigational product in a first-in-human clinical trial;

e. General recommendations regarding a future first-in-human trial in a target clinical population where the population is novel and there is no prior precedent or guidance;

f. Recommendations on approach for further development of an early-stage product with limited CMC, pharmacology/toxicology, and/or clinical data that were collected outside of a US IND

II. PDUFA Meeting Management Procedural Goals

Table 1: Summary of Meeting Management Procedural Goals

Meeting Type	FDA's Response to Request	FDA's Receipt of Meeting Package	FDA's Preliminary Responses to Requester (if applicable)	Requester's Response to FDA's Preliminary Responses (not applicable to WRO)	FDA's Scheduled Meeting Date (days from receipt of request)	FDA's Meeting Minutes to Requester (if applicable)
A	14 days	With meeting request	No later than 2 days before meeting	N/A	Within 30 days	30 days after meeting
B	21 days	No later than 30 days before meeting or expected WRO	No later than 2 days before meeting	N/A	Within 60 days	30 days after meeting
B (EOP)	14 days	No later than 50 days before meeting or expected WRO	No later than 5 days before meeting	No later than 3 days after receipt of Preliminary Responses	Within 70 days	30 days after meeting
C	21 days	No later than 47 days before meeting or expected WRO	No later than 5 days before meeting	No later than 3 days after receipt of Preliminary Responses	Within 75 days	30 days after meeting
C Early consultations on the use of a new surrogate endpoint	21 days	With meeting request; WRO not applicable for these meetings	No later than 5 days before meeting	No later than 3 days after receipt of Preliminary Responses	Within 75 days	30 days after meeting

Meeting Type	FDA's Response to Request	FDA's Receipt of Meeting Package	FDA's Preliminary Responses to Requester (if applicable)	Requester's Response to FDA's Preliminary Responses (not applicable to WRO)	FDA's Scheduled Meeting Date (days from receipt of request)	FDA's Meeting Minutes to Requester (if applicable)
D	14 days	With meeting request	No later than 5 days before meeting	No later than 3 days after receipt of Preliminary Responses	Within 50 days	30 days after meeting
INTERACT	21 days	With meeting request	No later than 5 days before meeting	No later than 3 days after receipt of Preliminary Responses	Within 75 days	preliminary responses will be annotated and resent within 30 calendar days if advice provided changes as a result of the meeting. With WRO, the WRO will serve as meeting minutes from FDA.

Additional notes:

- If the requested date for any meeting type is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date. Note: This does not apply to WRO. WRO must adhere to the applicable PDUFA milestones.

- If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA's receipt of the meeting request, the requester's meeting package will be due no sooner than 6 calendar days after FDA's response time for issuing the letter granting the meeting.

- If the scheduled date of a Type C meeting is earlier than 75 days from FDA's receipt of the meeting request, the meeting package will be due no sooner

than 7 calendar days after FDA's response time for issuing the letter granting the meeting.

III. PDUFA Content of Meeting Requests

A. Should contain:

1. The product name and application number if already assigned;

2. Chemical name, established name, and/or structure (if appropriate). If chemical name and structure is not appropriate, please include a description of your product;

3. Proposed regulatory pathway (e.g., BLA, NDA)

4. Proposed indication or context of product development.

5. Type of meeting being requested (Type A, Type B, Type B(EOP), Type C, Type D, or INTERACT).

6. Dosage form, route of administration, and dosing regimen (frequency and duration)**.**

7. Pediatric study plans, if applicable.

a. Refer to the Policy section of this SOPP (General – number 3) for information on when these are applicable.

8. Human factors engineering plan, if applicable

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

10. Suggested dates and times (e.g., morning or afternoon) for the meeting that are consistent with the appropriate scheduling time frame for the meeting type being requested. Non-availability dates and times should also be included.

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

B. Must Include:

1. Proposed meeting format, e.g., Face-to-Face (in-person or virtual only), teleconference, or written responses only (WRO)

2. The date the meeting background package will be sent by the requester. Note that meeting packages should be included with the meeting request for all

Type A, Type C meetings to discuss early consultation on the use of new surrogate endpoints, Type D, and INTERACT meetings.

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 and clinical trials 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 trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.

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

5. A list of planned external attendees, including their names and titles. The list should also include the names, titles, and affiliations of consultants and interpreters, if applicable.

6. 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 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.

IV. PDUFA Content of Meeting packages

A. The product name and application number if already assigned.

B. Chemical name and structure (if appropriate). If chemical name and structure is not appropriate, please include a description of your product.

C. Proposed regulatory pathway (e.g., BLA, NDA).

D. Proposed indication or context of product development.

E. Dosage form, route of administration, and dosing regimen (frequency and duration).

F. Pediatric study plans, if applicable.

G. Human factors engineering plan, if applicable

H. Combination product information (e.g., constituent parts, intended device, intended packaging, planned human factors studies), if applicable.

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

J. A background section that includes the following:

1. A brief history of the development program and relevant communications with FDA prior to the meeting;

2. Substantive changes in product development plans (e.g. new indication, population, basis for a combination), when applicable;

3. The current status of product development.

K. A brief statement summarizing the purpose of the meeting and identifying the type of milestone meeting, if applicable.

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

M. A list of the final 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 products should be grouped together.

N. Data to support discussion organized by FDA discipline and question.

1. Protocols, full study reports, or detailed data generally are not appropriate for meeting packages; the summarized material should describe the results of relevant studies and clinical trials with some degree of quantification, and any conclusions about clinical trials that resulted.

2. The trial endpoints should be stated, as should whether endpoints were altered or analyses changed during the course of the trial.

O. Summary information relevant to the product(s) and supplementary information to enable the development of responses to the questions should also be provided. For example:

1. Pre-IND meeting - a summary of manufacturing information including completed or proposed testing and specifications; any pre-clinical studies completed or proposed; any known experience with the product in humans; the proposed eventual clinical use with rationale; a reasonably complete protocol or protocol synopsis; and information on any unique characteristics which differentiate the product from other similar entities.

The requester is expected to submit their development plan for complying with PREA.

2. End of Phase 1 meeting – a summary of data obtained in the Phase 1 study and the proposed Phase 2/Phase 3 development plan.

3. End of Phase 2/Pre-Phase 3 meeting - a synopsis of data from studies completed to date and proposed Phase 3 protocol(s) including detailed statistical plan. Outlines of any contractual arrangements for product manufacture and details of the characterization of the product to be used in the studies should also be submitted. If the Phase 3 product is not the same as the product intended for the market, proposals for studies to determine the comparability of the products are necessary. The requester is expected to submit their development plan for complying with PREA.

4. Pre-BLA/NDA meeting - a summary of the data from the pivotal studies completed; the proposed indication; proposed format of the submission, manufacturing information on the products used in the study(ies) and product intended for distribution if different; outlines of any contractual arrangements for product manufacture, proposed format of the submission and a timeline for submission. The requester is expected to submit their development plan for complying with PREA. For products that qualify under the PDUFA Program, the requester should also include what, if any, information the company proposes to submit late (within 30 calendar days).

5. Establishment issues meeting - identification of the product(s) produced with a brief description of the manufacturing process; a production process flow chart; floor plans with manufacturing process, personnel flow, water system, water and heating, ventilation, and air conditioning (HVAC) system, air pressure differentials, and air qualities described; a brief description of HVAC systems; changeover procedures and product/personnel separation information for multi-use facilities; a brief description of validation procedures including the validation master plan; and any unique issues pertinent to the facility.

P. If additional information is received after receipt of the meeting package, CBER may inform the requester that the new information or questions will not be reviewed or answered. The meeting may be rescheduled; if the meeting is held it will proceed as scheduled with only the meeting package information/questions. Discussion of the additional information may be the subject of a subsequent meeting.

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SOPP 8101.1 - Appendix D: Considerations for Meetings versus Written Responses Only (WRO) for PDUFA Meetings

I. Introduction

While CBER will make every effort to grant formal meetings in the format requested, there are times when select meetings may be converted to Written Response Only (WRO). This appendix outlines CBER's recommended approach for granting formal meetings versus issuing a WRO.

II. Considerations for granting the requested meeting format or issuing a WRO:

1. As best practice, CBER aims to prioritize granting the following meetings in the format requested, though conversion to WRO could be warranted, particularly if more than one of the items described in #2 below also apply.

- **a.** Type C for early consultation on the use of new biomarkers as surrogate endpoints
- **b.** Type A
- **c.** Type B, End of Phase 2 (EOP-2)
- **d.** Type B, Pre-BLA/NDA
- **e.** Type B, Initial multi-comprehensive meeting following a Breakthrough Therapy (BT) and/or RMAT designation
- **f.** Meetings that include critical or complex issues
- **g.** Novel product issues for CBER
- **h.** New CBER requester, e.g.,
  - **i.** has not met with or has had few meetings with CBER, or
  - **ii.** has few or no products regulated by CBER
- **i.** BT and/or RMAT designated product
- **j.** Pre-efficacy supplement
- **k.** Type C facility meetings

2. CBER may convert to WRO in the following circumstances:

- **a.** Questions are straightforward, e.g., can be answered based on published draft or final FDA guidance, regulations (CFR), standards (UPS, ISO, etc.), or documented CBER policy in SOPPs.

- **b.** Proven track record of reliability or experience of the requester, e.g.,
  - **i.** Requester has had multiple meetings with the same review office for various products.
  - **ii.** Requester is known to have typically incorporated CBER's advice into their regulatory submissions.

- **c.** Same requester proposing similar approaches to same review office, e.g.,

i. Product or development approach similar to another product or approach they have previously submitted.
ii. The office has previously provided responses or held meetings.