Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA

Guidance for Industry

DRAFT GUIDANCE

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

October 2017
Generics

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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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 describes an enhanced pathway for discussions between FDA and a prospective applicant preparing to submit or an applicant that has submitted an abbreviated new drug application (ANDA) for a complex product to FDA as defined in this guidance. Specifically, this guidance provides information on requesting and conducting product development meetings, pre-submission meetings, and mid-review-cycle meetings with FDA.

This guidance reflects a unified approach to all formal meetings between FDA and ANDA applicants or prospective ANDA applicants for complex products.[2, 3] This guidance will assist ANDA applicants and prospective ANDA applicants in generating and submitting to FDA a meeting request and the associated meeting package for complex products as defined in this guidance to be submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 355(j)) and as contemplated in the reauthorization of the Generic Drug User Fee Amendments for Fiscal Years (FYs) 2018-2022 (GDUFA II).[4]

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 Office of Generic Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

[2] For purposes of this guidance, *formal meeting* includes any meeting that is requested by a prospective ANDA applicant following the request procedures provided in this guidance and includes meetings conducted in any format.

[3] This guidance uses the term *ANDA applicant* when discussing meetings that occur after an ANDA is received (i.e., the mid-review-cycle meeting) and the term *prospective ANDA applicant* when discussing meetings that occur before an ANDA is received (i.e., the product development and pre-submission meetings).

[4] Generic Drug User Fee Amendments of 2017, Title III, FDA Reauthorization Act of 2017 (Public Law 115-52).

II. BACKGROUND

As part of GDUFA II, FDA committed to developing a program to assist ANDA applicants and prospective ANDA applicants of complex products before the submission of an ANDA to FDA. As stated in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Goals or Commitment Letter),[5] this pre-ANDA program is intended to:

> . . . clarify regulatory expectations for prospective applicants early in product development, assist applicants to develop more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of review cycles required to obtain ANDA approval, particularly for [complex products].[6]

As defined in the GDUFA II Commitment Letter, complex products are:

1. Products with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of [active pharmaceutical ingredients], naturally sourced ingredients); complex formulations (e.g., liposomes, colloids); complex routes of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions, or gels); or complex dosage forms (e.g., transdermals, metered dose inhalers, extended-release injectables);

2. Complex drug-device combination products (e.g., auto-injectors, metered dose inhalers); and

3. Other products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.[7]

To facilitate development of complex products that may be submitted in an ANDA, FDA and industry agreed to a series of meetings between ANDA applicants or prospective ANDA applicants and FDA to discuss the proposed complex product and support submission of a high-quality, approvable ANDA.

In addition to developing a robust pre-ANDA program, FDA agreed to respond to requests for and conduct meetings related to the development of complex products submitted on or after October 1, 2017, within specific time frames.[8] These GDUFA II performance goals are described further in section IV of this guidance.

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[5] Available at http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf.
Id. at 14.

[7] Id. at 25.

[8] FDA has received, responded to, and granted certain pre-ANDA meeting requests for products that do not fit within the definition of a complex product as defined in the GDUFA II Commitment Letter and as used in this guidance. The recommendations in this guidance and the performance goals only apply to meeting requests for complex products that may be submitted in an ANDA on or after October 1, 2017. Meeting requests for products that do not fit within the scope of this guidance will be granted based on the workload and availability of staff and the anticipated value to the ANDA review process.

III. MEETING TYPES

A. Product Development Meetings

Product development meetings for complex products that may be submitted in an ANDA provide for discussion of specific scientific issues or questions (e.g., a proposed study design, alternative approach, or additional study expectations), in which FDA will provide targeted advice regarding an ongoing ANDA development program.[9] To engage in a substantive discussion, FDA expects that the prospective ANDA applicant has enough knowledge of the complex product to allow FDA to provide appropriate feedback that will advance product development early in the process (e.g., the prospective ANDA applicant has generated its own data to be discussed). FDA anticipates that some prospective ANDA applicants of complex products may request more than one product development meeting. FDA recommends that the prospective ANDA applicant submit no more than one request for a product development meeting for the specific complex product per year.

The GDUFA II Commitment Letter identifies when a product development meeting *will* and when a product development meeting *may* be granted. A product development meeting *will* be granted if, in FDA's judgment, the requested meeting concerns development of a complex product for which FDA has not issued: (1) a product-specific guidance, or (2) an alternative equivalence evaluation (i.e., change in study type, such as in vitro to clinical) for a complex product for which FDA has issued a product-specific guidance. A product development meeting *may* be granted if the meeting concerns complex product development issues other than those identified above (e.g., FDA has developed a product-specific guidance and the prospective ANDA applicant is not proposing an alternative equivalence evaluation), dependent on available resources.

In addition to demonstrating that the proposed product development falls within the scope outlined above, prospective ANDA applicants should ensure all of the following criteria are met or FDA will not grant the product development meeting:

1. The prospective ANDA applicant submits a complete meeting package, including a data package and specific proposals for product development (e.g., details regarding the proposed product development plan, such as an alternative study design, and sufficient justification to support the proposal), as applicable.

2. A controlled correspondence would not adequately address the prospective ANDA applicant's questions.

3. A product development meeting would significantly improve ANDA review efficiency (e.g., ultimately decrease the number of review cycles for the application).[10]

[9] GDUFA II Commitment Letter at 27.
[10] Id. at 15.

B. Pre-Submission Meetings

Pre-submission meetings for complex products provide an opportunity for prospective ANDA applicants to discuss and explain the format and content of the ANDA to be submitted (e.g., data to support equivalence claims, types of data that will be contained in the ANDA).[11] The pre-submission meeting does not include substantive review of summary data or full study reports, but FDA will identify items or information that should be clarified before submission of the ANDA. The pre-submission meeting is not an opportunity to determine whether the application is acceptable for filing.[12] FDA anticipates that the pre-submission meeting will take place approximately 6 months before submission of the ANDA. FDA attendees at the pre-submission meeting will generally include staff that attended the product development meeting, if held, and additional review staff that may review the ANDA once received.

Prospective ANDA applicants of complex products may request a pre-submission meeting whether or not they had a product development meeting. Note that a prospective ANDA applicant that had a product development meeting or received written responses from FDA is not obligated to request the pre-submission meeting. FDA will generally grant pre-submission meetings for prospective ANDA applicants that have had a product development meeting or received a written response. FDA may grant a pre-submission meeting to a prospective ANDA applicant of a complex product that did not have a product development meeting if, in FDA's judgment, the pre-submission meeting would improve review efficiency.

C. Mid-Review-Cycle Meetings

A mid-review-cycle meeting for a complex product is held only during the first review cycle with ANDA applicants that have participated in a prior product development or pre-submission meeting. The mid-review-cycle meeting will generally take place 30 days after the mid-point of the review cycle.[13] The mid-review-cycle meeting affords an opportunity for FDA to discuss issues identified during review with the applicant. The Regulatory Project Manager (RPM) assigned to the ANDA will contact the applicant to schedule the meeting (held by teleconference); ANDA applicants that participated in a product development and/or pre-submission meeting should not request a mid-review-cycle meeting. The applicant may decline the mid-review-cycle meeting because these meetings are optional. If an applicant does wish to decline the mid-review-cycle meeting, FDA recommends that the applicant submit a letter to the ANDA file indicating that it wishes to decline the mid-review-cycle meeting.

During the mid-review-cycle meeting, the RPM and certain members of the review team, as appropriate considering any deficiencies or requests for clarification communicated to the applicant, will participate in the teleconference. FDA will provide the applicant with an update

[11] Id.

[12] For example, the prospective ANDA applicant should not request or expect guidance on whether certain components needed for filing consideration may be omitted from the ANDA.

[13] The GDUFA II Commitment Letter states that the mid-review-cycle meeting will take place after the last key discipline has issued its information request (IR) and/or discipline review letter (DRL) (at 26). Because FDA may issue an IR or DRL at any time during the review, the mid-review-cycle meeting will take place at a specific time during the review cycle as stated in this guidance (i.e., generally 30 days after the mid-point of the review cycle).

on the status of the review of its application.[14] An agenda will be provided to the applicant by the RPM. The agenda will generally consist of possible deficiencies found by a discipline reviewer and/or review team for its portion of the pending application at the conclusion of the discipline review (i.e., the content of a Discipline Review Letter (DRL)[15]). If a DRL has already been issued, the agenda will generally provide for a status update. FDA intends to send the agenda to the applicant 7 calendar days before the teleconference.

IV. GDUFA II PERFORMANCE GOALS

As indicated in section II, FDA committed to meet certain performance review goals associated with the pre-ANDA meetings for complex products described in this guidance. The goals described below only apply to meetings related to complex products under GDUFA II (i.e., requests submitted on or after October 1, 2017, and subject to the criteria described in this guidance).

A. Performance Goals for Product Development Meetings

FDA will grant or deny 90 percent of product development meeting requests for complex products under GDUFA II:

1. Within 30 calendar days of receipt in fiscal years (FYs) 2018 and 2019.

2. Within 14 calendar days of receipt in FYs 2020, 2021, and 2022.[16]

FDA will conduct product development meetings for complex products pursuant to the following performance goals:

1. In FY 2018, 60 percent of the meetings will be conducted within 120 calendar days of granting the request.

2. In FY 2019, 70 percent of the meetings will be conducted within 120 calendar days of granting the request.

3. In FY 2020, 80 percent of the meetings will be conducted within 120 calendar days of granting the request.

4. In FYs 2021 and 2022, 90 percent of the meetings will be conducted within 120 calendar days of granting the request.[17]

[14] Id. at 17.
[15] Id. at 26.
[16] Id. at 16.
[17] Id.

FDA can also meet the product development meeting goal by providing meaningful written responses to the prospective ANDA applicant, within the applicable goal date, that address relevant drug development and/or regulatory issues.[18]

B. Performance Goals for Pre-Submission Meetings

FDA will grant or deny 90 percent of pre-submission meeting requests for complex products under GDUFA II:

1. Within 30 calendar days of receipt in FYs 2018 and 2019.

2. Within 14 calendar days of receipt in FYs 2020, 2021, and 2022.[19]

FDA will conduct pre-submission meetings for complex products pursuant to the following performance goals:

1. In FY 2018, 60 percent of the meetings will be conducted within 120 calendar days of granting the request.

2. In FY 2019, 70 percent of the meetings will be conducted within 120 calendar days of granting the request.

3. In FY 2020, 80 percent of the meetings will be conducted within 120 calendar days of granting the request.

4. In FYs 2021 and 2022, 90 percent of the meetings will be conducted within 120 calendar days of granting the request.[20]

C. Performance Goals for Mid-Review-Cycle Review Meetings

There is no specified performance review goal associated with the mid-review-cycle meetings. As stated in section III.C, these meetings will generally be held 30 days after the mid-point of the review cycle. The date for the mid-review-cycle is subject to change if, for example, the applicant submits an unsolicited amendment.[21]

[18] Id.
[19] Id. at 16-17.
[20] Id.
[21] See guidance for industry *ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA.*

V. MEETING REQUESTS FOR PRODUCT DEVELOPMENT AND PRE-SUBMISSION MEETINGS

A request for a product development or pre-submission meeting[22] for complex products that may be submitted in an ANDA should be sent to GenericDrugs@fda.hhs.gov. The meeting request should clearly identify in the subject line that the prospective applicant is requesting a product development or pre-submission meeting and should include adequate information for FDA to assess the potential utility of the meeting and to identify the appropriate staff that should attend the meeting. If FDA determines that the meeting request does not contain the information specified in the list in this section, the request will not be considered to be submitted for purposes of GDUFA II performance goals. The meeting request should include the following information:

1. Pre-assigned ANDA number.[23]
2. Established product name.
3. Chemical structure.
4. Reference listed drug (RLD) and its application number.
5. Proposed indication(s).
6. Dosage form, route of administration, and dosing regimen (frequency and duration).
7. Meeting type being requested (i.e., product development or pre-submission).
8. A brief statement indicating how the product meets the criteria for a complex product (see section II).[24]
9. A brief statement of the purpose and objectives of the meeting. This statement should include a brief background of the issues underlying the agenda.
10. A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the requester's (i.e., prospective applicant's) organization, including consultants and interpreters.

[22] Applicants should not submit meeting requests for the mid-review-cycle meeting because the RPM will contact the applicant to schedule the meeting. See section III.C of this guidance.

[23] See information regarding requesting a pre-assigned application number available on FDA's website at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm114027.htm.

[24] A request for a product development or pre-submission meeting as described in this guidance for a product that does not meet the criteria of a complex product (see section II) will be denied (see section IV.A). As stated in footnote 8, FDA may entertain meeting requests for products that do not fit within the scope of this guidance subject to the workload and availability of staff and the anticipated value to the ANDA review process. A pre-ANDA meeting request for such a product should be clearly identified as a pre-ANDA meeting for a non-complex product.

11. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame of the meeting type being requested (e.g., within a period of 120 days after the date the meeting may be granted (see section IV)). Nonavailability dates and times should also be included.

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

13. The meeting package (see section VIII of this guidance), which should be received at the time of the meeting request for both a product development and pre-submission meeting.

14. Contact person for the meeting, with their title and affiliation, secure email[25] address, and phone number.

15. A list of proposed questions, grouped by discipline, as applicable, with each question clearly numbered (e.g., 1, 2, 3 without subquestions). The request should also contain a restatement of each question with a brief explanation of the context and purpose of the question and any supporting rationale or data, as applicable. The prospective ANDA applicant should consider the duration of the meeting (approximately 1 to 1.5 hours) when determining the proposed questions.

A request for a pre-submission meeting should clearly indicate whether the requester had a product development meeting with FDA. If no product development meeting was held, the requester should explain why a pre-submission meeting should be granted.

VI. ASSESSING MEETING REQUESTS FOR PRODUCT DEVELOPMENT AND PRE-SUBMISSION MEETINGS

The Office of Generic Drugs' (OGD's) Office of Research Standards (ORS), with input from the Office of Pharmaceutical Quality, will determine whether to grant a product development and/or pre-submission meeting for complex products that may be submitted in an ANDA, and a response will be provided to the requester by granting or denying the meeting pursuant to the performance goals stated in the GDUFA II Commitment Letter and in section IV of this guidance.

A. Meeting Denied

If a request for a product development or pre-submission meeting for a complex product is denied, written 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 product development

[25] Secure email between CDER and ANDA applicants and prospective ANDA applicants is useful for informal communications when confidential information may be included in the message (e.g., trade secrets or patient information). Secure email should not be used for formal regulatory submissions. For more information on establishing a secure email link with CDER, please contact SecureEmail@fda.hhs.gov.

or pre-submission meeting may be denied because the product does not meet the criteria for a complex product as provided in section II of this guidance or because a meeting is premature for the stage of product development in light of the insufficiency of the data generated. A subsequent request to schedule the product development or pre-submission meeting will be considered as a new request.

B. Meeting Granted

If a request for a product development or pre-submission meeting is granted, FDA will provide notification to the requester of the decision by email. If FDA plans to provide a written response instead, FDA will advise the requester that a written response is forthcoming. If FDA plans to hold a meeting, FDA will schedule the meeting by determining the date, time, length, place, and expected FDA participants. All of the scheduling information will be forwarded to the requester as soon as possible following notification that the meeting has been granted, and the meeting will be scheduled within the specified GDUFA II performance goals stated in section IV.

VII. RESCHEDULING AND CANCELING PRODUCT DEVELOPMENT AND PRE-SUBMISSION MEETINGS[26]

Circumstances may arise that necessitate the rescheduling or canceling of a meeting. For product development and pre-submission meetings, FDA will determine whether the meeting should be rescheduled or canceled, depending on the specific circumstances.

A. Rescheduled Meetings

If a meeting needs to be rescheduled, FDA will reschedule it 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.

A meeting may be rescheduled if, for example:

1. The review team determines that additional information is needed from the prospective ANDA applicant to address the prospective ANDA applicant's questions.

2. Essential attendees are no longer available for the scheduled date and time because of an emergency.

3. Attendance by additional FDA offices not originally anticipated or requested by the prospective ANDA applicant is critical and the offices' availability precludes holding the meeting on the original date.

[26] In general, the subsections below apply only to product development and pre-submission meetings for complex products. However, the mid-review-cycle meeting for complex products may also be rescheduled or canceled. If a mid-review-cycle meeting is rescheduled, FDA will seek to reschedule the meeting within 14 calendar days of the originally scheduled date.

4. There is a regulatory policy issue that is yet to be resolved that may affect the response to the prospective ANDA applicant's questions.

5. The Federal Government is closed or opening is delayed due to inclement weather, emergency, or other reason.

If a prospective ANDA applicant requests that a product development or pre-submission meeting be rescheduled, FDA will make every effort to ensure the meeting occurs within the goal date (see section IV). If FDA is unable to reschedule the meeting within the original goal date, FDA will still consider the performance goal met if the Agency is able to schedule and conduct the meeting within a 30-day extension added on to the original goal date.

B. Canceled Meetings

If a meeting is canceled, a subsequent request to schedule a meeting will be considered a new request.

A product development or pre-submission meeting may be canceled if, for example:

1. The prospective ANDA applicant withdraws the meeting request.

2. The prospective ANDA applicant determines its questions have been adequately answered by the preliminary response.

3. FDA issues product-specific guidance on establishing bioequivalence to the RLD that is the basis of submission for the prospective ANDA applicant.[27]

If a prospective ANDA applicant cancels a product development or pre-submission meeting, FDA will count the performance goal as met. If FDA cancels the meeting, the meeting request will not be counted for performance goal purposes.

VIII. MEETING PACKAGE CONTENT AND SUBMISSION FOR PRODUCT DEVELOPMENT AND PRE-SUBMISSION MEETINGS[28]

Pre-meeting preparation is critical for achieving a productive discussion or exchange of information at the product development and pre-submission meetings for complex products that may be submitted in an ANDA. Preparing the meeting package should help the prospective ANDA applicant focus on describing its principal areas of interest. The meeting package should

[27] FDA publishes new and revised product-specific guidances describing the Agency's current recommendations for demonstrating bioequivalence and certain other approval requirements. Please check for the availability of new and revised product-specific guidances in the *Federal Register* and on the FDA website at the following address: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm.

[28] In general, the subsections below do not apply to the mid-review-cycle meeting for complex product ANDAs. As stated in this guidance, FDA will schedule and prepare the agenda for the mid-review-cycle meeting for any complex product ANDA for which there was a product development or pre-submission meeting.

provide information relevant to the discussion topics and enable FDA to prepare adequately for the meeting.

A. Timing of Submission

The meeting package for both a product development and a pre-submission meeting for a complex product should be submitted to OGD so that it is received concurrent with the meeting request.

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

Both the product development and pre-submission meeting packages should be sent electronically to GenericDrugs@fda.hhs.gov with the meeting request. It is not necessary to submit any paper copies of the meeting package.

C. Meeting Package Content

The meeting package should provide information relevant to the product, development stage, and meeting type requested, in addition to any supplementary information needed to develop responses to issues raised by the prospective ANDA applicant or FDA. The meeting package should contain sufficient detail to meet the intended meeting objectives.

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. Pre-assigned ANDA number.
2. Established name.
3. Chemical structure.
4. RLD and application number.
5. Proposed indication(s).
6. Dosage form, route of administration, and dosing regimen (frequency and duration).
7. A background section that includes the following:
    a. A brief history of the development program.
    b. The status of product development.
8. A brief statement summarizing the purpose of the meeting.

9. A proposed agenda, including estimated times needed for discussing each agenda item.

10. A list of questions for discussion, grouped by discipline, as applicable, with each question clearly numbered (e.g., 1, 2, 3 without subquestions). For each question, there should be a brief explanation of the context and purpose of the question and any supporting rationale or data, as applicable. The prospective ANDA applicant should consider the duration of the proposed meeting when determining the proposed questions. The package should be organized such that following a summary list of all questions, each question is followed by the corresponding supporting justification, rationale, or data as applicable, followed by the next question.

11. Data to support discussion organized by discipline and question. The level of detail should be appropriate to the meeting type requested and the product development stage (e.g., if an approach or alternative approach is proposed for establishing equivalence, sufficient rationale together with at least preliminary data should be provided).

IX. PRE-MEETINGS AND COMMUNICATIONS WITH REQUESTERS FOR PRODUCT DEVELOPMENT AND PRE-SUBMISSION MEETINGS[29]

Before the product development or pre-submission meeting for a complex product, FDA holds internal meetings to discuss meeting packages and gain internal alignment on the preliminary responses to a prospective ANDA applicant's questions. For a product development meeting, if FDA is not providing a written response to the prospective ANDA applicant, FDA intends to provide preliminary written comments to the prospective ANDA applicant's point of contact 5 calendar days before the meeting.[30] If FDA determines it is appropriate to provide preliminary written comments before a pre-submission meeting, any such comments will be sent by email to the prospective ANDA applicant's designated point of contact identified in the original meeting request 5 calendar days before the meeting.[31]

Communications before the meeting between prospective ANDA applicants and FDA, including preliminary written comments, can serve as a foundation for discussion or as the final meeting responses. Nevertheless, preliminary written comments should not be construed as final unless there is agreement between the prospective ANDA applicant and FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the prospective ANDA applicant is satisfied with FDA's preliminary responses), or the prospective ANDA applicant and FDA agree a particular question is considered resolved, allowing extra time for discussion of other questions during the meeting. Preliminary responses communicated by FDA should not generate the submission of new questions, and new questions will not be entertained at the meeting.

[29] In general, preliminary responses will not be provided in advance of a mid-review-cycle meeting, as FDA sets the agenda for this meeting.

[30] GDUFA II Commitment Letter at 16.

[31] Id. at 17.

X. PROCEDURES FOR CONDUCT OF MEETINGS

A. Introductions and Agenda

Product development and pre-submission meetings for complex products will be chaired by an FDA staff member, generally the ORS director or designee, and will begin with introductions[32] and a statement of the agenda. In general, the meeting participants will discuss the questions posed and the data provided by the prospective ANDA applicant to assist its complex product development program.

The RPM assigned to the ANDA will chair the mid-review-cycle meeting. The agenda will be provided by FDA and, as explained in section III.C, will generally consist of a status update and possible deficiencies identified by a discipline reviewer and/or review team at the conclusion of the discipline review or will provide for a discussion of deficiencies that have been communicated to the prospective ANDA applicant before the meeting.

B. End of Meeting Summary

Before the end of the meeting, FDA attendees and the prospective ANDA applicant or ANDA applicant attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the prospective ANDA applicant or ANDA applicant 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. The summary can be done at the end of the meeting or after the discussion of each question.

C. Presentations

Presentations by prospective ANDA applicants or ANDA applicants are not generally needed because the information necessary for review and discussion should be part of the meeting package. If a prospective ANDA applicant or ANDA applicant plans to make a presentation, the presentation should be discussed ahead of time with the FDA point of contact to determine whether a presentation is warranted and ensure that FDA 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, or data that were not included in the original meeting package submitted to FDA for review, FDA staff may not be able to provide comments on the new data.

FDA does not expect that the applicant attendees of the mid-review-cycle meeting will provide any presentations.

[32] In general, FDA attendees may include, as applicable, additional staff from CDER's OGD, Office of Pharmaceutical Quality, Office of Surveillance and Epidemiology, and Office of New Drugs. Center for Devices and Radiological Health staff may also attend if the complex product has device component.

XI. DOCUMENTATION AND MEETING MINUTES

Documentation of meeting outcomes, agreements and disagreements, issues for further discussion, and action items is critical to ensuring that this information is preserved for meeting attendees and for future reference. FDA minutes are the official record of the meeting. FDA will issue the official, finalized minutes to the prospective ANDA applicant within 30 days of the product development or pre-submission meeting.[33] FDA intends to issue minutes to the mid-review-cycle meeting within 30 days of the meeting.

XII. RESOLUTION OF DISPUTE ABOUT MEETING MINUTES

On occasion, there may be disputes regarding the accuracy and sufficiency of the minutes of a product development or pre-submission meeting. A prospective ANDA applicant or ANDA applicant requesting additional clarification of the meeting minutes issued by FDA should contact the assigned FDA point of contact for advice. This process addresses issues with the meeting minutes only. If a prospective ANDA applicant needs to discuss additional issues that were not addressed at the product development or pre-submission meeting, the prospective ANDA applicant should submit a controlled correspondence or a new meeting request. If an ANDA applicant needs to discuss additional issues that were not addressed at the mid-review-cycle meeting, the ANDA applicant should contact the RPM. FDA recommends that the prospective ANDA applicant or ANDA applicant submit its concerns about the meeting minutes in writing to FDA within 10 calendar days of receipt of the meeting minutes.

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

The prospective ANDA applicant's or ANDA 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 determined to accurately and sufficiently reflect the meeting discussion, the point of contact will convey this decision to the prospective ANDA applicant or ANDA applicant and the minutes will stand as the official documentation of the meeting. If, after discussions with the requester, FDA deems it necessary to change the official minutes, the changes will be documented in an addendum to the official minutes. The addendum will also document any continued requester objections.

[33] GDUFA II Commitment Letter at 16-17.

APPENDIX:

SUMMARY OF SCOPE AND CRITERIA FOR MEETINGS FOR COMPLEX PRODUCTS UNDER GDUFA II

Meeting Type	Purpose/Scope	Criteria	Additional Considerations
Product Development	(a) Development of a complex product for which FDA has not issued product-specific guidance	• Meets the purpose/scope • Prospective ANDA applicant submits a complete meeting package • Controlled correspondence response would not adequately address the prospective applicant's questions • Product development meeting would significantly improve ANDA review efficiency	• Goal may be met by conducting a meeting or providing a meaningful written response
	(b) Alternative equivalence evaluation for a complex product for which FDA has issued a product-specific guidance	• Meets the purpose/scope • Prospective ANDA applicant submits a complete meeting package • Controlled correspondence response would not adequately address the prospective applicant's questions • Product development meeting would significantly improve ANDA review efficiency	• Goal may be met by conducting a meeting or providing a meaningful written response
	(c) Complex product development issues other than those described in (a) and (b) above	• Meets the purpose/scope • Prospective ANDA applicant submits a complete meeting package • Controlled correspondence response would not adequately address the prospective applicant's questions • Product development meeting would significantly improve ANDA review efficiency	• Granting of meeting is dependent on available resources • Goal may be met by conducting a meeting or providing a meaningful written response
Pre-Submission	Opportunity for prospective ANDA applicants to discuss and explain the format and content of the ANDA to be submitted	• FDA will generally grant a pre-submission meeting request for prospective ANDA applicants that had a product development meeting or received a written response • FDA may grant a pre-submission meeting to a prospective ANDA applicant of a complex product that did not have a product development meeting if, in FDA's judgment, the pre-submission meeting would improve review efficiency	• Prospective ANDA applicant that had a product development meeting or received a written response is not obligated to request a pre-submission meeting

Mid-Review-Cycle	Opportunity for FDA to discuss issues identified during review with the applicant	• Held only during the first review cycle with ANDA applicants that have participated in a prior product development or pre-submission meeting	• Mid-review-cycle meeting will be scheduled by FDA; FDA will provide agenda • ANDA applicant that had product development or pre-submission meeting is not obligated to attend (i.e., may decline) mid-review-cycle meeting

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