
Guidance for Industry Formal Meetings Between the FDA and Sponsors or Applicants

**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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Revision 1

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Guidance for Industry¹

Formal Meetings Between the FDA and Sponsors or Applicants

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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 *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. For the purposes of this guidance, *formal meeting* includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference, or videoconference).

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

This guidance supersedes the guidance for industry *Formal Meetings With Sponsors and Applicants for PDUFA Products* published February 2000. The 2000 guidance implemented section 119(a) of the Food and Drug Administration Modernization Act of 1997, and reflected a unified approach to all formal multidisciplinary meetings between sponsors or applicants and the FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

¹ This guidance has been prepared by the Office of New Drugs Meeting Management Process Improvement Team, comprising individuals from the Office of New Drugs, in cooperation with other offices in the Center for Drug Evaluation and Research (CDER) and with the Center for Biologics Evaluation and Research at the Food and Drug Administration.

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be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Each year, FDA review staff participate in many meetings with sponsors or applicants who seek guidance 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 regulatory process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The GMMPs in this guidance are intended to provide consistent procedures that will promote well-managed meetings, and ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately.

III. MEETING TYPES²

There are three types of meetings that occur between sponsors or applicants and FDA staff: Type A, Type B, and Type C. Each meeting type is subject to different procedures, as described below.

A. Type A Meeting

A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed. Examples of a Type A meeting include:

- Dispute resolution meetings as described in 21 CFR 10.75, 312.48, and 314.103 and in the guidance for industry *Formal Dispute Resolution: Appeals Above the Division Level*³
- Meetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled and a new path forward should be discussed
- Special protocol assessment meetings that are requested by sponsors or applicants after receipt of FDA evaluation of protocols under the special protocol assessment procedures as described in the guidance for industry *Special Protocol Assessment*

² The meeting types and goal dates were negotiated under PDUFA and apply to formal meetings between FDA staff and sponsors or applicants of PDUFA products; they do not apply to meetings with CDER Office of Generic Drugs (OGD), CDER Office of Compliance, or CDER Division of Drug Marketing, Advertising, and Communications (DDMAC). However, OGD will attempt to meet the time frames set out under Type A and Type C meetings, and CDER Office of Compliance and DDMAC will apply GMMPs to the extent possible with the exception of the specific meeting types and goal dates.

³ We update guidances periodically. To make sure you have the most recent version of a guidance, check the CDER guidance Web page at <http://www.fda.gov/cder/guidance/index.htm>.

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If sponsors or applicants are considering a request for a Type A meeting, before submitting the request they should contact the review division in either CBER or CDER to discuss the appropriateness of the request. Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request. If a sponsor or applicant requests a meeting date that is beyond 30 days from the date of the request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date.

B. Type B Meeting

Type B meetings are as follows:⁴

- Pre-investigational new drug application (pre-IND) meetings (21 CFR 312.82)
- Certain end-of-phase 1 meetings (21 CFR 312.82)
- End-of-phase 2 and pre-phase 3 meetings (21 CFR 312.47)
- Pre-new drug application/biologics license application meetings (21 CFR 312.47)

Type B meetings should be scheduled to occur within 60 days of FDA receipt of the written meeting request. If a sponsor or applicant requests a meeting date that is beyond 60 days from the date of request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date.

To promote efficient management of formal meetings, the requestor should try to anticipate future needs and, to the extent practical, combine product development issues into the fewest possible meetings. Generally, we will not grant more than one of each of the Type B meetings for each potential application (e.g., investigational new drug application (IND), new drug application (NDA), biologics license application (BLA)) or combination of closely related products developed by the same sponsor or applicant (e.g., same active ingredient but different dosage forms being developed concurrently), but we can do so when it would be beneficial to hold separate meetings to discuss unrelated issues. It also may be appropriate to conduct more than one of some of the Type B meetings for concurrent development of a product for unrelated claims.

C. Type C Meeting

A Type C meeting is any meeting other than a Type A or Type B meeting between CBER or CDER and a sponsor or applicant regarding the development and review of a product.

Type C meetings should be scheduled to occur within 75 days of FDA receipt of the written meeting request. If a sponsor or applicant requests a meeting date that is beyond 75 days from

⁴ Type B meetings are not held in OGD.

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the date of the request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date.

IV. MEETING REQUESTS BY SPONSORS OR APPLICANTS

To make the most efficient use of FDA resources, before seeking a meeting with CBER or CDER, sponsors or applicants should consider other sources of input applicable to their product development program, such as FDA and International Conference on Harmonization (ICH) guidances. If a meeting is still needed, written correspondence to request such a meeting should be submitted to the sponsor's or applicant's application (e.g., IND, NDA, BLA) through the controlled document system. If there is no application, the request should be submitted to either the appropriate CDER division director with a copy sent to the division's chief of the project management staff or to the appropriate office contact within CBER. Before submitting any meeting request by fax or e-mail when there is no application, the sponsor or applicant should contact the appropriate review division to determine to whom the request should be directed, how the request should be submitted, the appropriate format for the request, and to arrange for confirmation of receipt of the request. This prevents the possibility that faxed or e-mailed requests will be overlooked because of the volume of e-mails received daily by FDA staff. Faxed or e-mailed requests should be sent during official business hours (8:00 a.m. to 4:30 p.m. EST/EDT) Monday through Friday (except Federal government holidays). Processing and receipt may be delayed for requests where confirmation of receipt has not been pre-arranged.

The meeting request, regardless of the method of submission, 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. Product name.
2. Application number (if applicable).
3. Chemical name and structure.
4. Proposed indication(s) or context of product development.
5. Type of meeting being requested (i.e., Type A, Type B, or Type C). If a Type A meeting is requested, the rationale should be included.
6. A brief statement of the purpose and objectives 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 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 should 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.
7. A proposed agenda.
8. A list of proposed questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question.

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9. A list of all individuals with their titles and affiliations who will attend the requested meeting from the sponsor's or applicant's organization and consultants.
10. A list of FDA staff, if known, or disciplines asked to participate in the requested meeting.
11. 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.
12. The format of the meeting (i.e., face to face, teleconference, or videoconference).

The sponsor or applicant, when writing a meeting request that contains the above components (items 1-12), should define the specific areas of input needed from CBER or CDER. A well-written meeting request that uses the above components as a guide can help the FDA understand and assess the utility and timing of the meeting related to product development or review. Although CBER or CDER will determine the final meeting type (i.e., Type A, Type B, or Type C), the sponsor or applicant should provide its meeting type assessment as it relates to the product's development. The list of sponsor or applicant 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 projected attendees can change. Therefore, an updated list of attendees with their 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.).

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 sponsor or applicant 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.

V. ASSESSING MEETING REQUESTS

The CBER or CDER division director or designee who receives a meeting request will determine whether to hold the meeting and will respond to the sponsor or applicant by granting or denying the meeting within 14 days of receipt of the request for Type A meetings and within 21 days for Type B and Type C meetings.

A. Meeting Denied

If a meeting request is denied, notification to the sponsor or applicant 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. 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 III).

B. Meeting Granted

If a meeting request is granted, CBER or CDER will notify the sponsor or applicant of the decision and schedule the meeting by determining the meeting type, date, time, length, place, and

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expected FDA participants. All of the scheduling information will be forwarded to the sponsor or applicant as soon as possible following the granting notification, and within the specified PDUFA timelines.

VI. RESCHEDULING AND CANCELLING MEETINGS

Occasionally, circumstances arise that necessitate the rescheduling or cancelling of a meeting. If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A new meeting request should not be submitted and new time frames should not be set for rescheduled meetings. However, if a meeting is cancelled, we 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 III). Sponsors or applicants and the FDA should take reasonable steps together to avoid rescheduling and cancelling 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 sponsor or applicant following the meeting. It will be at the discretion of the review division whether the meeting should be rescheduled or cancelled depending on the specific circumstances.

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

- The sponsor or applicant experiences a minor delay in submitting the meeting package. The sponsor or applicant should contact the CDER regulatory project manager (RPM) or appropriate point of contact in CBER 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 sponsor's or applicant's questions or other important issues for discussion, but it is possible to identify the additional information needed and arrange for its submission.
- There is insufficient time to review the material because the meeting package is voluminous (see section VII.C.), despite submission within the specified time frames and the appropriateness of the content.
- Essential attendees are no longer available for the scheduled date and time because of an emergency.
- After the meeting package is submitted, the sponsor or applicant sends CBER or CDER 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 organizations not originally anticipated or requested by the sponsor or applicant, such as the Office of the Chief

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Counsel, are critical and their availability precludes holding the meeting on the original date.

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

- The sponsor or applicant determines that premeeting responses to its questions are sufficient for its needs and additional discussion is not necessary (see section VIII.). In this case, the sponsor or applicant should contact the CDER RPM or appropriate point of contact in CBER to request cancellation of the meeting. The division will consider whether it agrees that the meeting should be cancelled. 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 premeeting communications seem sufficient to answer the sponsor's or applicant's questions. If the division agrees that the meeting can be cancelled, the division will document the reason for cancellation and the premeeting communication will represent the final responses and the official record.
- The meeting package is not received by the FDA within the specified time frames (see section VII.A.) 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.

VII. MEETING PACKAGE CONTENT AND SUBMISSION

Premeeting preparation is critical for achieving a productive discussion or exchange of information. Preparing the meeting package should help the sponsor or applicant 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 premeeting communications.

A. Timing of Submission

A meeting package should be submitted to the appropriate review division so that it is received in accordance with the following time frames:

- Type A meeting — At least 2 weeks before the formal meeting.
- Type B meeting — At least 4 weeks before the formal meeting.
- Type C meeting — At least 4 weeks before the formal meeting.

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

Meeting packages should be submitted to the appropriate review division. The meeting package should identify the date, time, and subject of the meeting. An archival copy should be submitted to the relevant application (e.g., IND, NDA, or BLA); if there is no established application (e.g., for a pre-IND meeting), the responsible point of contact in the review division will provide instructions on how to submit the meeting packages. We encourage sponsors or applicants to submit the archival meeting package electronically according to the electronic submission formatting recommendations (see the draft guidance for industry *Providing Regulatory Submissions in Electronic Format — General Considerations*⁵).

The number of copies of a meeting package will vary based on the meeting. The responsible point of contact in the review division will advise on the number of copies needed for the meeting attendees. To facilitate the meeting process, we strongly suggest that copies of meeting packages provided in electronic format also be provided in paper.

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 sponsor or applicant or review division. Full study and trial reports or detailed data generally are not appropriate for meeting packages; the summarized material should describe the decisions and results of relevant studies and clinical trials with some degree of quantification. The trial endpoints should be stated, as should whether endpoints were altered or analyses changed. Also, merely describing a result as *significant* does not provide the division with enough information to give good advice or identify important problems the sponsor or applicant may have missed. It is critical that the 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 identify and address many issues related to product development and should be considered in planning, developing, and providing information needed to support a meeting with the FDA. If a product development plan deviates from current guidances, or from current practices, the deviation should be recognized and explained. Known difficult design and evidence issues should be raised for discussion (e.g., use of a surrogate endpoint, reliance on a single study use of a noninferiority design, adaptive designs).

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 (individual sections can be numbered separately, as long as there is an overall pagination covering the whole submission) with a table of contents, appropriate indices, appendices, cross references, and tabs differentiating sections. Meeting packages generally should include the following information:

1. Product name and application number (if applicable).
2. Chemical name and structure.

⁵ When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the CDER guidance Web page at <http://www.fda.gov/cder/guidance/index.htm>.

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3. Proposed indication.
4. Dosage form, route of administration, and dosing regimen (frequency and duration).
5. An updated list of sponsor or applicant attendees, affiliations, and titles.
6. A background section that includes the following:
 - a. A brief history of the development program and the events leading up to the meeting.
 - b. The status of product development (e.g., the target indication for use).
7. A brief statement summarizing the purpose of the meeting.
8. A proposed agenda.
9. A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question.
10. Data to support discussion organized by discipline and question. For example, for an end-of-phase 2 meeting, this section should include the following, if not already provided in the background section (refer to item #6 above): description and results of controlled trials conducted to determine dose-response information; adequately detailed descriptors of planned phase 3 trials identifying major trial features such as trial population, critical exclusions, trial design (e.g., randomization, blinding, choice of control group, with explanation of the basis for any noninferiority margin if a noninferiority trial is used), choice of dose, primary and secondary trial endpoints; and major analyses (including planned interim analyses and adaptive features, and major safety concerns).

VIII. PREMEETINGS AND COMMUNICATIONS WITH SPONSORS OR APPLICANTS

CBER and CDER hold internal meetings to discuss meeting packages and to gain internal agreement on the preliminary responses to a sponsor's or applicant's questions. We may communicate these preliminary responses to the sponsor or applicant. Communications before the meeting between sponsors or applicants and the FDA, including preliminary responses, can serve as a foundation for discussion or can be the final meeting responses. Nevertheless, premeeting communications should not be construed as *final* unless there is agreement between sponsor or applicant and the FDA that additional discussion is not necessary. Preliminary responses communicated by the FDA are not intended to generate the submission of a new meeting agenda and new questions. If, however, a sponsor or applicant provides new data or a revised or new proposal, the FDA may not be able to provide comments on the new data or it may generate the need for the submission of a new meeting request by the sponsor or applicant.

IX. PROCEDURES FOR THE CONDUCT OF MEETINGS

Meetings will be chaired by an FDA staff member and will begin with introductions and a statement of the agenda. Presentations by sponsors or applicants generally are not needed because the information necessary for review and discussion should be part of the meeting package. If a sponsor or applicant plans to make a presentation, the presentation should be discussed ahead of time with the CBER or CDER point of contact to determine if a presentation is warranted and ensure that CBER or CDER has the presentation materials ahead of the meeting if possible. All presentations should be kept brief to maximize the time available for discussion.

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The length of the meeting will not be increased to accommodate a presentation. If a presentation contains more than a small amount of new data that are distinct from clarifications or explanations of previous data and that were not included in the original meeting package submitted to CBER or CDER for review, FDA staff may not be able to provide comments on the new data.

Before the end of the meeting, FDA attendees and the sponsor or applicant attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the sponsor or applicant will be asked to present the summary to ensure that there is mutual understanding of meeting outcomes and actions. 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. The summary can be done at the end of the meeting or after the discussion of each question.

X. DOCUMENTATION OF MEETINGS

Documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this information is preserved for meeting attendees and future reference. FDA minutes are the official record of the meeting. The official, finalized minutes will be issued to all FDA attendees (with copies to appropriate files) and to the sponsor or applicant within 30 days of the meeting.

XI. RESOLUTION OF DISPUTE ABOUT MINUTES

This section refers to disputes about the accuracy and sufficiency of the minutes, not to whether the positions taken by the FDA are the correct ones. The latter is subject to the standard appeal procedures (21 CFR 10.75; 21 CFR 312.48 and 314.103).

A sponsor or applicant who needs additional clarification of the meeting minutes issued by the FDA should contact the assigned FDA point of contact for guidance. This process addresses issues with the meeting minutes only. If a sponsor or applicant needs to discuss additional issues that were not addressed at the meeting, it should submit a correspondence or a new meeting request.

If, after following up as described above, there are still significant differences in understanding regarding the content of the official meeting minutes, the sponsor or applicant should notify the FDA in writing of specific disagreements. The sponsor or applicant should submit the correspondence to its application or, if there is no application, forward a letter to the division director of the responsible division, with a copy to the point of contact describing the concern.

The sponsor's or applicant's concerns will be taken under consideration by the review division and the office director if the office director was present at the meeting. If the minutes are deemed to accurately reflect the meeting discussion, the point of contact will convey this decision to the sponsor or applicant and the minutes will stand as the official documentation of

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the meeting. If after discussions with the sponsor or applicant the FDA 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 sponsor or applicant objections.