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DRAFT GUIDANCE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) Rachel Hartford at 301-796-0319 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-7800.

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 2

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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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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,[2] 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 *requester(s)*) following the request procedures provided in this guidance and includes meetings conducted in any format (i.e., face to face, teleconference, videoconference, or written response).

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.

[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] In the Generic Drug User Fee Act Program Performance Goals and Procedures, referenced in section 301(b) of the Generic Drug User Fee Amendments (GDUFA) of 2012, the FDA committed to certain performance goals for holding 30-minute teleconferences when requested by abbreviated new drug application applicants within 10 business days of the FDA issuing a first cycle complete response letter. See the GDUFA Program Performance Goals and Procedures (commitment letter) available at http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm282513.htm.

This guidance revises the guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants* issued in May 2009. After it has been finalized, this guidance will replace the May 2009 guidance. This draft guidance has been updated in accordance with the Meeting Management Goals section of the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures; Fiscal Years 2013 through 2017.[3] Significant changes from the 2009 version include:

- Addition of the written response meeting format for pre-investigational new drug application (pre-IND) and Type C meetings
- Designation of a post-action meeting requested within 3 months after an FDA regulatory action other than approval as a Type A meeting
- Designation of a post-action meeting requested 3 or more months after an FDA regulatory action other than approval as a Type B meeting
- Designation of a meeting regarding risk evaluation and mitigation strategies (REMS) or postmarketing requirements that occur outside the context of the review of a marketing application as a Type B meeting
- Inclusion of a meeting package in Type A meeting requests
- Designation of meetings to discuss the overall development program for products granted breakthrough therapy designation status as a Type B meeting

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

II. BACKGROUND

Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of 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 to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately.

[3] See http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

III. MEETING TYPES[4]

There are three types of formal meetings under PDUFA that occur between requesters 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 that is necessary for an otherwise stalled product development program to proceed (a *critical path* meeting) or to address an important safety issue. 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 draft guidance for industry and review staff *Formal Dispute Resolution: Appeals Above the Division Level*[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 reviewed by the FDA, but the FDA and the requester agree that the development is stalled and a new path forward should be discussed

- Special protocol assessment meetings that are requested after receipt of an FDA letter in response to protocols submitted under the special protocol assessment procedures as described in the guidance for industry *Special Protocol Assessment*[6]

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

If requesters 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

[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 OGD, CDER Office of Compliance, or CDER Office of Prescription Drug Promotion (OPDP). However, OGD will attempt to meet the time frames set out in this guidance as applicable, and CDER Office of Compliance and OPDP will apply GMMPs to the extent possible with the exception of the specific meeting types and goal dates. See the PDUFA Web page at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm.

[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 FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[6] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

written meeting request. If a request is for a meeting date that is beyond 30 days from the date of the request receipt, the meeting date should be within 14 calendar days of the requested date.

B. Type B Meeting

Type B meetings are as follows:

- Pre-IND meetings (21 CFR 312.82). Alternatively, the requester can request a written response to pre-IND questions rather than a face-to-face meeting, videoconference, or teleconference. In some cases, even though the requester can request a face-to-face meeting, the FDA may determine that a written response would be the most appropriate means for responding to the questions. In both scenarios, the FDA intends to notify the requester of the date it intends to send the written response within the specified time frame for assessing the meeting request (i.e., within 21 days for a Type B meeting request).

- Pre-emergency use authorization meetings.

- Certain end-of-phase 1 meetings for subpart E or subpart H or similar products (21 CFR 312.82).

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

- 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 an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).

- Meetings regarding REMS 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 designation status. Subsequent meetings for breakthrough therapy-designated products will be considered either Type B or possibly Type A meetings if the meeting request meets the criteria for a Type A meeting.

The FDA intends to schedule Type B meetings to occur within 60 days of FDA receipt of the written meeting request. If a request is for a meeting date that is beyond 60 days from the date of request receipt, the meeting date should be within 14 calendar days of the requested date.

Generally, requests for Type B meetings will be honored except in the most unusual circumstances. However, to promote efficient management of formal meetings, the requester should try to anticipate future needs and, to the extent practical, combine product development issues into the fewest possible meetings. Generally, with the exception of products granted breakthrough therapy designation status, 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 requester (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 regarding the development and review of a product.

The FDA intends to schedule Type C meetings to occur within 75 days of FDA receipt of the written meeting request. If a request is for a meeting date that is beyond 75 days from the date of request receipt, the meeting date should be within 14 calendar days of the requested date.

In the case of Type C meeting requests, the requester can request a written response to the questions rather than a face-to-face meeting, videoconference, or teleconference. In some cases, even though a face-to-face meeting was requested, the FDA may determine that a written response would be the most appropriate means for responding. In both scenarios, the FDA should notify the requester of the date it intends to send the response within the specified time frame for assessing the meeting request (i.e., within 21 days for a Type C meeting request). The written response should be transmitted within 75 days of FDA receipt of the meeting request.

IV. MEETING REQUESTS

To make the most efficient use of FDA resources, before seeking a meeting, requesters should consider other sources of input applicable to product development, such as FDA and International Conference on Harmonisation (ICH) guidances. If a meeting is still needed, written correspondence to request such a meeting should be submitted to the application (e.g., IND, NDA, BLA). 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 email when there is no application, the requester 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 reduces the possibility that faxed or emailed requests will be overlooked because of the volume of faxes and emails received daily by FDA staff. Faxed or emailed 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).

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 or indications, or context of product development.

5. Meeting type being requested (i.e., Type A, Type B, or Type C). If a Type A meeting is requested, the rationale and meeting package (as described in section VII) should be included. Generally, the FDA will deny requests for Type A meetings that do not include the meeting packages in the original request.

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 requester intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in overall development plans. Although the statement should not provide 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, including estimated times needed for discussion of each agenda item not to exceed the total allotted meeting time.

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.

9. 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.

10. A list of FDA staff, if known, or disciplines asked to participate in the requested meeting. Note that requests for attendance by FDA staff who are not otherwise essential to the application's review may affect the ability to hold the meeting within the specified time frame of the meeting type being requested. Therefore, when attendance by nonessential FDA staff is requested, the meeting request should state whether or not a later meeting date is acceptable to the requester to accommodate the nonessential FDA attendees.

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. Nonavailability dates and times also should be included.

12. The proposed format of the meeting (i.e., written response, face to face, teleconference, or videoconference).

13. The approximate date that the meeting package will be sent. The meeting package should be received at the time of the meeting request for Type A meetings and at least 1 month in advance of the scheduled meeting for Type B and Type C meetings (including those for which a written response will be provided).

The requester, when writing a meeting request that contains the above components (items 1-13), 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 requester should provide its meeting type assessment as it relates to the product's development. 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 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 requester and to focus the discussion should the meeting be granted. Each question should be precise and include a brief explanation of the context and purpose of the question. The questions submitted within a single meeting request should be limited to those that can be reasonably answered within the allotted meeting time, taking into consideration the complexity of the questions submitted. Similar considerations regarding the complexity of the questions submitted should be applied to requests for written responses (e.g., pre-IND or Type C meetings).

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 requester 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 requester 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). Generally, the FDA will deny requests for Type A meetings that do not include an adequate meeting package in the original request.

B. Meeting Granted

If a meeting request is granted, CBER or CDER will notify the requester of the decision and schedule the meeting by determining the meeting type, date, time, length, place, and expected FDA participants. All of the scheduling information will be forwarded to the requester as soon as possible following the granting notification, and within the specified PDUFA timelines.

VI. RESCHEDULING AND CANCELING MEETINGS

Occasionally, circumstances arise that necessitate the rescheduling or cancellation 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. However, if a meeting is canceled, 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). Requesters and the FDA should take reasonable steps together 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 a minor delay in submitting the meeting package. The requester should contact the CBER or CDER regulatory project manager (RPM) 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.), despite submission within the specified time frames and the appropriateness of the content.

- After the meeting package is submitted, the requester 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 personnel not originally anticipated or requested are critical and their availability 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.) 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.). In this case, the requester should contact the CBER or CDER RPM to request cancellation of the meeting. The division 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 division agrees that the meeting can be canceled, the division will document the reason for cancellation and the preliminary responses will represent the final responses and the official record.

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 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.

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 — Concurrent with the meeting request
- Type B meeting — At least 1 month before the formal meeting
- Type C meeting — At least 1 month before the formal meeting

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

Meeting packages should be submitted to the appropriate CBER or CDER 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 requester should contact the review division for additional instructions. We encourage requesters 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*[7]).

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 requester or review division. Full study and trial 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 decision 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. Also, merely describing a result as *significant* does not provide the review division with enough information to give good advice or identify important problems the requester may have missed.

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 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 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:

[7] When final, this guidance will represent the FDA's current thinking on this topic.

1. Product name and application number (if applicable).

2. Chemical name and structure.

3. Proposed indication.

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

5. 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.

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.

7. A brief statement summarizing the purpose of the meeting.

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

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. Full study and trial 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 decision about clinical trials that resulted. 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 REQUESTERS

CBER and CDER hold internal meetings to discuss meeting packages and to gain internal alignment on the preliminary responses to a requester's questions. Our goal is to communicate these preliminary responses to the requester no later than 2 days before the scheduled meeting date. Communications before the meeting between requesters and the FDA, including preliminary responses, can serve as a foundation for discussion or as the final meeting responses. Nevertheless, preliminary responses should not be construed as *final* unless there is agreement

between the requester and the FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the requester is satisfied with the FDA's preliminary responses), or a particular question is considered resolved allowing 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 a new meeting agenda 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 data or it may necessitate the submission of a new meeting request by the requester.

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 requesters generally are not needed because the information necessary for review and discussion should be part of the meeting package. If a requester plans to make a presentation, the presentation should be discussed ahead of time with the 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. 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 to CBER or CDER for review, FDA staff may not be able to provide commentary.

Before the end of the meeting, FDA attendees and the requester attendees should summarize the important discussion points, agreements, clarifications, and action items. 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 PDFUA V Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs,[8] the applicant 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. Summation 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 FDA intends to issue the official, finalized minutes to the requester within 30 days of the meeting.

[8] The Program applies to all new molecular entity NDAs and original BLAs that are received from October 1, 2012, through September 30, 2017. See http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm.

XI. RESOLUTION OF DISPUTE ABOUT MINUTES

This section refers to disputes regarding the accuracy and sufficiency of the minutes. A requester who needs additional clarification of the meeting minutes issued by the FDA should contact the assigned FDA point of contact for advice. This process addresses issues with the meeting minutes only. If a requester 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 the requester's and the FDA's understanding of the content of the official meeting minutes, the requester should notify the FDA in writing with respect to specific disagreements. The requester 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 requester'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 and sufficiently reflect the meeting discussion, the point of contact will convey this decision to the requester and the minutes will stand as the official documentation of the meeting. If after discussions with the requester 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 requester objections.