Product-Specific Guidance Meetings Between FDA and ANDA Applicants 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DRAFT GUIDANCE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)

February 2023
Generic Drugs

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Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

This guidance provides recommendations to industry on product-specific guidance (PSG) meetings between FDA and a prospective applicant preparing to submit to FDA or an applicant that has submitted to FDA an abbreviated new drug application (ANDA) under section 505(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)).[2] Specifically, this guidance provides information on requesting and conducting PSG meetings with FDA (PSG teleconferences, pre-submission PSG meetings, and post-submission PSG meetings), as contemplated in the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter).[3] And this guidance is intended to provide procedures that will promote well-managed PSG meetings and help ensure that such meetings are scheduled and conducted in accordance with the time frames set forth in the GDUFA III commitment letter.

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 guidance 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 at the Food and Drug Administration.

[2] This guidance uses the term *ANDA applicant* when discussing meetings that occur after an ANDA is received, the term *prospective ANDA applicant* when discussing meetings that occur before an ANDA is received, and the terms *applicant* or *applicants* when referring to both prospective ANDA applicants and ANDA applicants.

[3] The GDUFA III commitment letter is available at https://www.fda.gov/media/153631/download.

II. BACKGROUND

The Generic Drug User Fee Amendments of 2012 (GDUFA I)[4] amended the FD&C Act to authorize FDA to assess and collect user fees to provide the Agency with resources to help ensure patients have access to quality, safe, and effective generic drugs. GDUFA fee resources[5] bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's ability to assess and collect GDUFA fees and this user fee program has been reauthorized two times since GDUFA I, most recently in the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023.[6] As described in the GDUFA III commitment letter applicable to this latest reauthorization, FDA has agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

To receive approval for an ANDA, an applicant generally must demonstrate, among other things, that its proposed drug product is bioequivalent to the reference listed drug (RLD).[7] As noted in 21 CFR 320.24, in vivo and/or in vitro methods can be used to establish bioequivalence (BE). FDA recommends that applicants consult published PSGs when considering an appropriate BE study and/or other studies for a proposed drug product.[8,9] PSGs provide recommendations for developing generic drug products and describe FDA's current thinking on the evidence needed to demonstrate that an ANDA is therapeutically equivalent to a specific RLD product.

As described in the GDUFA III commitment letter, FDA agreed to certain time frames and procedures for scheduling and conducting: (1) PSG teleconferences to provide feedback on the potential impact of a new or revised PSG on the applicant's development program; and (2) pre-

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[4] Title III of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144.
[5] User fees are available for obligation in accordance with appropriations acts.
[6] See Division F, Title III of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).
[7] See section 505(j)(2)(A)(iv) of the FD&C Act (21 U.S.C. 355(j)(2)(A)(iv)) and 21 CFR 314.94(a)(7).
[8] For more information about FDA's PSG publications and to search for the most recent version of a PSG, see the Product-Specific Guidances for Generic Drug Development web page at https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development.
[9] In addition to consulting published PSGs, FDA also recommends that applicants consult FDA's web page on upcoming new and revised PSGs in planning the development of their drug products and prior to submitting their ANDAs. This information is available at https://www.fda.gov/drugs/guidances-drugs/upcoming-product-specific-guidances-generic-drug-product-development. FDA may refuse to receive an ANDA if the ANDA contains one or more BE studies that were not recommended in the PSG, without adequate justification (21 CFR 314.101(d)(3) (stating that FDA may refuse to receive an ANDA if it is incomplete because it does not on its face contain information required under section 505(j) of the FD&C Act); 21 CFR 314.94(a)(7)). Adequate justification should include justification for an approach that deviates from the published guidance, including data and appropriate references. See the guidance for industry *ANDA Submissions—Refuse-to-Receive Standards* (Rev. 2) (December 2016). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

submission PSG meetings and post-submission PSG meetings to provide a forum in which the applicant can discuss the scientific rationale for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations.[10]

III. MEETING TYPES

As described in the GDUFA III commitment letter, there are three types of PSG meetings that occur between applicants and FDA: PSG teleconferences (which includes pre-submission PSG teleconferences and post-submission PSG teleconferences), pre-submission PSG meetings, and post-submission PSG meetings.

PSG teleconferences provide a forum for applicants to obtain FDA's feedback on the potential impact of a new or revised PSG on the applicant's development program when the applicant has already commenced (i.e., the study protocol was signed by the study sponsor and/or the contract research organization) or completed an in vivo BE study. A prospective ANDA applicant can request a pre-submission PSG teleconference prior to submission of the ANDA. An ANDA applicant can request a post-submission PSG teleconference if the ANDA has been submitted. When FDA states in a PSG teleconference that a new or revised PSG would impact an applicant's development program, this statement is an indicator that the applicant has already commenced or completed in vivo study alone is unlikely to be sufficient to demonstrate BE in accordance with the relevant statutes and regulations.

If an applicant seeks further feedback from FDA after a PSG teleconference to ensure that any proposed changes or additions to an applicant's in vivo study would result in an approach that complies with the relevant statutes and regulations, the applicant may request a pre-submission PSG meeting or post-submission PSG meeting, as appropriate, to discuss the scientific rationale for an approach other than the approach recommended in the PSG.

As described in the GDUFA III commitment letter, a prospective ANDA applicant is eligible to have a pre-submission PSG meeting if it first requests and has a pre-submission PSG teleconference with FDA.[11] The pre-submission PSG teleconference and the subsequent pre-submission PSG meeting should occur before submission of the ANDA (i.e., within the pre-submission phase) so that the prospective ANDA applicant obtains FDA's feedback on an approach other than the approach recommended in the PSG before submission of the ANDA.[12]

As described the GDUFA III commitment letter, an ANDA applicant is eligible to have a post-submission PSG meeting if it first requests and has a post-submission PSG teleconference with

[10] GDUFA III commitment letter at 24.
[11] Ibid.
[12] FDA intends to deny a post-submission PSG meeting request and recommend the ANDA applicant submit a controlled correspondence if the prospective ANDA applicant had a pre-submission PSG teleconference, submitted the ANDA, and then requests a post-submission PSG meeting. FDA will not simultaneously assess the adequacy of an ANDA's demonstration of BE and consider and respond to questions submitted in a PSG meeting package.

FDA.[13] The post-submission PSG teleconference and the subsequent post-submission PSG meeting should occur before responding to a possible BE deficiency identified in a discipline review letter (DRL) or a BE deficiency identified in a complete response letter (CRL). For example, if FDA has issued a CRL, the ANDA applicant should request and attend the post-submission PSG meeting prior to responding to the BE deficiency identified in the CRL so that the ANDA applicant can consider FDA's feedback in developing a response to the CRL.[14, 15]

As an alternative to a pre-submission PSG meeting or a post-submission PSG meeting, applicants can consider obtaining FDA's feedback on an approach other than the approach recommended in the PSG through controlled correspondence or another meeting type, as appropriate.[16] FDA recommends that applicants consider the types of questions on which they want to obtain FDA's feedback, the status of their ANDA, and the eligibility criteria for controlled correspondence or a particular meeting type in determining which pathway to seek FDA's feedback. Applicants should not submit multiple meeting requests or controlled correspondence at or around the same time with the same or similar questions. If FDA receives multiple meeting requests or controlled correspondence that contain the same or similar question(s), FDA will determine which meeting to grant or controlled correspondence to answer and may deny the other(s).

A. PSG Teleconferences

PSG teleconferences provide an opportunity for an applicant to obtain FDA's feedback on the potential impact of a new or revised PSG on the applicant's development program when the applicant has already commenced an in vivo BE study.[17] During a PSG teleconference, FDA will provide feedback on the potential impact of the recommendations in the PSG, but FDA will not discuss the applicant's questions regarding an approach other than the approach recommended in the PSG. During a PSG teleconference, FDA may, if applicable, recommend a path for future communication with FDA, such as controlled correspondence, pre-submission PSG meeting, post-submission PSG meeting, or other meeting type.

When FDA publishes a new or revised PSG which includes a recommendation to conduct an in vitro BE study only and an applicant has already commenced or completed an in vivo BE study,

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[13] GDUFA III commitment letter at 24.

[14] If the ANDA applicant responds to the BE deficiency identified in a CRL and then requests the post-submission PSG meeting, FDA intends to deny the post-submission meeting request and recommend the ANDA applicant submit a controlled correspondence because FDA will not simultaneously assess the adequacy of an ANDA's demonstration of BE and consider and respond to questions submitted in a PSG meeting package.

[15] We note that, in some instances, due to either timing of the PSG meeting (i.e., after FDA issues a CRL) and/or the type of information necessary to establish BE using an alternative approach involving an ANDA applicant's already commenced or completed in vivo BE study, it may not be possible to address and provide all the necessary BE information within the same assessment cycle.

[16] For more information on controlled correspondence, see the guidance for industry *Controlled Correspondence Related to Generic Drug Development* (December 2020). For more information on other meeting types, see the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2022).

[17] GDUFA III commitment letter at 24.

FDA generally would consider the submission of the in vivo BE study as an acceptable approach for demonstrating BE. Therefore, applicants in such a situation in general should not request a PSG teleconference, but FDA recommends, to ensure the ANDA submission is acceptable for receipt and scientific review, that an applicant in such a situation include supporting information with its ANDA to justify the in vivo approach used that deviates from the in vitro approach recommended in the PSG to demonstrate BE.[18]

Applicants should submit a request for a PSG teleconference within 60 days after publication of the new or revised PSG so that FDA can provide timely feedback to applicants.[19] Applicants can request a PSG teleconference more than 60 days after publication of the new or revised PSG, however, the 30-day time frame for conducting PSG teleconferences[20] (discussed in section IV of this guidance) is only applicable for complete packages submitted within 60 days after publication of the PSG and otherwise meet the criteria set forth in section V of this guidance.

1. Pre-Submission PSG Teleconferences

A prospective ANDA applicant can request a pre-submission PSG teleconference when FDA publishes a new or revised PSG that introduces or revises a recommendation related to an in vivo BE study, the ANDA has not been submitted, and the prospective ANDA applicant has already commenced an in vivo BE study as of the published date for the new or revised PSG (i.e., the study protocol was signed by the study sponsor and/or the contract research organization before the PSG publication date).[21] With the pre-submission PSG teleconference request, a prospective ANDA applicant should submit the title page, protocol summary, and the signature page of the relevant in vivo BE study protocol signed and dated by the study sponsor and/or the contract research organization (see section V.A for additional information on the contents for the meeting request).[22]

After a pre-submission PSG teleconference has been held, a prospective ANDA applicant can request a pre-submission PSG meeting (if the ANDA has not been submitted), utilize the controlled correspondence process, or request another meeting type, as appropriate, to seek further feedback from FDA regarding an alternative BE approach to the recommendations in the PSG.[23, 24]

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[18] See footnote 9.

[19] FDA issues a notice in the *Federal Register* announcing the availability of new and revised PSGs posted on the product-specific web page (available at https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm). These notices are also available under docket number FDA-2007-D-0369, which can be accessed at https://www.regulations.gov/docket/FDA-2007-D-0369. FDA considers the publication date of a PSG to be the day that the PSG is posted on the product-specific web page, which is stated on the product-specific web page and is generally the business day before the notice announcing the PSG's availability publishes in the *Federal Register*.

[20] GDUFA III commitment letter at 24.

[21] Ibid.

[22] Ibid.

[23] Ibid.

[24] See footnote 16.

2. Post-Submission PSG Teleconferences

An ANDA applicant can request a post-submission PSG teleconference when FDA publishes a new or revised PSG that introduces or revises a recommendation related to an in vivo BE study, the ANDA has been submitted, and an applicant has already commenced or completed an in vivo BE study (i.e., the study protocol has been signed by the study sponsor and/or the contract research organization before the PSG publication date).[25]

FDA also intends to offer the opportunity for a post-submission PSG teleconference in the following two situations, which are not described in the GDUFA III commitment letter:

- An ANDA applicant can request a post-submission PSG teleconference when FDA publishes a new PSG which includes a recommendation to conduct an in vivo BE study and the ANDA applicant did not conduct an in vivo BE study.[26]

- An ANDA applicant can request a post-submission PSG teleconference when FDA publishes a revised PSG which includes a recommendation to conduct an in vivo BE study, the previous PSG did not include a recommendation to conduct an in vivo BE study, and the ANDA applicant commenced or completed the in vitro BE study or studies either that were recommended by FDA in the previous PSG or that the ANDA applicant decided to pursue after a prior product development meeting.[27]

After a post-submission PSG teleconference has been held, an ANDA applicant can request a post-submission PSG meeting (discussed in more detail below), utilize the controlled correspondence process, or request another meeting type, as appropriate, to seek further feedback from FDA regarding an alternative BE approach to the recommendations in the PSG.[28]

B. Pre-Submission PSG Meetings

After a pre-submission PSG teleconference has been held and if the ANDA has not been submitted, the prospective ANDA applicant can request a pre-submission PSG meeting. The purpose of the pre-submission PSG meeting is to provide a forum in which the prospective ANDA applicant can discuss the scientific rationale for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations.[29] During a pre-submission PSG meeting, FDA will discuss the prospective ANDA applicant's questions related to their proposed alternative BE approach which differs from the

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[25] GDUFA III commitment letter at 24.

[26] FDA offers the ability to request a PSG teleconference to applicants under this scenario even though such applicants may not meet all the criteria in the GDUFA III commitment letter. This offer is thus made at FDA's discretion.

[27] Ibid. This offer for the ability to request a post-submission PSG teleconference does not include when a PSG is revised to include an in vivo BE study as an additional option to the in vitro BE study that was recommended in the previous PSG and the ANDA applicant followed the recommendations in the previous PSG.

[28] GDUFA III commitment letter at 24. See also footnote 16.

[29] GDUFA III commitment letter at 24.

recommendations in the current PSG. FDA will not discuss questions unrelated to the alternative BE approach to the recommendations in the current PSG.

Prospective ANDA applicants should request a pre-submission PSG meeting in a timely manner after the pre-submission PSG teleconference, considering the time needed to develop the meeting package for a pre-submission PSG meeting with FDA, and before submitting the ANDA. Prospective ANDA applicants can request a pre-submission PSG meeting regardless of whether they have had a product development meeting.[30]

As an alternative to requesting a pre-submission PSG meeting after a pre-submission PSG teleconference, prospective ANDA applicants can consider submitting controlled correspondence or requesting another meeting type, such as a product development meeting, as appropriate, to seek feedback from FDA.[31]

C. Post-Submission PSG Meetings

After a post-submission PSG teleconference has been held, the ANDA applicant can request a post-submission PSG meeting.[32] The purpose of the post-submission PSG meeting is to provide a forum in which ANDA applicants can discuss the scientific rationale for an approach other than the approach recommended in the PSG to ensure that the approach complies with the relevant statutes and regulations.[33] During a post-submission PSG meeting, FDA will discuss the ANDA applicant's questions related to their proposed alternative BE approach which differs from the recommendations in the current PSG. FDA will not discuss questions unrelated to the proposed alternative BE approach to the recommendations in the current PSG.

FDA recommends that an ANDA applicant consider the status of the ANDA and its assessment cycle as well as the time needed to develop the meeting package in determining when to submit a request for a post-submission PSG meeting. For example, FDA recommends that an ANDA applicant refrain from requesting the post-submission PSG meeting during the assessment cycle until after FDA has issued a DRL or a CRL to allow FDA to complete its scientific evaluation of the ANDA applicant's submitted evidence of BE.[34] Between assessment cycles (e.g., FDA previously issued a CRL to the ANDA applicant and the post-submission PSG teleconference was subsequently held), FDA recommends that the ANDA applicant request the post-submission PSG meeting once the ANDA applicant has developed the meeting package. If an ANDA applicant intends to request a post-submission PSG meeting, the ANDA applicant should request

[30] Ibid at 25.
[31] See footnote 16.
[32] ANDA applicants can request a post-submission PSG meeting regardless of whether they have had a product development or a post-CRL scientific meeting (GDUFA III commitment letter at 25).
[33] GDUFA III commitment letter at 24.
[34] FDA will not simultaneously assess the adequacy of an ANDA's demonstration of BE and consider and respond to questions submitted in a PSG meeting package.

and attend the post-submission PSG meeting prior to responding to the possible BE deficiency identified in a DRL or the BE deficiency identified in the CRL.[35]

During the assessment cycle, as an alternative to a post-submission PSG meeting, ANDA applicants can consider submitting controlled correspondence or requesting another meeting type, such as an enhanced mid-cycle review meeting, as appropriate, to seek feedback from FDA after a post-submission PSG teleconference.[36] After a CRL, as an alternative to a post-submission meeting, ANDA applicants can consider submitting controlled correspondence or requesting another meeting type, such as a post-CRL scientific meeting, as appropriate, to seek feedback from FDA.[37]

IV. GDUFA III PERFORMANCE GOALS

As reflected in the GDUFA III commitment letter, FDA committed to certain goals and procedures for scheduling and conducting PSG teleconferences, pre-submission PSG meetings, and post-submission PSG meetings for ANDAs.[38, 39] Applicants can request PSG teleconferences for PSGs published on or after October 1, 2022.[40] The goals described below only apply to requests submitted on or after October 1, 2022, and subject to the criteria described in this guidance.

FDA agreed to hold a PSG teleconference within 30 days after the receipt of the meeting request if the request is granted.[41] This goal only applies to PSG teleconference requests submitted within 60 days after the PSG publication.[42]

For pre-submission PSG meetings, FDA agreed to grant or deny the meeting request within 14 days after FDA has received the request.[43] If granted, FDA agreed to hold the pre-submission PSG meeting within 120 days after FDA received the request.[44]

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[35] See footnote 14. ANDA applicants may respond to other possible non-BE related deficiencies that may be included in a DRL. Once an applicant responds to a possible BE deficiency identified in a DRL or a BE deficiency identified in a CRL involving the new or revised PSG, FDA intends to deny or cancel the post-submission PSG meeting.

[36] See footnote 16.

[37] See footnote 16.

[38] GDUFA III commitment letter at 24-25.

[39] Consistent with FDA's other user fee programs, FDA will calculate the goal date from the day after a submission (GDUFA III commitment letter at 4). Also refer to FDA's guidance for industry *Providing Regulatory Submissions in Electronic Format—Receipt Dates* (February 2014) for information on how FDA calculates receipt dates for regulatory submissions in electronic format. As described in that guidance, requests will be received by the Agency Monday through Friday from 12:00 a.m. to 11:59 p.m., Eastern Standard Time/Eastern Daylight Time, excluding Federal holidays and days when the FDA office that will review the request is closed.

[40] FDA in its discretion may grant PSG teleconference requests for PSGs published prior to October 1, 2022, that are submitted within 60 days after the PSG publication.

[41] GDUFA III commitment letter at 24.

[42] See footnote 19.

[43] GDUFA III commitment letter at 24.

[44] Ibid.

For post-submission PSG meetings, FDA agreed to grant or deny the meeting request within 14 days after FDA has received the request.[45] If granted, FDA agreed to hold the post-submission PSG meeting within 90 days after FDA received the request.[46]

V. MEETING REQUESTS

A request for a PSG teleconference, pre-submission PSG meeting, and post-submission PSG meeting should be submitted electronically, as explained below in this section.

Requests for a pre-submission PSG meeting can be submitted after the prospective ANDA applicant had a pre-submission PSG teleconference and if the ANDA has not been submitted. The pre-submission PSG meeting request should clearly indicate that the prospective ANDA applicant had a pre-submission PSG teleconference with FDA.

Requests for a post-submission PSG meeting can be submitted after the ANDA applicant had a post-submission PSG teleconference. The post-submission PSG meeting request should clearly indicate that the ANDA applicant had a post-submission PSG teleconference with FDA.

If FDA determines that the meeting request does not contain the information specified in this section, the request will not be considered to be submitted for purposes of GDUFA III performance goals.

An applicant should not request a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting if the applicant has requested or has been granted but not yet had another meeting with FDA, such as a pre-submission meeting, an enhanced mid-cycle review meeting, or a post-CRL scientific meeting. FDA also recommends that applicants not submit a controlled correspondence and a request for a pre-submission PSG meeting or a post-submission PSG meeting at or around the same time with the same or similar questions. If FDA receives multiple requests that contain the same or similar question(s), FDA intends to determine which request to grant and may deny the other(s).

A. PSG Teleconferences

A prospective ANDA applicant should submit a request for a pre-submission PSG teleconference electronically through the CDER Direct NextGen Collaboration Portal.[47] An ANDA applicant should submit a request for a post-submission PSG teleconference electronically through the Enterprise Submission Gateway. The cover page should identify the submission as a "PSG Teleconference Request."

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[45] Ibid.
[46] Ibid.
[47] The CDER Direct NextGen Collaboration Portal may be accessed at https://edm.fda.gov.

A request for a PSG teleconference meeting should include the following information:

(1) Pre-assigned ANDA number[48] or ANDA number.

(2) Meeting type being requested (i.e., PSG Teleconference).

(3) Month and year the current PSG was published.

(4) A summary of how the applicant's BE study(ies) differ from the study(ies) recommended in the PSG.

(5) Signature page of the relevant in vivo BE study protocol signed by the study sponsor and/or contract research organization, if applicable.[49]

(6) RLD and its application number.

(7) Established Name.

(8) Proposed indication(s).

(9) Dosage form, route of administration, and strength(s).

(10) A statement indicating whether the submission is being made by the applicant or by a U.S. agent on behalf of the applicant.

(11) Contact person for the meeting (i.e., the person submitting the request), with their title and affiliation, secure email address,[50] and phone number. This is the person with whom FDA will communicate about the meeting.

(12) The meeting package (see section VIII of this guidance), which should be received at the time of the meeting request.

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

[49] See section III.A.2 of this guidance for scenarios where an in vivo BE study was not conducted.

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

B. Pre-Submission PSG Meetings

A prospective ANDA applicant should submit a request for a pre-submission PSG meeting electronically through the CDER Direct NextGen Collaboration Portal.[51] The cover page should identify the submission as a "Pre-Submission PSG Meeting."

A request for a pre-submission PSG meeting should include the following information:

(1) Pre-assigned ANDA number.

(2) Meeting type being requested (i.e., pre-submission PSG meeting).

(3) RLD and application number.

(4) Established Name.

(5) Proposed indication(s).

(6) Dosage form, route of administration, and strength(s).

(7) Date pre-submission PSG teleconference was held and event ID.

(8) A statement indicating whether the submission is being made by the prospective ANDA applicant or by a U.S. agent on behalf of the prospective ANDA applicant.

(9) Contact person for the meeting (i.e., the person submitting the request), with their title and affiliation, secure email address,[52] and phone number. This is the person with whom FDA will communicate about the meeting.

(10) The meeting package (see section VIII of this guidance), which should be received at the time of the meeting request.

C. Post-Submission PSG Meetings

An ANDA applicant should submit a request for a post-submission PSG meeting electronically through the Enterprise Submission Gateway. The cover page should identify the submission as a "Post-Submission PSG Meeting."

A request for a post-submission PSG meeting should include the following information:

(1) ANDA number.

[51] See footnote 47.
[52] See footnote 50.

(2) Meeting type being requested (i.e., post-submission PSG meeting).

(3) RLD and application number.

(4) Established Name.

(5) Proposed indication(s).

(6) Dosage form, route of administration, and strength(s).

(7) Date post-submission PSG teleconference was held and event ID

(8) Title and study number of the study impacted by the recommendations in the PSG.

(9) A statement indicating whether the submission is being made by the ANDA applicant or by a U.S. agent on behalf of the ANDA applicant.

(10) Contact person for the meeting (i.e., the person submitting the request), with their title and affiliation, secure email address,[53] and phone number. This is the person with whom FDA will communicate about the meeting.

(11) The meeting package (see section VIII of this guidance), which should be received at the time of the meeting request.

VI. EVALUATING MEETING REQUESTS

FDA will determine whether to grant a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting, and a response will be provided to the applicant by granting or denying the meeting request pursuant to the performance goals stated in the GDUFA III commitment letter (see section IV of this guidance) and as described below. Although applicants can request a particular meeting type and format, FDA evaluates each meeting request and determines whether the request should be granted, the final meeting type, and the appropriate format.

A. Meeting Request Denied

If a meeting request is denied, written notification to the applicant will include an explanation of the reason for the denial.

Denials of meeting requests submitted in conformity with the GDUFA III performance goals will be based on a substantive reason. For example:

[53] See footnote 50.

- FDA may deny a PSG teleconference request if the applicant's in vivo BE study started after the PSG was published or the request is incomplete (e.g., does not include the signature page of the relevant in vivo study protocol signed by the study sponsor and/or the contract research organization).

- FDA intends to deny a pre-submission PSG meeting request if the prospective ANDA applicant did not have a pre-submission PSG teleconference or if the applicant submitted the ANDA after the pre-submission PSG teleconference. In addition, FDA may deny the request if the request is incomplete, FDA determines that the inquiry would be appropriately addressed through a controlled correspondence, or the prospective ANDA applicant submitted the same or similar questions in a request for another meeting type or in controlled correspondence.[54]

- FDA intends to deny a post-submission PSG meeting request if the ANDA applicant did not have a post-submission PSG teleconference or if the ANDA applicant had a pre-submission PSG teleconference and then submitted the ANDA. In addition, FDA may deny the request if the request is incomplete, FDA determines the inquiry would be appropriately addressed through a controlled correspondence, FDA determines that the questions in the meeting package have been addressed during the ANDA assessment, the ANDA applicant responded to the possible BE deficiency identified in a DRL or BE deficiency identified in a CRL, or the ANDA applicant submitted the same or similar questions in a request for another meeting type or in controlled correspondence.

FDA may grant a pre-submission PSG meeting request or post-submission PSG meeting request after a controlled correspondence response was issued if FDA determines that any issue(s) remain unresolved or would be more appropriately resolved in a pre-submission PSG meeting or post-submission PSG meeting.[55]

If a meeting request is denied, a subsequent request to schedule a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting will be considered as a new request (i.e., a request that is assigned a new set of time frames as described in section IV of this guidance, GDUFA III Performance Goals).

B. Meeting Request Granted

If a request for a meeting is granted, FDA will provide written notification to the applicant of the decision. FDA may indicate that the request is granted in part for the questions that are appropriate for the meeting type requested and denied in part for the questions that are not appropriate for the meeting type requested. If FDA will be providing written responses only instead of holding a meeting or teleconference, FDA will advise the applicant that a written response only is forthcoming. If FDA plans to hold a meeting or teleconference, FDA will schedule the meeting or teleconference by determining the date, time, length, format, and

[54] GDUFA III commitment letter at 25.

[55] Ibid.

expected FDA participants. The scheduling information will be forwarded to the applicant either with the notification granting the meeting or teleconference or as soon as possible following notification that the request has been granted, and the meeting or teleconference will be scheduled within the GDUFA III performance goals (see section IV of this guidance).

VII. RESCHEDULING AND CANCELING MEETINGS

A. Rescheduling Meetings

Occasionally, circumstances may arise that necessitate the rescheduling of a meeting. If a meeting needs to be rescheduled, FDA will work to reschedule it as soon as possible after the original date. A new meeting request should not be submitted. Applicants and FDA should take reasonable steps to avoid rescheduling meetings. 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 applicant following the meeting. It will be at FDA's discretion whether the meeting should be rescheduled depending on the specific circumstances.

A meeting may be rescheduled by FDA if, for example:

(1) The assessment team determines that additional information is needed from the applicant to address the 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 applicant is critical and the offices' availability precludes holding the meeting on the original date.

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

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

B. Canceling Meetings

Occasionally, circumstances may arise that necessitate the canceling of a meeting. If a meeting is canceled, a subsequent request to schedule a meeting will be considered a new request. Applicants and FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no longer necessary). It will be at FDA's discretion whether the meeting should be canceled depending on the specific circumstances.

A pre-submission PSG teleconference may be canceled if, for example:

(1) The prospective ANDA applicant withdraws the request, or

(2) The prospective ANDA applicant submits the ANDA

A post-submission PSG teleconference may be canceled if, for example:

(1) The ANDA applicant withdraws the request, or

(2) FDA refuses to receive the ANDA

A pre-submission PSG meeting may be canceled if, for example:

(1) The prospective ANDA applicant withdraws the request

(2) The prospective ANDA applicant informs FDA that its questions have been adequately answered by the preliminary written comments, or

(3) The prospective ANDA applicant submits the ANDA

A post-submission PSG meeting may be canceled if, for example:

(1) The ANDA applicant withdraws the request

(2) FDA refuses to receive the ANDA

(3) The ANDA applicant informs FDA that its questions have been adequately answered by the preliminary written comments, or

(4) The ANDA applicant submits a response to the possible BE deficiency identified in a DRL or the BE deficiency identified in the CRL

If an applicant cancels a 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

The meeting package should provide information relevant to the discussion topics and enable FDA to prepare adequately for the meeting. The meeting package should clearly indicate the meeting type the applicant is requesting and include adequate information for FDA to assess the potential utility of the meeting and to identify the appropriate staff that should attend the meeting.

A. Timing of Submission

The meeting package for a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting should be submitted to FDA so that it is received concurrently with the meeting request.

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

A prospective ANDA applicant should submit the meeting package for a pre-submission PSG teleconference or for a pre-submission PSG meeting electronically to the CDER Direct NextGen Collaboration Portal at the same time as the meeting request.

An ANDA applicant should submit the meeting package for a post-submission PSG teleconference or for a post-submission PSG meeting electronically via the Enterprise Submission Gateway at the same time as 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 help FDA develop responses to issues raised by applicant. 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, so 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.

1. PSG Teleconferences

A meeting package for a PSG teleconference generally should include the following information:

(1) Pre-assigned ANDA number or ANDA number.

(2) Month and year the current PSG was published.

(3) Signature page of the relevant in vivo BE study protocol signed by the study sponsor and/or contract research organization, if applicable.[56]

(4) RLD and application number.

[56] See section III.A.2 of this guidance for scenarios where an in vivo BE study was not conducted.

(5) Established name.

(6) Dosage form, route of administration, strength(s), and dosing regimen (frequency and duration).

(7) A background section that includes the following:

- A brief history of the development program.
- The status of product development.
- A brief statement of the purpose and objectives of the teleconference, including a brief background of the issues underlying the agenda, a description of how the applicant's study differs from the recommendations in the PSG, and if applicable, a statement indicating that the applicant's in vivo study is impacted by the new or revised PSG.
- Summary of prior correspondence, meeting requests, and meetings with FDA regarding the specific drug product that the teleconference request is regarding.

(8) The title page, protocol summary, and the signature page of the relevant in vivo study protocol signed by the study sponsor and/or the contract research organization, if applicable.

(9) The requested format[57]—teleconference[58] or written response only.[59] For requested teleconferences, the request package should also include the following information:

- A proposed agenda outlining how the 60-minute time allotted for the PSG teleconference should be apportioned to each agenda item.
- Suggested dates and times (e.g., morning or afternoon) for the teleconference that are within the time frame of the meeting type being requested (see section IV). Non-available dates and times should also be included.

[57] For applicants that meet the criteria in the GDUFA III commitment letter for a PSG teleconference, FDA will generally grant the applicant's requested format. If FDA provides the opportunity for a PSG teleconference to an applicant that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to provide a written response only or direct the applicant to submit controlled correspondence instead of holding a teleconference.

[58] Teleconference means a verbal communication by telephone, and not a written response, unless otherwise agreed to by the applicant. GDUFA III commitment letter at 48.

[59] Written response only are responses sent in lieu of a teleconference. If an applicant requests or otherwise agrees to written response only, the written responses only count toward meeting the GDUFA goal.

- A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the applicant's organization, including consultants and interpreters.[60]

2. Pre-Submission PSG Meetings

A meeting package for a pre-submission PSG meeting generally should include the following information:

(1) Pre-assigned ANDA number.

(2) Month and year the current PSG was published.

(3) In vivo BE study protocol signature date, if applicable.

(4) Title and study number of the study impacted by the recommendations in the PSG.

(5) RLD and application number.

(6) Established Name.

(7) Dosage form, route of administration, strength(s), and dosing regimen (frequency and duration).

(8) A background section that includes the following:

- A brief history of the development program.
- The status of product development, including status of the in vivo study.
- A brief summary of the PSG teleconference discussion.

(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 and a description of how the applicant's study differs from the recommendations in the PSG.

(10) The specific alternative approach to establishing BE, with justification, rationale, and data to support discussion.

[60] The applicant should notify their point of contact (POC) immediately if the list of meeting participants from the applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 30-day window, FDA will consider the GDUFA III goal of conducting the teleconference within 30 days after the receipt of the teleconference request as met.

(11) The requested format—face-to-face,[61] videoconference,[62] teleconference, or written response only. For requested formats other than written response only, the request package should also include the following information:

- A proposed agenda outlining how the 60-minute time allotted for the pre-submission PSG meeting should be apportioned to each proposed question.

- Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame of the meeting type being requested (see section IV). Non-available dates and times should also be included.

- A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the applicant's organization, including consultants and interpreters.[63]

3. Post-Submission PSG Meetings

A meeting package for a post-submission PSG meeting generally should include the following information:

(1) ANDA number.

(2) Month and year the current PSG was published.

(3) In vivo BE study protocol signature date, if applicable.

(4) RLD and application number.

(5) Established Name.

(6) Dosage form, route of administration, strength(s), and dosing regimen (frequency and duration).

(7) A background section that includes the following:

- A brief history of the development program.

- The status of product development.

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[61] Face-to-face meetings are those in which the majority of attendees participate in person at the FDA.

[62] Videoconferences are meetings in which the attendees participate from various remote locations via a video connection.

[63] The prospective ANDA applicant should notify their POC immediately if the list of meeting participants from the prospective ANDA applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 120-day window, FDA will consider the GDUFA III goal of conducting the meeting within 120 days after the receipt of the meeting request as met.

- A description of BE deficiencies, if any, received in previous assessment cycles.

- A brief summary of the PSG teleconference discussion.

(1) A brief statement of the purpose and objectives of the meeting. This statement should include a brief background of the issues underlying the agenda and a description of how the applicant's study differs from the recommendations in the PSG.

(2) The specific alternative approach to establishing BE, with justification, rationale, and/or data to support discussion.

(3) The proposed format[64]—face-to-face, videoconference, teleconference, or written response only. For requested formats other than written response only, the request package should also include the following information:

- A proposed agenda outlining how the 60-minute time allotted for the post-submission PSG meeting should be apportioned to each proposed question.

- Suggested dates and times (e.g., morning or afternoon) for the meeting that are within the time frame of the meeting type being requested (see section IV). Non-available dates and times should also be included.

- A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the applicant's organization, including consultants and interpreters.[65]

IX. PRE-MEETING COMMUNICATIONS WITH APPLICANTS

In general, FDA will not provide preliminary written comments in advance of a PSG teleconference.

For pre-submission PSG meetings and post-submission PSG meetings, if FDA is not providing a written response only to the applicant, FDA intends to provide preliminary written comments to the applicant's point of contact 5 calendar days before the meeting or teleconference.

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[64] For ANDA applicants that meet the criteria in the GDUFA III commitment letter for a post-submission PSG meeting, FDA will generally grant the ANDA applicants' requested format. If FDA in its discretion provides the opportunity for a post-submission PSG meeting that does not meet the criteria in the GDUFA III commitment letter, FDA has the discretion to select the format and may provide a teleconference or written response only instead of a meeting.

[65] The ANDA applicant should notify their POC immediately if the list of meeting participants from the ANDA applicant's organization and consultants changes. In this situation, FDA may reschedule the meeting if the revised list of meeting participants requires additional FDA personnel. In the event this meeting is ultimately rescheduled outside the 90-day window, FDA will consider the GDUFA III goal of conducting the meeting within 90 days after the receipt of the meeting request as met.

Communications before the meeting between applicants and FDA, including preliminary written comments, can serve as a foundation for discussion or as the final meeting responses if the meeting is canceled. Nevertheless, preliminary written comments should not be construed as final unless there is agreement between the applicant and FDA that additional discussion is not necessary for any question (i.e., when the meeting is canceled because the applicant is satisfied with FDA's preliminary written comments), or the applicant and FDA agree a particular question is considered resolved, allowing extra time for discussion of other questions during the meeting. After receiving the preliminary written comments, the applicant should provide an updated agenda with its list of questions for discussion in order of priority, no later than 48 hours before the scheduled meeting. Preliminary written comments communicated by FDA should not generate the submission of new questions, and new questions will not be entertained at the meeting.

X. PROCEDURES FOR CONDUCT OF MEETINGS

A. Introductions and Agenda

PSG teleconferences will be chaired by an FDA staff member, will include a division director or designee from the generic drug program, and will begin with introductions and a statement of the agenda. In general, the meeting participants will discuss the potential impact of the new or revised PSG on the applicant's development program.

Pre-submission PSG meetings and post-submission PSG meetings will be chaired by an FDA staff member, will include a division director or designee from the generic drug program, and will begin with introductions and a statement of the agenda. In general, the meeting participants will discuss questions posed and the data provided by the applicant.

B. End of Meeting Summary

Before the end of the meeting, FDA attendees and the applicant attendees should summarize the important discussion points, agreements, clarifications, and action items. Generally, the applicant will be asked to present the summary to ensure that there is mutual understanding of the 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 discussion of each question.

C. Presentations

Presentations by applicants are not generally needed because the information necessary for review and discussion should be part of the meeting package. If an applicant plans to make a presentation, the presentation should be discussed ahead of time with the FDA point of contact to 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 contains 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 information.

FDA does not expect that applicant attendees of a PSG teleconference will provide any presentations.

XI. DOCUMENTATION AND MEETING MINUTES

Documentation of meeting outcomes (responses to the questions and outcomes of any discussions regarding the responses), agreements, and disagreements is critical to ensuring that this information is preserved for meeting participants and for future reference. FDA minutes are the official record of the meeting. FDA intends to issue the official, finalized minutes to the applicant within 30 days after the PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting.

XII. RESOLUTION OF DISPUTE ABOUT MEETING MINUTES

On occasion, there may be disputes regarding the accuracy and sufficiency of the minutes of a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting. An applicant requesting additional clarification of the meeting minutes issued by FDA should contact the assigned FDA point of contact. FDA recommends that the applicant submit its concerns about the meeting minutes in writing to FDA within 10 calendar days of receipt of the official meeting minutes. This process addresses issues with the meeting minutes only.

If an applicant needs to discuss additional issues that were not addressed at the meeting or teleconference, the applicant should submit a controlled correspondence or a new meeting request, as appropriate.

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

The applicant's concerns will be taken under consideration by the assessment discipline and senior management if senior management were present at the meeting. If the minutes are deemed to accurately and sufficiently reflect the meeting discussion, the FDA point of contact will convey this decision to the applicant and the minutes will stand as the official documentation of the meeting. If, after discussions with the prospective ANDA applicant or ANDA applicant, 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 objections.[66]

[66] Any addendum will be shared with the applicant by FDA.