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

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Jennifer Mercier at 301-796-0957 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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

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

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

This guidance provides recommendations to industry on formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants relating to the development and review of drug or biological drug products (hereafter referred to as *products*) regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This guidance does not apply to abbreviated new drug applications, applications for biosimilar biological products, or submissions for medical devices. 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 face-to-face, virtual face-to-face (video conference), teleconference, and written response only (WRO) see in section IV, Meeting Formats).

This guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings. The general principles in this guidance may be extended to other nonapplication-related meetings with external constituents, insofar as this is possible.[2]

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.

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

[2] The guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants* (December 2017) and the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (June 2018) have been withdrawn.

II. BACKGROUND

Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of investigational new drugs and biologics, and drug or biological product marketing applications. Because these meetings often represent critical points in the drug and biological product development, 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.

FDA review staff and requesters are expected to adhere to the meeting management goals that were established under reauthorizations of the Prescription Drug User Fee Act (PDUFA).[3] They are described individually throughout this guidance and summarized in the Appendix.

III. MEETING TYPES[4]

There are six types of formal meetings under PDUFA that occur between requesters and FDA staff: Type A, Type B, Type B (end of phase (EOP)), Type C, Type D, and Initial Targeted Engagement for Regulatory Advice on CDER and CBER ProducTs (INTERACT).

A. Type A Meeting

Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Reasons for a Type A meeting include the following:

- Dispute resolution meetings as described in 21 CFR 10.75, 312.48, and 314.103 and in the guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the Division Level* (November 2017).[5]

- 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

[3] See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/151712/download.

[4] The meeting types and goal dates were negotiated under the Prescription Drug User Fee Act (PDUFA) and apply to formal meetings between FDA staff and requesters of PDUFA products; they do not apply to meetings with CDER Office of Generic Drugs, CDER Office of Compliance, or CDER Office of Prescription Drug Promotion. See the Prescription Drug User Fee Act (PDUFA) web page at https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.

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

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).

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

- Meetings requested within 30 days of FDA issuance of a refuse-to-file letter. To file an application over protest, applicants must first request and have this meeting (21 CFR 314.101(a)(3)).

B. Type B Meeting

Type B meetings are as follows:

- Pre-investigational new drug application (pre-IND) meetings.

- Pre-emergency use authorization meetings.

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

- Post-action meetings requested 3 or more months after receipt of an FDA regulatory action other than an approval (e.g., issuance of a complete response letter, refuse to file).

- Meetings regarding risk evaluation and mitigation strategies or postmarketing requirements that occur outside the context of the review of a marketing application.

- Meetings held to discuss the overall development program for products granted breakthrough therapy or regenerative medicine advanced therapy (RMAT) designation status. All 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) Meeting

Type B (EOP) meetings are as follows:

- 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)

- End-of-phase 2 (i.e., pre-phase 3) meetings (21 CFR 312.47)

D. Type C Meeting

A Type C meeting is any meeting other than a Type A, Type B, Type B (EOP), Type D, or INTERACT meeting regarding the development and review of a product, including meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use.

E. Type D Meeting

A Type D meeting is focused on a narrow set of issues that are used to discuss issues at key decision points to provide timely feedback critical to move the program forward (e.g., often one, but typically not more than two issues and associated questions). Requests could include the following:

- 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)

- A narrow issue on which the sponsor is seeking Agency input with only a few (e.g., three to five questions total) associated questions

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

Type D meetings should be limited to no more than two focused topics. If the sponsor has more than two focused topics or a highly complex single issue that includes multiple questions, a Type C meeting should be requested rather than requesting a Type D meeting. A Type C meeting should also be requested when there are more questions than appropriate for a Type D meeting. Sponsors should not request several Type D meetings in temporal proximity instead of a single Type C meeting. In addition, the issue should not require input from more than three disciplines or divisions. If the scope of the meeting is broad or includes complex questions/issues that require input from more than three disciplines or divisions, or requires cross-center responses, or additional regulatory review, then 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 resubmitting a new meeting request.

Examples and Scenarios

- A sponsor has a specific question about an aspect of a complex or innovative trial design (e.g., innovative pediatric design approach)

- A sponsor has a specific question about presenting data following a pre-BLA/NDA meeting

- A sponsor has a specific follow-up question about a new idea stemming from a Type C meeting

F. INTERACT Meeting

INTERACT meetings are intended for novel products and development programs that present unique challenges in early development (i.e., before filing of an IND or before having a pre-IND meeting). The issues typically relate to IND requirements, for example, questions about design of IND-enabling toxicity studies (e.g., species, endpoints), complex manufacturing technologies or processes, development of innovative devices used with a drug or biologic, or the use of New Approach Methodologies. INTERACT meetings are intended to facilitate IND-enabling efforts when the sponsor is facing a novel, challenging issue that might otherwise delay progress of the product toward entry into the clinic in the absence of this early FDA input. 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.

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

- Questions for novel products and development programs that present unique challenges in early development for all CDER and CBER products (i.e., questions for which there is no existing guidance or other information in writing the company could reference from FDA).

- Issues that a sponsor needs to address before a pre-IND meeting, including issues such as the following:

  - Choice of appropriate preclinical models or necessary toxicology studies for novel drug platforms or drug candidates

  - Chemistry, manufacturing, and controls issues or testing strategies aimed to demonstrate product safety adequate to support first-in-human study

  - 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

  - General recommendations about a future first-in-human trial in a target clinical population for which the population is novel and there is no prior precedent or guidance

  - Recommendations on approach for further development of an early-stage product with limited chemistry, manufacturing, and controls; pharmacology/toxicology; and/or clinical data that were collected outside of a U.S. IND

  - Other topics that would be agreed upon by FDA

IV. MEETING FORMATS

There are four meeting formats: In person face-to-face, virtual face-to-face, teleconference, and WRO, as follows:

1. In person face-to-face — Core attendees[6] 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 at all 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.

2. Virtual face-to-face (video conference) — Attendees participate remotely via virtual meeting platform (e.g., Zoom) (with core attendees' cameras on).

3. Teleconference — Attendees participate via an audio only connection (e.g., telephone, virtual meeting platform without cameras on).

4. Written Response Only (WRO) — Written responses are sent to requesters in lieu of meetings conducted in one of the other formats described above.

V. MEETING REQUESTS

To make the most efficient use of FDA resources, requesters should use the extensive sources of product development information that are publicly available before seeking a meeting (e.g., guidances). To disseminate a broad range of information in a manner that can be easily and rapidly accessed by interested parties, the FDA develops and maintains web pages, portals, and databases, and participates in interactive media as a means of providing information on scientific and regulatory issues.

To promote efficient meeting management, requesters should try to anticipate future needs and, to the extent practical, address relevant and related product development issues in the fewest possible meetings while avoiding meetings with too many questions (or subparts of questions) that would be impractical to discuss in the context of any single meeting. Furthermore, having

[6] FDA will have its core participants with a 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).

too many questions is not recommended when the topics are complex or if the combined issues would involve voluminous material for FDA review. As discussed below, there should generally be no more than 10 total questions to the FDA.

When a meeting is needed, a written request must be submitted to the FDA via the electronic gateway or, in CDER, via the CDER Nextgen Portal, as appropriate.[7] For additional ways to submit to CBER, please see https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper. Requests should be addressed to the appropriate Center and review division or office and, if previously assigned, submitted to the application (e.g., investigational new drug application (IND), new drug application (NDA), biologics license application (BLA), pre-application tracking system (PTS) Number (CBER)). If necessary, noncommercial IND holders may also submit the meeting request via the appropriate center's document room.

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

The meeting request should include the following information:

1. The application number (if previously assigned).
2. The product name.
3. The chemical name, established name, and/or structure.
4. The proposed regulatory pathway (e.g., 505(b)(1), 505(b)(2)).
5. The proposed indication(s) or context of product development.
6. The meeting type being requested (i.e., Type A, Type B, Type B (EOP), Type C, Type D, or INTERACT).
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.
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 (see Table 2 in section VI.B., Meeting Granted). Dates and times when the requester is not available should also be included.

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

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

The meeting request must include the following information:[8]

1. The proposed meeting format (i.e., in person face-to-face, virtual face-to-face, teleconference, and WRO (see section IV, Meeting Formats)).

2. The date the meeting package will be sent by the requester (see section VII.A., Timing of Meeting Package Submission). Meeting packages should be included with the meeting request for all Type A meetings, Type C meetings where the objective is to facilitate early consultation on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use, all Type D meetings, and all INTERACT meetings.

3. A brief statement of the purpose of the meeting that should include a background of the issues underlying the agenda and a summary of completed or planned studies and clinical trials or data that the requester intends to discuss at the meeting. The statement should then include a description of the general issues being raised of the 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 that are necessary to provide the FDA an understanding of the questions to be addressed at the meeting.

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

5. A list of planned attendees from the requester's organization, 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). 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 nonessential FDA attendees.

A well-written meeting request that includes the above components can help the FDA understand and assess the utility and timing of the meeting related to product development or review. The list of requester attendees and the list of requested FDA attendees can be useful in providing or preparing for the input needed at the meeting. However, during the time between the request and the meeting, the planned attendees can change. Therefore, an updated list of attendees with their

[8] See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/151712/download.

titles and affiliations should be included in the meeting package and a final list provided to the appropriate FDA contact before the meeting (see section VII.C., Meeting Package Content).

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, whether or not the questions can be feasibly addressed within the time frame associated with the meeting type requested, 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 about the complexity of questions submitted within a WRO should be applied. In general, there should be no more than 10 questions listed consecutively regardless of discipline. The FDA requests that meeting requesters not submit subquestions, as they will be counted toward the overall number of questions. For example, if Question 1 has three parts, the numbering should be 1, 2, and 3 rather than numbering them 1a, 1b, and 1c (i.e., with each as "subquestions"). If there are three clinical questions and three nonclinical questions, for a total of six questions, each question should have its own number (i.e., 1, 2, 3, 4, 5, 6, not Clinical 1, 2, 3 and then Nonclinical 1, 2, 3). The numbering of each question in the meeting request (see section VI, Assessing and Responding to Meeting Requests) should be identical to the numbering of each question in the meeting package.

VI. ASSESSING AND RESPONDING TO MEETING REQUESTS

For any type of meeting, the sponsor may request a WRO to its questions rather than another meeting format. The FDA will review the request and make a determination on whether a WRO is appropriate or whether an in person face-to-face, virtual face-to-face, teleconference, or WRO (see section IV., Meeting Formats) meeting is necessary. If a written response is requested and deemed appropriate, the FDA will notify the requester of the date it intends to send the written response in the Agency's response to the meeting request.

For pre-IND, Type C, Type D, and INTERACT meetings, although the sponsor may request an in-person, virtual, or teleconference meeting, the Agency may determine that a written response to the sponsor's questions would be the most appropriate means for providing feedback and advice to the sponsor. When it is determined that the meeting request can be appropriately addressed through a written response, the FDA will notify the requester of the date it intends to send the written response in the Agency's response to the meeting request. If the sponsor believes a meeting is needed, the sponsor may provide a rationale in a follow-up correspondence to the division, explaining their rationale for the meeting. The FDA will consider the follow-up correspondence and may or may not convert the WRO back to an appropriate format.

Requests for Type B and Type B (EOP) meetings will be honored if the sponsor is at the appropriate stage of development to make such a meeting productive. For example, a request for an EOP2 meeting should clearly describe the status of the phase 2 trial(s) and whether summary efficacy and safety data from these trial(s) will be available in the briefing document, as the lack

of these data will render an EOP2 meeting request premature. With the exception of products granted breakthrough therapy or RMAT designation status, the FDA generally will not grant more than one of each of the Type B meetings for each potential application (e.g., IND, NDA, BLA) or combination of closely related products developed by the same requester (e.g., same active ingredient but different dosage forms being developed concurrently), but the FDA can do so when it would be beneficial to hold separate meetings to discuss unrelated issues. For example, it may be appropriate to conduct more than one end-of-phase 2 meeting with different review divisions or disciplines for concurrent development of a product for unrelated claims or a separate meeting to discuss manufacturing development when the clinical development is on a different timeline. For novel programs, with many complex issues, discussion with the relevant division may lead to an agreement that additional meetings are needed.

A. Meeting Denied

If a meeting request is denied, the FDA will notify the requester in writing according to the timelines described in Table 1. The FDA's letter will include an explanation of the reason for the denial. Denials will be based on a substantive reason, not merely on the absence of a minor element of the meeting request or meeting package items. For example, a meeting can be denied because it is premature for the stage of product development or because the meeting package does not provide an adequate basis for the meeting discussion (see section IX., Rescheduling and Canceling Meetings, for the effect of inadequate meeting packages on other meeting types when the package is received after the meeting is granted). The FDA may also deny requests for meetings that do not have substantive required elements described in section V., Meeting Requests. A subsequent request to schedule the meeting will be considered as a new request (i.e., a request that merits a new set of time frames as described in section below, 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 face-to-face, virtual face-to-face, and teleconference meetings, the FDA's letter will include the date, time, conferencing arrangements, and/or location of the meeting, as well as expected FDA participants. For WRO requests, the FDA's letter will include the date the FDA intends to send the written responses (see Table 3 for FDA WRO response timelines). As shown in Tables 2 and 3, FDA WRO response timelines are the same as those for scheduling an in-person face-to-face, virtual face-to-face, or teleconference meeting of the same meeting type.

For in person face-to-face, virtual face-to-face, and teleconference meetings, the FDA will schedule the meeting on the 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 requestor's requested date for any meeting type is greater than the specified time frame, the meeting date should be scheduled by the FDA within 14 calendar days of that requested date.

Table 1. FDA Meeting Request/WRO Request Response Timelines

Meeting Type (any format)	Response Time (calendar days from receipt of meeting request/WRO request)
A	14 days
B	21 days
B (EOP)	14 days
C	21 days
D	14 days
INTERACT	21 days

Table 2. FDA Meeting Scheduling Time Frames

Meeting Type	Meeting Scheduling (calendar days from receipt of meeting request)
A	30 days
B	60 days
B (EOP)	70 days
C	75 days
D	50 days
INTERACT	75 days

Table 3. FDA WRO Response Timelines

Meeting Type	WRO Response Time (calendar days from receipt of WRO request)
A	30 days
B	60 days
B (EOP)	70 days
C	75 days
D	50 days
INTERACT	75 days

VII. MEETING PACKAGE

Premeeting preparation is critical for achieving a productive discussion or exchange of information. Preparing the meeting 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. In addition, the timely submission of the meeting package is important for ensuring that there is sufficient time for meeting preparation, accommodating adjustments to the meeting agenda, and accommodating appropriate preliminary responses to meeting questions. Requestors are encouraged to include their meeting package for all meeting types, if possible, but must meet the required due dates for certain meetings (see Table 4 below).

A. Timing of Meeting Package Submission

Requesters must submit the meeting package for each meeting type (including WRO) according to the meeting package timelines described in Table 4.[9]

Table 4. Requester Meeting Package Timelines

Meeting Type	FDA Receipt of Meeting Package (calendar days)
A, C*, D, INTERACT	At the time of the meeting request
B	No later than 30 days before the scheduled date of the meeting or WRO response time
B (EOP)	No later than 50 days before the scheduled date of the meeting or WRO response time**
C	No later than 47 days before the scheduled date of the meeting or WRO response time***

*For Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used as the primary basis for product approval in a proposed context of use, the meeting package is due at the time of the meeting request.
** If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA receipt of the meeting request, the requester's meeting package will be due no sooner than 6 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted).
*** If the scheduled date of a Type C meeting is earlier than 75 days from FDA receipt of the meeting request, the meeting package will be due no sooner than 7 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted).

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

Requesters should submit the archival meeting package to the relevant application(s) (e.g., pre-IND, IND, NDA, BLA or PTS (CBER)) via the electronic gateway or, in CDER, via the CDER Nextgen Portal (https://cdernextgenportal.fda.gov/), as applicable.[10] For additional ways to submit to CBER, please see https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper. If necessary, noncommercial IND holders may also submit the package via the appropriate center's document room.

C. Meeting Package Content

The meeting package should provide *summary* information relevant to the product and any supplementary information needed to develop responses to issues raised by the requester or review division. It is critical that the entire meeting package content support the intended meeting objectives. The meeting package content will vary depending on the product, indication, phase of product development, and issues to be discussed. FDA and ICH guidances

[9] See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/151712/download.

[10] See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Providing Regulatory Submissions in Electronic Format — General Considerations* (January 1999).

identify and address many issues related to product development and should be considered when planning, developing, and providing information needed to support a meeting with the FDA. If a product development plan deviates from current guidances, or from existing precedent, the deviation should be identified and explained. Known difficult design and questions about providing substantial evidence of effectiveness should be raised for discussion (e.g., use of a surrogate endpoint, reliance on a single study, use of a noninferiority design, adaptive designs). Also, merely describing a result as *significant* does not provide the review division with enough information to give the most constructive advice or identify important problems the requester may have missed.

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 with appropriate electronic linkage, appropriate indices, appendices, and cross references. It should 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, preferably in the order listed below:

Meeting packages should include the same first nine items provided for the meeting request (see above section V.), and in addition, should include:

1. 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.

2. A background section that includes the following:

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

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

    c. The current status of product development (e.g., drug development plan)

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

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

5. 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.

6. Data to support discussion organized by FDA discipline and question. 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 conclusion about clinical trials that resulted. The

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

For example, for an end-of-phase 2 meeting, this section of the meeting package should include the following: A description and the results of controlled trials conducted to determine dose-response information, summary efficacy and safety data from the phase 2 trial(s); adequately detailed descriptors of planned phase 3 trials identifying major trial features such as population, critical exclusions, trial design (e.g., randomization, blinding, and choice of control group, with an explanation of the basis for any noninferiority margin if a noninferiority trial is used), dose selection, and primary and secondary endpoints; and major analyses (including planned interim analyses and adaptive features, and major safety concerns).

VIII. 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. 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 responses and comments are clear to the requester), or a particular question is considered resolved allowing extra time for discussion of the more complex 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, or it may necessitate the submission of a new meeting request by the requester.

The FDA holds an internal meeting 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 meeting date for Type B (EOP), Type C, Type D, and INTERACT meetings. The requester will notify the FDA no later than 3 calendar days following receipt of the FDA's preliminary responses for these meeting types of whether the meeting is still needed, and if it is, the requester will send the FDA a revised meeting agenda indicating which questions the requestor considers as resolved and which questions the requestor will want to further discuss within the allotted time as reasonable.[11] For Type A and Type B (other than Type B (EOP)), the FDA intends to send the requester its preliminary responses no later than 2 calendar days before the meeting.

IX. RESCHEDULING AND CANCELING MEETINGS

[11] See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at https://www.fda.gov/media/151712/download.

Occasionally, circumstances arise that necessitate rescheduling or canceling a meeting. If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A new meeting request should not be submitted. However, if a meeting is canceled, the FDA will consider a subsequent request to schedule a meeting to be a new request (i.e., a request that merits a new set of time frames as described in section VI., Assessing and Responding to Meeting Requests). Requesters and the FDA should take reasonable steps to avoid rescheduling and canceling meetings (unless the meeting is no longer necessary). For example, if an attendee becomes unavailable, a substitute can be identified, or comments on the topic that the attendee would have addressed can be forwarded to the requester following the meeting. It will be at the discretion of the review division whether the meeting should be rescheduled or canceled depending on the specific circumstances.

The following situations are examples of when a meeting can be rescheduled. Some of the examples listed also represent reasons that a meeting may be canceled by the FDA. This list includes representative examples and is not intended to be an exhaustive list.

- The requester experiences any delay in submitting the meeting package. The requester should contact the FDA project manager to explain why it cannot meet the time frames for submission and when the meeting package will be submitted.

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

- There is insufficient time to review the material because the meeting package is voluminous (see section VII.C., Meeting Package Content), despite submission within the specified time frames and the appropriateness of the content.

- After the meeting package is submitted, the requester sends the FDA additional questions or data that are intended for discussion at the meeting and require additional review time.

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

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

The following situations are examples of when a meeting can be canceled:

- The meeting package is not received by the FDA within the specified time frames (see section VII.A., Timing of Meeting Package Submission) or is grossly inadequate. Meetings are scheduled on the condition that appropriate information to support the discussion will be submitted with sufficient time for review and preparatory discussion. Adequate planning should avoid this problem.

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

X. MEETING CONDUCT

Meetings will be chaired by an FDA staff member and begin with introductions and an overview of the agenda. FDA policy prohibits audio or visual recording of discussions at meetings.

Presentations by requesters are usually unnecessary 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 materials should be provided ahead of the meeting. All presentations should be kept brief to maximize the time available for discussion. The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of content distinct from clarifications or explanations of previous data and that were not included in the original meeting package submitted for review, FDA staff may not be able to provide commentary.

Either a representative of the FDA or the requester should summarize the important discussion points, agreements, clarifications, and action items. Summation can be done at the end of the meeting or after the discussion of each question. Generally, the requester will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and action items. FDA staff can add or further clarify any important points not covered in the summary, and these items can be added to the meeting minutes. At pre-NDA and pre-BLA meetings for applications reviewed under the PDUFA Program for Enhanced Review Transparency and Communication for New Molecular Entity (NME) NDAs and Original BLAs (also known as *the Program*),[12] 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.

XI. 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

[12] See https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm.

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. The minutes should be sufficiently detailed that they provide clarity about the agreements, such as on study design elements, or statistical testing, or enrollment criteria and similar important areas of the development program. The minutes are not intended to represent a transcript of the meeting.

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

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

- For INTERACT meetings, preliminary responses will be annotated and resent within 30 days if advice provided changes as a result of the meeting.

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

The following steps should be taken when there is a difference of understanding regarding the minutes:

- Requesters should contact the FDA project manager if there is a significant difference in their and the FDA's understanding of the content of the final meeting minutes issued to the requesters

- If after contacting the FDA project manager there are still significant differences in the understanding of the content, the requester should submit a description of the specific disagreements either:

  – To the application; or

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

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

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

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

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

For all meeting types, to ensure the sponsor's understanding of FDA feedback from meeting discussions or a WRO, sponsors may submit a "follow-up opportunity/clarifying questions" correspondence to the agency in a formal submission to their application. Only questions of a clarifying nature should be submitted (i.e., to confirm something in minutes or in a WRO issued by the FDA) rather than new issues or new proposals. If the FDA determines that the requests are not in scope (i.e., are not simply clarifications of advice provided at the meeting), the division may advise the sponsor to request a new meeting to address the issue. However, if the out-of-scope issue is narrow and focused, the review division, at their discretion, may provide a response (as a general correspondence) as soon as reasonably possible. 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 minutes or WRO, to include if the preliminary comments serve as the final minutes for a cancelled meeting. 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 minutes or WRO.

REFERENCES

Related Guidances[13]

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

Guidance for review staff and industry *Good Review Management Principles and Practices for PDUFA Products* (April 2005)

Related CDER MAPP[14]

MAPP 6025.6 *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics*

Related CBER SOPPs[15]

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

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

[13] Guidances can be found on the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[14] MAPPs can be found on the CDER Manual of Policies and Procedures web page at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm.

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

APPENDIX:
SUMMARY OF MEETING MANAGEMENT PROCEDURAL GOALS

Table A is a summary of Prescription Drug User Fee Act meeting management procedural goals.

Table A. Meeting Management Procedural Goals

Meeting Type	FDA Response to Request	FDA Receipt of Meeting Package	FDA Preliminary Responses to Requester (if applicable†)	Requester Response to FDA Preliminary Responses (if applicable†)	FDA Scheduled Meeting Date (days from receipt of request)	FDA Meeting Minutes to Requester (if applicable†)
A	14 days	With meeting request	No later than 2 days before meeting	--	Within 30 days	30 days after meeting
B	21 days	No later than 30 days before meeting	No later than 2 days before meeting	--	Within 60 days	30 days after meeting
B (EOP)*	14 days	No later than 50 days before meeting**	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***	No later than 5 days before meeting	No later than 3 days after receipt of preliminary responses	Within 75 days	30 days after meeting
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 the meeting	No later than 3 days after receipt of preliminary responses	Within 75 days	Preliminary responses annotated 30 days after meeting

† Not applicable to written response only.
* EOP = end of phase.

** If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA receipt of the meeting request, the requester's meeting package will be due no sooner than 6 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted).

*** If the scheduled date of a Type C meeting is earlier than 75 days from FDA receipt of the meeting request, the meeting package will be due no sooner than 7 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted). For Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used as the primary basis for product approval in a proposed context of use, the meeting package is due at the time of the meeting request.