

Guidance for Industry

Formal Meetings With Sponsors and Applicants for PDUFA Products

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GUIDANCE FOR INDUSTRY¹

Formal Meetings with Sponsors and Applicants for PDUFA Products

I. INTRODUCTION

This document is intended to provide guidance to industry on procedures adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants regarding the development and review (including activities and materials related to the initial launch) of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 379g(1)) (PDUFA products). This guidance document describes procedures for requesting, scheduling, conducting, and documenting such formal meetings.

CDER and CBER participate in many meetings each year with sponsors of investigations and applicants for marketing who seek guidance relating to the development of new PDUFA products or the review of marketing applications for PDUFA products. These meetings often represent critical points in the regulatory process. It is essential that FDA maintain procedures for the timely and effective conduct of such meetings. CDER first established formal policies and procedures for meetings with external constituents, including all sponsors and applicants, in March 1996 (MAPP 4512.1, *Formal Meetings Between CDER and External Constituents*) to ensure that such meetings are scheduled within a reasonable time, are conducted efficiently, and are documented appropriately. Procedures for the conduct of meetings with CBER applicants and sponsors have been provided to CBER staff in specific standard operating procedures. This industry guidance reflects procedures and policies common to all CDER and CBER review divisions.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) directs FDA to meet with sponsors and applicants, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim in a new drug application (NDA) submitted under section 505(b) of the Act or in a biologics license application (BLA) submitted under section 351 of the Public Health Service Act. These meetings are included in this guidance as *special protocol assessment meetings*.

¹This guidance has been prepared by the Review Management Working Group comprising individuals in the Centers for Drug Evaluation and Research (CDER) and Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on formal meetings with sponsors and applicants for PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

In conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 in November 1997 (PDUFA 2), FDA agreed to specific performance goals (PDUFA goals) for the management of meetings between sponsors and applicants for PDUFA products. The PDUFA goals are described in the *PDUFA Reauthorization Performance Goals and Procedures*, an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords.

The procedures and policies described in this guidance document are designed to promote efficient, well-managed meetings between sponsors, applicants, and CDER or CBER. These procedures implement section 119(a) of the Modernization Act, are consistent with the PDUFA goals, and further the procedures described in CDER MAPP 4512.1 and CBER SOPP 8101.1. The formal meetings described in this document are not intended to replace informal discussions between the Agency and a sponsor or applicant. However, the procedures in this guidance document do not apply to such informal discussions.

Although many of the procedures in this guidance affect CDER and CBER staff, sponsors and applicants also have an important role in the meeting process and should be aware of the Agency's efforts to improve the productivity of meetings. The Agency anticipates that this guidance document will promote mutual understanding between FDA, sponsors, and applicants, and will encourage the support of sponsors and applicants in conducting more efficient and effective meetings.

FDA participates in formal meetings with various external constituents who seek guidance relating to the development or marketing of drug and biological products. This document is the first of two guidances describing CDER's and CBER's procedures for formal meetings. FDA intends to issue additional guidance documents describing CDER's and CBER's procedures for formal meetings with sponsors and applicants for non-PDUFA products (including generic drug products), and for non-application related meetings with external constituents.

II. TYPES OF MEETINGS

There are three categories of meetings between sponsors or applicants for PDUFA products and CDER or CBER staff: Type A; Type B; and Type C. Each type of meeting will be subject to different procedures, as described below.

A. Type A Meeting

A Type A meeting is one that is immediately necessary for an otherwise stalled drug development program to proceed (i.e., a *critical path* meeting).

Type A meetings generally will be reserved for dispute resolution meetings, meetings to discuss clinical holds, and special protocol assessment meetings that are requested by sponsors after

FDA's evaluation of protocols in assessment letters.²

Type A meetings should be scheduled to occur within 30 days of FDA's receipt of a written request for a meeting from a sponsor or applicant for a PDUFA product. If the sponsor or applicant requests a date for the meeting that is beyond 30 days from the date the Agency receives the request, the meeting should be scheduled to occur no later than 14 days after the date requested.

B. Type B Meeting

Type B meetings are (1) pre-IND meetings (21 CFR 312.82), (2) certain end of Phase 1 meetings (21 CFR 312.82), (3) end of Phase 2/pre-Phase 3 meetings (21 CFR 312.47), and (4) pre-NDA/BLA meetings (21 CFR 312.47).

FDA will honor requests for Type B meetings except in the most unusual circumstances (e.g., submitted information or data are inadequate for meaningful Agency comment). Type B meetings should be scheduled to occur within 60 days of the Agency's receipt of the written request for a meeting. If the sponsor or applicant requests a date for the meeting that is beyond 60 days from the date the Agency receives the request, the meeting should be scheduled to occur no later than 14 days after the date requested.

To promote efficient management of formal meetings, each requestor should try to anticipate future needs and combine drug development issues to the extent practical. As a result of this consolidation, FDA expects generally to grant only one of each of the Type B meetings for each potential application (i.e., NDA, BLA) or combination of closely related products (e.g., same active ingredient but different dosage forms being developed concurrently). The Agency may grant more than one of each of the Type B meetings when it would be beneficial to hold separate meetings to discuss unrelated issues. Simultaneous development of a drug for unrelated claims may require more than one of some of the Type B meetings.

C. Type C Meeting

A Type C meeting is any meeting other than a Type A or Type B meeting between FDA and a sponsor or applicant regarding the development and review of a product in a human drug application as described in section 735(1) of the Act. Meetings that do not pertain to the review of human drug applications for PDUFA products (e.g., most meetings about advertising and promotional labeling for approved drug products except meetings about launch activities

² In March 1999 (64 FR 13587), FDA made available for comment a draft guidance for industry, *Formal Dispute Resolution: Appeals Above the Division Level*, describing policies and procedures that will be adopted by CDER and CBER to resolve disputes with sponsors and applicants. FDA intends to issue additional guidance describing CDER's and CBER's general procedures for special protocol assessment.

and materials, postmarketing safety evaluation meetings) are not Type C meetings and are not addressed in this guidance document.

Type C meetings should be scheduled to occur within 75 days of the Agency's receipt of the written request for a meeting. If the sponsor or applicant requests a date for the meeting that is beyond 75 days from the date the Agency receives the request, the meeting should be scheduled to occur no later than 14 days after the date requested.

III. PROCEDURES FOR REQUESTING MEETINGS

A sponsor or applicant for a PDUFA product who is interested in meeting with the Agency should submit a written request (i.e., letter or fax) to the appropriate FDA component as follows:

- § Requests for meetings with CDER should be submitted to the appropriate Division Director within the Office of Review Management (ORM), Office of Pharmaceutical Science (OPS), or Office of Medical Policy (i.e., the Division of Drug Marketing, Advertising, and Communication (DDMAC)), when appropriate. Requests for Type A meetings should be copied to the appropriate Office Director within ORM and OPS, when appropriate.
- § Requests for meetings with CBER should be submitted to the appropriate applications Division Director in the office with product review responsibility, or the Advertising and Promotional Labeling Staff (APLS), when appropriate.

A meeting request should be submitted as an amendment to an application. If the underlying product is subject to an IND, the request should be submitted in triplicate with Form FDA 1571 attached. If the underlying product is subject to an NDA or BLA, the meeting request should be submitted to the NDA or BLA in triplicate with Form FDA 356h attached. If a sponsor is interested in meeting with the Agency prior to the submission of an IND, the sponsor should submit a meeting request in triplicate to the director of the appropriate division in CDER or CBER as identified above.

Prior to submitting a written request for a meeting by fax, the sponsor or applicant should contact the appropriate review division to determine to whom the fax should be directed and to arrange for confirmation of receipt of the fax. All faxed meeting requests should subsequently be submitted in hard copy to the review division as described above. Faxes received after Agency business hours will be considered received the next business day.

To make the most efficient use of Agency resources, any meeting request should include adequate information for the appropriate FDA component to determine the utility of the meeting and to identify Agency staff necessary to discuss proposed agenda items. The meeting request should include the following information:

1. Product name and application number (if applicable).
2. Chemical name and structure.
3. Proposed indication(s).
4. The type of meeting being requested (i.e., Type A, Type B, or Type C).
5. A brief statement of the purpose of the meeting. This statement could include a discussion of the types 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.
6. A list of the specific objectives/outcomes expected from the meeting.
7. A preliminary proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s).
8. A draft list of specific questions, grouped by discipline.³
9. A list of all individuals (including titles) who will attend the proposed meeting from the sponsor's or applicant's organization and consultants.
10. A list of Agency staff requested by the sponsor or applicant to participate in the proposed meeting. If a sponsor or applicant is not sure which Agency officials should attend the meeting, the applicant does not need to include specific individuals in the request, but should include requested disciplines, if known.
11. The approximate date on which supporting documentation (i.e., the information package described in section IV) will be sent to the review division.
12. Suggested dates and times (i.e., morning or afternoon) for the meeting.

The Division Director or delegate in the FDA component who receives a request for a meeting should promptly determine whether to hold the meeting. The review division should respond to the sponsor or applicant *within 14 days* of receipt of the meeting request. If FDA agrees to the meeting, the written response (i.e., letter or fax) should include the date, time, length, and place of the meeting as well as the

³ FDA may often provide additional comment not specifically solicited by the questions (e.g., if the sponsor has not identified a critical issue), but questions provided by the sponsor or applicant should frame much of the meeting content. Therefore, the questions should be as comprehensive and precise as possible.

expected FDA participants.

If a meeting request is denied, the notification to the sponsor or applicant should include a clear explanation of the reason(s) for the denial (e.g., the meeting request was inadequate). The Agency will consider a subsequent request to schedule the meeting to be a new request (i.e., a request that merits a new set of time frames described above).

If a meeting is scheduled by FDA and is later canceled or postponed by the applicant or sponsor, the Agency will consider a subsequent request to schedule the meeting to be a new request (i.e., a request that merits a new set of time frames described above). FDA will take reasonable steps to avoid the cancellation or postponement of a scheduled meeting. However, when a meeting is postponed by the Agency, the FDA component should generally reschedule the meeting to take place within 30 days of the date of the originally scheduled meeting.

IV. INFORMATION PACKAGE

A. Timing of Submission

FDA's receipt of a full information package, including clear, thoughtful questions, in advance of a formal meeting with sufficient lead time to enable Agency staff to review the data adequately is critical to achieving a productive meeting. A sponsor or applicant for a PDUFA product should submit an information package to FDA so that it is received in accordance with the following time frames.

Type A Meetings:

At least 2 weeks prior to the formal meeting.

Type B Meetings:

At least 4 weeks prior to the formal meeting.

Type C Meetings:

At least 2 weeks prior to the formal meeting, although it is generally beneficial for the Agency to receive the information package approximately 4 weeks prior to a Type C meeting.

FDA may postpone or cancel a meeting if supporting documentation essential for a productive meeting has not been received by the Agency within the prescribed time frames. Failure to submit an adequate information package within the time frames will be considered a request by

the sponsor or applicant to cancel the meeting.

B. Content of Information Packages

The sponsor or applicant should submit an information package to the appropriate Division Director in CDER or CBER with product review responsibility. Product launch materials should be submitted to DDMAC (CDER) or APLS (CBER). The information package should provide summary information relevant to the product(s) and any supplementary information needed to develop responses to issues raised by the sponsor, applicant, or reviewing division. The content of the information package should support the intended objectives of the formal meeting with FDA.

If the content of the information package is not sufficient to provide the basis for a meaningful discussion (e.g., critical data have not been generated or analyzed or have not been included in the package), the Agency may cancel the meeting. The FDA component will briefly explain to the sponsor or applicant the basis for finding that the information package is deficient. To schedule another meeting with the Agency, the sponsor or applicant should submit another meeting request to the appropriate Division Director.

To facilitate FDA's review, the sponsor or applicant should organize the contents of the information package according to the proposed agenda. A *fully paginated* document with a table of contents, appropriate indices, appendices, cross references, and tabs differentiating sections is recommended. Hard copies of the information package should be provided for each FDA participant, with an extra 5 copies for consultation. The project manager or division contact can advise on the numbers of copies needed. The cover letter accompanying the information package should clearly identify the date, time, and subject of the meeting. Although the contents of the information package will vary depending on the product, indication, phase of drug development, and issues to be discussed, information packages generally should include the following:

1. Product name and application number (if applicable).
2. Chemical name and structure.
3. Proposed indication(s).
4. Dosage form, route of administration, and dosing regimen (frequency and duration).
5. A brief statement of the purpose of the meeting. This statement could include a discussion of the types 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.

6. A list of the specific objectives/outcomes expected from the meeting.
7. A proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s).
8. A list of specific questions grouped by discipline.
9. Clinical data summary (as appropriate).
10. Preclinical data summary (as appropriate).
11. Chemistry, manufacturing, and controls information (as appropriate).

Although CDER and CBER also request the information listed in items 1 - 8 above in the request for a formal meeting, these items should be updated in the information package to reflect the most current and accurate information available to the sponsor or applicant. If a sponsor or applicant wishes specific guidance regarding the contents of the information package, it should contact the project management staff assigned to the submission. If the product is in the early stages of development and no project manager has been assigned, the sponsor or applicant should contact the appropriate Chief, project management staff in CDER or the applications division in the CBER office with product responsibility.

Once the information package is received, the review division, DDMAC, or APLS will work with the sponsor or applicant to refine the agenda, as appropriate.

V. PROCEDURES FOR THE CONDUCT OF MEETINGS

The FDA chair or facilitator for a formal meeting should provide initial structure to the meeting by making introductions and stating the objectives and goals of the meeting. To ensure the accuracy of documentation, all representatives of the sponsor or applicant should provide business cards or provide the necessary information on a sign-in sheet. The chair or facilitator should identify the individual who will record the minutes and keep time, if appropriate.

At the end of the meeting, the FDA chair or facilitator should summarize all important discussion points, decisions, recommendations, agreements, disagreements, and action items for the benefit of all meeting attendees. Attendees should be provided the opportunity to comment. If there are any differences of opinion regarding the outcome of the discussion, the chair or facilitator should ensure that the issues are resolved to the extent practicable. The FDA recorder should document this summary as the official minutes.

VI. DOCUMENTATION

As noted above, an FDA recorder should prepare minutes of any formal meeting with a sponsor or applicant for a PDUFA product. The meeting minutes should summarize in bulleted form the important discussion points, decisions, recommendations, agreements, disagreements, issues for further discussion, and action items. The official minutes should be issued to all FDA attendees (with copies to appropriate files) and to the sponsor or applicant *within 30 days* of the formal meeting.

Sponsors or applicants may provide the assigned project manager with a draft of the firm's minutes in writing, or may identify at the end of the meeting the critical outcomes they believe should be included in the meeting documentation. Draft minutes provided by the sponsor or applicant are useful only if submitted promptly; if so submitted, they will be considered by the review division during the preparation of the official minutes. The draft provided by the sponsor or applicant will not be the official minutes of the meeting. The official minutes are prepared by FDA staff. FDA will not generally comment on draft minutes submitted to the Agency by a sponsor or applicant, but may do so where they reflect major differences in view as to the outcomes of the meeting. A sponsor or applicant who identifies major differences in view as to the outcomes of a meeting should raise attention to such issues with the review division. Major differences will ordinarily indicate a need for further discussion.

VII. DISPUTE RESOLUTION

If, after receiving the official minutes from FDA, a sponsor or applicant of a PDUFA product wishes additional clarification of the minutes or issues related to the meeting, it may contact the project manager of the FDA component for guidance or to arrange a teleconference with the appropriate Agency staff.

Sponsors and applicants may notify FDA of significant differences in understanding regarding the content of the official minutes of a meeting. If sponsors or applicants wish to effect a change in the official minutes, they may send a letter to the Division Director, with a copy to the project manager, citing their recommendations and rationale. The concerns of the sponsor or applicant should be taken under consideration by the review division, and the project manager should issue an appropriate response in writing. If the Agency agrees to change the official minutes, such changes should be documented in an addendum to the official minutes. The addendum should be signed by the official(s) who signed the original minutes and copies of the addendum should be issued to the sponsor or applicant, the administrative file, and all FDA attendees who received copies of the original official minutes.

If sponsors or applicants are not satisfied with the response provided by the FDA component, they may elect to pursue the Agency's procedures for internal review and dispute resolution (21 CFR 10.75, 21 CFR 312.48, 314.103).

DEFINITIONS

Applicant: As used in this guidance document, an applicant is a person who submits an NDA or BLA, or an amendment or supplement to an NDA or BLA, to obtain FDA marketing approval for a drug product.

Day: One calendar day.

External Constituents: Individuals outside the FDA organizational structure, including sponsors and applicants.

Information Package (*briefing package* or *backgrounder*): Information provided by an external constituent to CDER or CBER as background information for a meeting.

Meeting: As used in this guidance document, a meeting is any formal, planned interaction between FDA and an external constituent that occurs face-to-face, via teleconference, or via video conference.

Official Minutes: A record of meeting deliberations between FDA and external constituents that captures critical discussion points, decisions, recommendations, agreements/disagreements, issues for further discussion, and action items in summary form. The official minutes are prepared by FDA staff.

PDUFA Goals: Agency performance goals, summarized in *PDUFA Reauthorization Performance Goals and Procedures*, an enclosure to a letter dated November 12, 1997, from Donna E. Shalala, Secretary of Health and Human Services, to Senator James M. Jeffords.

PDUFA Product: A product described in section 735(1) of the Act.

Project Managers: Regulatory project management staff in the Office of Review Management and Office of Pharmaceutical Science in CDER responsible for assuring compliance with regulations and orchestrating the multidisciplinary activities necessary to complete a project (e.g., review of a regulatory submission) or staff in CBER assigned to perform comparable functions.

Sponsor: A person who takes responsibility for and initiates a clinical investigation (see 21 CFR 312.3).

Week: Seven calendar days.