Product-Specific Guidance Meetings Between FDA and ANDA Applicants Under GDUFA

Guidance for Industry

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

August 2024
Generic Drugs

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Contains Nonbinding Recommendations

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

This guidance represents 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 office 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 (i.e., pre-submission PSG teleconferences, post-submission 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 provides 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.

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[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] For purposes of this guidance, the term *ANDA applicant* refers to meetings that occur after an ANDA is received, the term *prospective ANDA applicant* refers to meetings that occur before an ANDA is received, and the terms *applicant* or *applicants* refer 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 methods, in vitro methods, or both 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.

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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 Title III of Division F (the FDA User Fee Reauthorization Act of 2022) of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).

[7] 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 it does not contain the BE studies that were recommended in the PSG absent justification (21 CFR 314.101(d)(3) (which states 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) and 21 CFR 314.94(a)(7)). Such justification should include the rationale for any deviation from the PSG, including data and appropriate references. See the guidance for industry *ANDA Submissions—Refuse-to-Receive Standards* (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.

As described in the GDUFA III commitment letter, FDA agreed to certain performance goals, including 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-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 a new or revised 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: (1) PSG teleconferences (which includes pre-submission PSG teleconferences and post-submission PSG teleconferences), (2) pre-submission PSG meetings, and (3) post-submission PSG meetings.

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 (i.e., the study protocol was signed by the study sponsor and/or the contract research organization) or completed an in vivo BE study.[11] A prospective ANDA applicant can request a pre-submission PSG teleconference before submitting the ANDA. An ANDA applicant can request a post-submission PSG teleconference if the ANDA has been submitted.

During a PSG teleconference, FDA will discuss the recommendations in the PSG and provide feedback on the potential impact of the recommendations in the PSG on the applicant's development program. For example, FDA may state that there are no potential impacts of the recommendations in the PSG on the applicant's development program or that the recommendations in the PSG impact the applicant's development program and therefore recommend changes to the applicant's development program.

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 for an applicant to seek feedback from FDA to ensure that any proposed changes or additions to an applicant's development program would be an acceptable approach to demonstrate BE in accordance with the relevant statutes and regulations.

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[10] GDUFA III commitment letter at section III.C.5.

[11] Ibid.

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, FDA generally would consider the submission of the in vivo BE study as an acceptable approach to demonstrate 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.[12]

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).[13] With the pre-submission PSG teleconference request, a prospective ANDA applicant should submit the title page, protocol summary, if one exists, 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., PSG Teleconferences for additional information on the contents for the meeting request).[14]

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), an ANDA applicant can request a post-submission PSG meeting (if the ANDA has been submitted), or an applicant can utilize the controlled correspondence process or request another meeting type, such as a pre-ANDA product development meeting, as appropriate, to seek further feedback from FDA regarding an alternative BE approach to the recommendations in the PSG.[15, 16] FDA recommends that applicants consider the types of questions for 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 and when to seek FDA's feedback. If

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[12] See footnote 9.

[13] GDUFA III commitment letter at section III.C.5.a.

[14] Ibid.

[15] For more information on controlled correspondence, see the guidance for industry *Controlled Correspondence Related to Generic Drug Development* (March 2024). The purpose of the controlled correspondence process is to provide a mechanism for a direct inquiry on FDA's position with respect to a particular element of generic drug development or postapproval submission requirements and for the Agency's direct, brief, timely response. For example, an ANDA applicant may submit a controlled correspondence to seek regulatory and/or scientific advice after issuance of a CRL or to request evaluations of alternative BE approaches (e.g., pharmacokinetic, in vitro, clinical).

[16] 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).

FDA receives multiple meeting requests or controlled correspondence that contain the same or similar question(s) from an applicant, FDA will determine which meeting to grant or controlled correspondence to answer and may deny the other(s).

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 the 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).[17]

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.[18]

- 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 that either were recommended by FDA in the previous PSG or that the ANDA applicant decided to pursue after a prior pre-ANDA product development meeting.[19]

After a post-submission PSG teleconference has been held, an ANDA applicant can request a post-submission PSG meeting, utilize the controlled correspondence process, or request another meeting type, such as a post-complete response letter (CRL) scientific meeting, as appropriate, to seek further feedback from FDA regarding an alternative BE approach to the recommendations in the PSG.[20] FDA recommends that applicants consider the types of questions for 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 and when to seek FDA's feedback. If FDA receives multiple meeting requests or controlled correspondence that contain the same or similar question(s) from an applicant, FDA will

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[17] GDUFA III commitment letter at section III.C.5.

[18] Under this scenario even though such applicants may not meet all the criteria in the GDUFA III commitment letter, FDA will grant requests for a post-submission PSG teleconference on a discretionary basis.

[19] Ibid. This opportunity to request a post-submission PSG teleconference does not apply to instances 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.

[20] GDUFA III commitment letter at section III.C.5.c. See also footnotes 15 and 16.

determine which meeting to grant or controlled correspondence to answer and may deny the other(s).

B. Pre-Submission PSG Meetings

After a pre-submission PSG teleconference has been held and before the ANDA is submitted, the prospective ANDA applicant can request a pre-submission PSG meeting.[21, 22] 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.[23] During a pre-submission PSG meeting, FDA will discuss the prospective ANDA applicant's questions related to its proposed alternative BE approach which differs from the 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, so that the prospective ANDA applicant obtains timely feedback from FDA before submitting the ANDA (i.e., within the pre-submission phase) on an approach other than the approach recommended in the PSG.

As an alternative to requesting a pre-submission PSG meeting after a pre-submission PSG teleconference, prospective ANDA applicants can consider submitting a controlled correspondence or requesting another meeting type, such as a pre-ANDA product development meeting, as appropriate, to seek feedback from FDA.[24]

C. Post-Submission PSG Meetings

After the ANDA has been submitted and a pre-submission PSG teleconference or a post-submission PSG teleconference has been held, the ANDA applicant can request a post-submission PSG meeting.[25,26] 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

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[21] GDUFA III commitment letter at section III.C.5.c.i.

[22] Prospective ANDA applicants can request a pre-submission PSG meeting regardless of whether they have had a pre-ANDA product development meeting (GDUFA III commitment letter at section III.C.5.c.iv).

[23] GDUFA III commitment letter at section III.C.5.c.

[24] See footnotes 15 and 16.

[25] GDUFA III commitment letter at section III.C.5.c.

[26] ANDA applicants can request a post-submission PSG meeting regardless of whether they have had a pre-ANDA product development or a post-CRL scientific meeting (GDUFA III commitment letter at section III.C.5.c.iv).

statutes and regulations.[27] During a post-submission PSG meeting, FDA will discuss the ANDA applicant's questions related to its proposed alternative BE approach which differs from the recommendations in the current PSG. FDA will not discuss questions that are 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 discipline review letter (DRL) or a CRL to allow FDA to complete its scientific evaluation of the ANDA applicant's submitted evidence of BE. During the assessment cycle, FDA generally 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. If an ANDA applicant intends to request a post-submission PSG meeting, the ANDA applicant should request and attend the post-submission PSG meeting prior to responding to the possible BE deficiency identified in a DRL involving recommendations in a new or revised PSG.[28] During the assessment cycle, as an alternative to a post-submission PSG meeting, ANDA applicants can consider submitting a controlled correspondence or requesting another meeting type, such as an enhanced mid-cycle review meeting, as appropriate, to seek feedback from FDA after a PSG teleconference.[29]

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 and attend the post-submission PSG meeting prior to responding to the BE deficiency identified in the CRL involving recommendations in the new or revised PSG.[30] After a CRL, as an alternative to a post-submission PSG meeting, ANDA applicants can

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[27] GDUFA III commitment letter at section III.C.5.c.

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

[29] See footnotes 15 and 16. The purpose of an enhanced mid-cycle review meeting is to provide an ANDA applicant an opportunity to ask questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s).

[30] If the ANDA applicant responds to the BE deficiency identified in a CRL involving recommendations in the new or revised PSG and then requests the post-submission PSG meeting, FDA intends to deny or cancel the post-submission PSG meeting 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.

consider submitting a controlled correspondence or requesting another meeting type, such as a post-CRL scientific meeting, as appropriate, to seek feedback from FDA.[31]

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.[32, 33] Applicants can request PSG teleconferences for PSGs published on or after October 1, 2022.[34] 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.[35]

For pre-submission PSG meetings, FDA agreed to grant or deny the meeting request within 14 days after FDA has received the request.[36] If granted, FDA agreed to hold the pre-submission PSG meeting within 120 days after FDA received the request.[37]

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[31] See footnotes 15 and 16. The purpose of a post-CRL scientific meeting is to provide an ANDA applicant scientific advice on possible approaches to address deficiencies identified in a CRL related to establishing equivalence. An applicant's post-CRL scientific meeting request must discuss one or more of the following: (1) a new equivalence study needed to address the deficiencies in the design identified in the CRL; (2) an approach that is different from that submitted in an ANDA (e.g., a change in study type from in vivo to in vitro); (3) a new comparative use human factors study; or (4) a new approach to demonstrating sameness of a complex active ingredient (GDUFA III commitment letter at section IV.C.).

[32] GDUFA III commitment letter at section III.C.5.

[33] 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 the 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.

[34] FDA in its discretion may grant PSG teleconference requests for PSGs published prior to Oct 1, 2022.

[35] GDUFA III commitment letter at section III.C.5.b.

[36] Id. at section III.C.5.c.i.

[37] Ibid.

For post-submission PSG meetings, FDA agreed to grant or deny the meeting request within 14 days after FDA has received the request.[38] If granted, FDA agreed to hold the post-submission PSG meeting within 90 days after FDA received the request.[39]

V. MEETING REQUESTS

A request for a pre-submission PSG teleconference or pre-submission PSG meeting should be submitted electronically, as explained below in this section. A request for a post-submission PSG teleconference or post-submission PSG meeting must be submitted electronically, as explained below in this section.[40]

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 PSG teleconference. The post-submission PSG meeting request should clearly indicate that the ANDA applicant had a 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 to address the applicant's BE approach, such as a pre-ANDA meeting, an enhanced mid-cycle review meeting, or a post-CRL scientific meeting.[41] 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) from an applicant, FDA intends to determine which request to grant and may deny the other(s).

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[38] GDUFA III commitment letter at section III.C.5.c.ii.

[39] Id.

[40] See the guidance for industry *Providing Regulatory Submissions in Electronic Format – Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014).

[41] FDA expects that, as applicable, the recommendations in the PSG and the applicant's development program would be discussed during these meetings.

A. PSG Teleconferences

A prospective ANDA applicant should submit a request for a pre-submission PSG teleconference electronically through the Center for Drug Evaluation and Research (CDER) NextGen Portal.[42] An ANDA applicant must submit a request for a post-submission PSG teleconference electronically through the Electronic Submissions Gateway.[43] The cover page should identify the submission as a "PSG Teleconference Request."

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

(1) Preassigned ANDA number[44] 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 or studies differ from the study or studies 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.[45]

(6) RLD and the RLD's 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.

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[42] The CDER NextGen Portal may be accessed at https://edm.fda.gov.

[43] See footnote 40.

[44] See information regarding FDA's Requesting a Pre-Assigned Application number on FDA's web page at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm114027.htm.

[45] See section III.A.2., Post-Submission PSG Teleconferences for scenarios where an in vivo BE study was not conducted.

(11) Contact person for the meeting (i.e., the person submitting the request), with their title and affiliation, secure email address,[46] 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.

B. Pre-Submission PSG Meetings

A prospective ANDA applicant should submit a request for a pre-submission PSG meeting electronically through the CDER NextGen Portal.[47] 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) Preassigned ANDA number.

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

(3) RLD and the RLD's 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,[48] and phone number. This is the person with whom FDA will communicate about the meeting.

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

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[46] 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.

[47] See footnote 42.

[48] See footnote 46.

C. Post-Submission PSG Meetings

An ANDA applicant must submit a request for a post-submission PSG meeting electronically through the Electronic Submissions Gateway.[49] 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.

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

(3) RLD and the RLD's application number.

(4) Established Name.

(5) Proposed indication(s).

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

(7) Date 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,[50] and phone number. This is the person with whom FDA will communicate about the meeting.

(11) The meeting package (see section VIII., Meeting Package Content), 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

[49] See footnote 40.

[50] See footnote 46.

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 FDA denies a meeting request, FDA will provide a written notification to the applicant explaining the reason for the denial.

FDA will base denials of meeting requests submitted in conformity with the GDUFA III performance goals on a substantive reason. For example:

- FDA may deny a pre-submission or post-submission PSG teleconference request if the request is incomplete (e.g., does not include the signature page of the relevant in vivo BE 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 ANDA has been submitted to FDA. In addition, FDA may deny the pre-submission PSG meeting 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.[51]

- FDA intends to deny a post-submission PSG meeting request if the ANDA applicant did not have a PSG teleconference. In addition, FDA may deny the post-submission PSG meeting 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 involving recommendations in the new or revised PSG, 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.[52]

If FDA denies a meeting request, FDA will consider a subsequent request to schedule a PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting as a new request

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[51] GDUFA III commitment letter at section III.C.5.c.iii.

[52] Id.

(i.e., a request that is assigned a new set of time frames as described in section IV., GDUFA III Performance Goals).

B. Meeting Request Granted

If FDA grants a request for a meeting, 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 requested meeting type and denied in part for the questions that are not appropriate for the requested meeting type. 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 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, GDUFA III Performance Goals).

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. FDA, in its discretion, will decide whether the meeting should be rescheduled depending on the specific circumstances.

FDA may reschedule a meeting if, for example:

(1) The assessment team determines that it needs additional information 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) A regulatory policy issue that is yet to be resolved 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). FDA, at its discretion, will decide 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[53]

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

[53] When FDA cancels a pre-submission PSG meeting because the prospective ANDA applicant submits the ANDA, the applicant can request a post-submission PSG meeting. See section III.C, Post-Submission PSG Meetings for information on post-submission PSG meetings.

(4) The ANDA applicant submits a response to the possible BE deficiency identified in a DRL or the BE deficiency identified in the CRL involving recommendations in the new or revised PSG

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 adequately prepare 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

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

B. Where and How to Submit a Meeting Package

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 NextGen Portal.

An ANDA applicant must submit the meeting package for a post-submission PSG teleconference or for a post-submission PSG meeting electronically via the Electronic Submissions Gateway.[54]

It is not necessary to submit any paper copies of the meeting package.

C. Meeting Package Content

The meeting package should provide information that is relevant to the product, development stage, and requested meeting type, in addition to any supplementary information needed to help FDA develop responses to issues raised by the 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 applicant's 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

[54] See footnote 40.

covering the whole submission) with a table of contents, appropriate indices, appendices, cross-references, and tabs differentiating sections.

1. PSG Teleconferences

In general, a meeting package for a PSG teleconference should include the following information:

(1) Preassigned 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.[55]

(4) RLD and the RLD's 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.
- A brief statement of the purpose and objectives of the PSG 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 PSG teleconference request is regarding.

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

[55] See section III.A.2., Post-Submission PSG Teleconferences for scenarios where an in vivo BE study was not conducted.

(9) The requested format[56]: teleconference[57] or written response only.[58] For requested PSG 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 PSG teleconference that are within the time frame of the requested meeting type (see section IV., GDUFA III Performance Goals). Nonavailable 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.[59]

2. Pre-Submission PSG Meetings

In general, a meeting package for a pre-submission PSG meeting should include the following information:

(1) Preassigned 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 the RLD's application number.

(6) Established name.

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[56] 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 a PSG teleconference is requested by 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 a controlled correspondence instead of holding a teleconference.

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

[58] 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.

[59] The applicant should notify their point of contact 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.

(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 pre-submission PSG 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/or data to support discussion.

(11) The requested format — in-person face-to-face,[60] videoconference,[61] 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). Nonavailable 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.[62]

3. Post-Submission PSG Meetings

In general, a meeting package for a post-submission PSG meeting should include the following information:

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

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

[62] 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.

(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 the RLD's 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.
- A description of BE deficiencies, if any, received in previous assessment cycles.
- A brief summary of the PSG teleconference discussion.

(8) A brief statement of the purpose and objectives of the post-submission PSG 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.

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

(10) The proposed format[63]: in-person face-to-face, videoconference, 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, afternoon) for the meeting that are within the time frame of the requested meeting type (see section IV., GDUFA III Performance Goals). Nonavailable dates and times should also be included.

[63] 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 written response only instead of a meeting.

– 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.[64]

IX. PREMEETING 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 (POC) 5 calendar days before the meeting.

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 FDA will not entertain new questions 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

[64] 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.

will discuss questions posed and the data provided by the applicant related to the proposed alternative BE approach to the recommendations in the PSG.

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 before the meeting, if possible. All presentations should be kept brief to maximize the time available for discussion.

FDA will not increase the length of the meeting 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 that requests additional clarification of the meeting minutes FDA issued should contact the assigned FDA POC. 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 describing the concern to the division director of the division that chaired the meeting or teleconference, with a copy to the FDA POC.

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 POC 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.[65]

[65] FDA will share any addendum with the applicant.