
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DRAFT GUIDANCE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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U.S. Department of Health and Human Services
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Contains Nonbinding Recommendations

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1 **Product-Specific Guidance Meetings Between FDA and ANDA**
2 **Applicants Under GDUFA**
3 **Guidance for Industry¹**
4

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6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
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15 **I. INTRODUCTION**
16

17 This guidance provides recommendations to industry on product-specific guidance (PSG)
18 meetings between FDA and a prospective applicant preparing to submit to FDA or an applicant
19 that has submitted to FDA an abbreviated new drug application (ANDA) under section 505(j) of
20 the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)).² Specifically, this
21 guidance provides information on requesting and conducting PSG meetings with FDA (PSG
22 teleconferences, pre-submission PSG meetings, and post-submission PSG meetings), as
23 contemplated in the Generic Drug User Fee Amendments (GDUFA) Reauthorization
24 Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III
25 commitment letter).³ And this guidance is intended to provide procedures that will promote
26 well-managed PSG meetings and help ensure that such meetings are scheduled and conducted in
27 accordance with the time frames set forth in the GDUFA III commitment letter.
28

29 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
30 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
31 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
32 the word *should* in Agency guidance means that something is suggested or recommended, but
33 not required.
34
35

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>.

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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 resources⁵ 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-

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>.

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

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70 **III. MEETING TYPES**

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

76

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

87

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

93

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

100

101 As described the GDUFA III commitment letter, an ANDA applicant is eligible to have a post-
102 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.

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103 FDA.¹³ The post-submission PSG teleconference and the subsequent post-submission PSG
104 meeting should occur before responding to a possible BE deficiency identified in a discipline
105 review letter (DRL) or a BE deficiency identified in a complete response letter (CRL). For
106 example, if FDA has issued a CRL, the ANDA applicant should request and attend the post-
107 submission PSG meeting prior to responding to the BE deficiency identified in the CRL so that
108 the ANDA applicant can consider FDA's feedback in developing a response to the CRL.^{14, 15}
109

110 As an alternative to a pre-submission PSG meeting or a post-submission PSG meeting,
111 applicants can consider obtaining FDA's feedback on an approach other than the approach
112 recommended in the PSG through controlled correspondence or another meeting type, as
113 appropriate.¹⁶ FDA recommends that applicants consider the types of questions on which they
114 want to obtain FDA's feedback, the status of their ANDA, and the eligibility criteria for
115 controlled correspondence or a particular meeting type in determining which pathway to seek
116 FDA's feedback. Applicants should not submit multiple meeting requests or controlled
117 correspondence at or around the same time with the same or similar questions. If FDA receives
118 multiple meeting requests or controlled correspondence that contain the same or similar
119 question(s), FDA will determine which meeting to grant or controlled correspondence to answer
120 and may deny the other(s).
121

A. PSG Teleconferences

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123
124 PSG teleconferences provide an opportunity for an applicant to obtain FDA's feedback on the
125 potential impact of a new or revised PSG on the applicant's development program when the
126 applicant has already commenced an in vivo BE study.¹⁷ During a PSG teleconference, FDA
127 will provide feedback on the potential impact of the recommendations in the PSG, but FDA will
128 not discuss the applicant's questions regarding an approach other than the approach
129 recommended in the PSG. During a PSG teleconference, FDA may, if applicable, recommend a
130 path for future communication with FDA, such as controlled correspondence, pre-submission
131 PSG meeting, post-submission PSG meeting, or other meeting type.
132

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

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.

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

141
142 Applicants should submit a request for a PSG teleconference within 60 days after publication of
143 the new or revised PSG so that FDA can provide timely feedback to applicants.¹⁹ Applicants can
144 request a PSG teleconference more than 60 days after publication of the new or revised PSG,
145 however, the 30-day time frame for conducting PSG teleconferences²⁰ (discussed in section IV
146 of this guidance) is only applicable for complete packages submitted within 60 days after
147 publication of the PSG and otherwise meet the criteria set forth in section V of this guidance.

1. Pre-Submission PSG Teleconferences

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

161
162 After a pre-submission PSG teleconference has been held, a prospective ANDA applicant can
163 request a pre-submission PSG meeting (if the ANDA has not been submitted), utilize the
164 controlled correspondence process, or request another meeting type, as appropriate, to seek
165 further feedback from FDA regarding an alternative BE approach to the recommendations in the
166 PSG.^{23, 24}
167

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.

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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

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.

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204 recommendations in the current PSG. FDA will not discuss questions unrelated to the alternative
205 BE approach to the recommendations in the current PSG.
206

207 Prospective ANDA applicants should request a pre-submission PSG meeting in a timely manner
208 after the pre-submission PSG teleconference, considering the time needed to develop the meeting
209 package for a pre-submission PSG meeting with FDA, and before submitting the ANDA.

210 Prospective ANDA applicants can request a pre-submission PSG meeting regardless of whether
211 they have had a product development meeting.³⁰
212

213 As an alternative to requesting a pre-submission PSG meeting after a pre-submission PSG
214 teleconference, prospective ANDA applicants can consider submitting controlled
215 correspondence or requesting another meeting type, such as a product development meeting, as
216 appropriate, to seek feedback from FDA.³¹
217

C. Post-Submission PSG Meetings

219
220 After a post-submission PSG teleconference has been held, the ANDA applicant can request a
221 post-submission PSG meeting.³² The purpose of the post-submission PSG meeting is to provide
222 a forum in which ANDA applicants can discuss the scientific rationale for an approach other
223 than the approach recommended in the PSG to ensure that the approach complies with the
224 relevant statutes and regulations.³³ During a post-submission PSG meeting, FDA will discuss
225 the ANDA applicant's questions related to their proposed alternative BE approach which differs
226 from the recommendations in the current PSG. FDA will not discuss questions unrelated to the
227 proposed alternative BE approach to the recommendations in the current PSG.
228

229 FDA recommends that an ANDA applicant consider the status of the ANDA and its assessment
230 cycle as well as the time needed to develop the meeting package in determining when to submit a
231 request for a post-submission PSG meeting. For example, FDA recommends that an ANDA
232 applicant refrain from requesting the post-submission PSG meeting during the assessment cycle
233 until after FDA has issued a DRL or a CRL to allow FDA to complete its scientific evaluation of
234 the ANDA applicant's submitted evidence of BE.³⁴ Between assessment cycles (e.g., FDA
235 previously issued a CRL to the ANDA applicant and the post-submission PSG teleconference
236 was subsequently held), FDA recommends that the ANDA applicant request the post-submission
237 PSG meeting once the ANDA applicant has developed the meeting package. If an ANDA
238 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.

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

241
242 During the assessment cycle, as an alternative to a post-submission PSG meeting, ANDA
243 applicants can consider submitting controlled correspondence or requesting another meeting
244 type, such as an enhanced mid-cycle review meeting, as appropriate, to seek feedback from FDA
245 after a post-submission PSG teleconference.³⁶ After a CRL, as an alternative to a post-
246 submission meeting, ANDA applicants can consider submitting controlled correspondence or
247 requesting another meeting type, such as a post-CRL scientific meeting, as appropriate, to seek
248 feedback from FDA.³⁷

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IV. GDUFA III PERFORMANCE GOALS

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252
253 As reflected in the GDUFA III commitment letter, FDA committed to certain goals and
254 procedures for scheduling and conducting PSG teleconferences, pre-submission PSG meetings,
255 and post-submission PSG meetings for ANDAs.^{38, 39} Applicants can request PSG
256 teleconferences for PSGs published on or after October 1, 2022.⁴⁰ The goals described below
257 only apply to requests submitted on or after October 1, 2022, and subject to the criteria described
258 in this guidance.

259
260 FDA agreed to hold a PSG teleconference within 30 days after the receipt of the meeting request
261 if the request is granted.⁴¹ This goal only applies to PSG teleconference requests submitted
262 within 60 days after the PSG publication.⁴²

263
264 For pre-submission PSG meetings, FDA agreed to grant or deny the meeting request within 14
265 days after FDA has received the request.⁴³ If granted, FDA agreed to hold the pre-submission
266 PSG meeting within 120 days after FDA received the request.⁴⁴

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.*

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

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272

273 **V. MEETING REQUESTS**

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

277

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

282

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

286

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

290

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

299

300 **A. PSG Teleconferences**

301

302 A prospective ANDA applicant should submit a request for a pre-submission PSG teleconference
303 electronically through the CDER Direct NextGen Collaboration Portal.⁴⁷ An ANDA applicant
304 should submit a request for a post-submission PSG teleconference electronically through the
305 Enterprise Submission Gateway. The cover page should identify the submission as a “PSG
306 Teleconference Request.”

307

⁴⁵ Ibid.

⁴⁶ Ibid.

⁴⁷ The CDER Direct NextGen Collaboration Portal may be accessed at <https://edm.fda.gov>.

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- 308 A request for a PSG teleconference meeting should include the following information:
309
310 (1) Pre-assigned ANDA number⁴⁸ or ANDA number.
311
312 (2) Meeting type being requested (i.e., PSG Teleconference).
313
314 (3) Month and year the current PSG was published.
315
316 (4) A summary of how the applicant's BE study(ies) differ from the study(ies)
317 recommended in the PSG.
318
319 (5) Signature page of the relevant in vivo BE study protocol signed by the study sponsor
320 and/or contract research organization, if applicable.⁴⁹
321
322 (6) RLD and its application number.
323
324 (7) Established Name.
325
326 (8) Proposed indication(s).
327
328 (9) Dosage form, route of administration, and strength(s).
329
330 (10) A statement indicating whether the submission is being made by the applicant or by a
331 U.S. agent on behalf of the applicant.
332
333 (11) Contact person for the meeting (i.e., the person submitting the request), with their title
334 and affiliation, secure email address,⁵⁰ and phone number. This is the person with whom
335 FDA will communicate about the meeting.
336
337 (12) The meeting package (see section VIII of this guidance), which should be received at the
338 time of the meeting request.
339

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.

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340 **B. Pre-Submission PSG Meetings**

341
342 A prospective ANDA applicant should submit a request for a pre-submission PSG meeting
343 electronically through the CDER Direct NextGen Collaboration Portal.⁵¹ The cover page should
344 identify the submission as a “Pre-Submission PSG Meeting.”
345

346 A request for a pre-submission PSG meeting should include the following information:
347

- 348 (1) Pre-assigned ANDA number.
349
350 (2) Meeting type being requested (i.e., pre-submission PSG meeting).
351
352 (3) RLD and application number.
353
354 (4) Established Name.
355
356 (5) Proposed indication(s).
357
358 (6) Dosage form, route of administration, and strength(s).
359
360 (7) Date pre-submission PSG teleconference was held and event ID.
361
362 (8) A statement indicating whether the submission is being made by the prospective ANDA
363 applicant or by a U.S. agent on behalf of the prospective ANDA applicant.
364
365 (9) Contact person for the meeting (i.e., the person submitting the request), with their title
366 and affiliation, secure email address,⁵² and phone number. This is the person with whom
367 FDA will communicate about the meeting.
368
369 (10) The meeting package (see section VIII of this guidance), which should be received at the
370 time of the meeting request.
371

372 **C. Post-Submission PSG Meetings**

373
374 An ANDA applicant should submit a request for a post-submission PSG meeting electronically
375 through the Enterprise Submission Gateway. The cover page should identify the submission as a
376 “Post-Submission PSG Meeting.”
377

378 A request for a post-submission PSG meeting should include the following information:
379

- 380 (1) ANDA number.
381

⁵¹ See footnote 47.

⁵² See footnote 50.

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- 382 (2) Meeting type being requested (i.e., post-submission PSG meeting).
383
384 (3) RLD and application number.
385
386 (4) Established Name.
387
388 (5) Proposed indication(s).
389
390 (6) Dosage form, route of administration, and strength(s).
391
392 (7) Date post-submission PSG teleconference was held and event ID
393
394 (8) Title and study number of the study impacted by the recommendations in the PSG.
395
396 (9) A statement indicating whether the submission is being made by the ANDA applicant or
397 by a U.S. agent on behalf of the ANDA applicant.
398
399 (10) Contact person for the meeting (i.e., the person submitting the request), with their title
400 and affiliation, secure email address,⁵³ and phone number. This is the person with whom
401 FDA will communicate about the meeting.
402
403 (11) The meeting package (see section VIII of this guidance), which should be received at the
404 time of the meeting request.
405

VI. EVALUATING MEETING REQUESTS

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

A. Meeting Request Denied

418
419 If a meeting request is denied, written notification to the applicant will include an explanation of
420 the reason for the denial.

421
422 Denials of meeting requests submitted in conformity with the GDUFA III performance goals will
423 be based on a substantive reason. For example:
424

⁵³ See footnote 50.

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- 425 • FDA may deny a PSG teleconference request if the applicant's in vivo BE study started
426 after the PSG was published or the request is incomplete (e.g., does not include the
427 signature page of the relevant in vivo study protocol signed by the study sponsor and/or
428 the contract research organization).
- 429
- 430 • FDA intends to deny a pre-submission PSG meeting request if the prospective ANDA
431 applicant did not have a pre-submission PSG teleconference or if the applicant submitted
432 the ANDA after the pre-submission PSG teleconference. In addition, FDA may deny the
433 request if the request is incomplete, FDA determines that the inquiry would be
434 appropriately addressed through a controlled correspondence, or the prospective ANDA
435 applicant submitted the same or similar questions in a request for another meeting type or
436 in controlled correspondence.⁵⁴
- 437
- 438 • FDA intends to deny a post-submission PSG meeting request if the ANDA applicant did
439 not have a post-submission PSG teleconference or if the ANDA applicant had a pre-
440 submission PSG teleconference and then submitted the ANDA. In addition, FDA may
441 deny the request if the request is incomplete, FDA determines the inquiry would be
442 appropriately addressed through a controlled correspondence, FDA determines that the
443 questions in the meeting package have been addressed during the ANDA assessment, the
444 ANDA applicant responded to the possible BE deficiency identified in a DRL or BE
445 deficiency identified in a CRL, or the ANDA applicant submitted the same or similar
446 questions in a request for another meeting type or in controlled correspondence.
- 447

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

452

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

457

B. Meeting Request Granted

458

459

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

⁵⁴ GDUFA III commitment letter at 25.

⁵⁵ Ibid.

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467 expected FDA participants. The scheduling information will be forwarded to the applicant either
468 with the notification granting the meeting or teleconference or as soon as possible following
469 notification that the request has been granted, and the meeting or teleconference will be
470 scheduled within the GDUFA III performance goals (see section IV of this guidance).
471
472

VII. RESCHEDULING AND CANCELING MEETINGS

A. Rescheduling Meetings

477 Occasionally, circumstances may arise that necessitate the rescheduling of a meeting. If a
478 meeting needs to be rescheduled, FDA will work to reschedule it as soon as possible after the
479 original date. A new meeting request should not be submitted. Applicants and FDA should take
480 reasonable steps to avoid rescheduling meetings. For example, if an attendee becomes
481 unavailable, a substitute can be identified, or comments on the topic that the attendee would have
482 addressed can be forwarded to the applicant following the meeting. It will be at FDA's
483 discretion whether the meeting should be rescheduled depending on the specific circumstances.
484

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

- 487 (1) The assessment team determines that additional information is needed from the applicant
488 to address the applicant's questions.
- 489 (2) Essential attendees are no longer available for the scheduled date and time because of an
490 emergency.
- 491 (3) Attendance by additional FDA offices not originally anticipated or requested by the
492 applicant is critical and the offices' availability precludes holding the meeting on the
493 original date.
- 494 (4) There is a regulatory policy issue that is yet to be resolved that may affect the response
495 to the applicant's questions.
- 496 (5) The Federal Government is closed or opening is delayed due to inclement weather,
497 emergency, or other reason.

B. Canceling Meetings

503 Occasionally, circumstances may arise that necessitate the canceling of a meeting. If a meeting
504 is canceled, a subsequent request to schedule a meeting will be considered a new request.
505 Applicants and FDA should take reasonable steps to avoid canceling meetings (unless the
506 meeting is no longer necessary). It will be at FDA's discretion whether the meeting should be
507 canceled depending on the specific circumstances.
508
509

510 A pre-submission PSG teleconference may be canceled if, for example:
511
512

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

514

515 (2) The prospective ANDA applicant submits the ANDA

516

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

518

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

520

521 (2) FDA refuses to receive the ANDA

522

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

524

525 (1) The prospective ANDA applicant withdraws the request

526

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

529

530 (3) The prospective ANDA applicant submits the ANDA

531

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

533

534 (1) The ANDA applicant withdraws the request

535

536 (2) FDA refuses to receive the ANDA

537

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

540

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

543

544 If an applicant cancels a meeting, FDA will count the performance goal as met. If FDA cancels
545 the meeting, the meeting request will not be counted for performance goal purposes.

546

547

548 **VIII. MEETING PACKAGE CONTENT**

549

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

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555 **A. Timing of Submission**

556
557 The meeting package for a PSG teleconference, pre-submission PSG meeting, or post-
558 submission PSG meeting should be submitted to FDA so that it is received concurrently with the
559 meeting request.

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

561
562 A prospective ANDA applicant should submit the meeting package for a pre-submission PSG
563 teleconference or for a pre-submission PSG meeting electronically to the CDER Direct NextGen
564 Collaboration Portal at the same time as the meeting request.

565
566 An ANDA applicant should submit the meeting package for a post-submission PSG
567 teleconference or for a post-submission PSG meeting electronically via the Enterprise
568 Submission Gateway at the same time as the meeting request.

569
570 It is not necessary to submit any paper copies of the meeting package.

571 **C. Meeting Package Content**

572
573 The meeting package should provide information relevant to the product, development stage, and
574 meeting type requested, in addition to any supplementary information needed to help FDA
575 develop responses to issues raised by applicant. The meeting package should contain sufficient
576 detail to meet the intended meeting objectives.

577
578 To facilitate FDA review, the meeting package content should be organized according to the
579 proposed agenda. The meeting package should be a sequentially paginated document (individual
580 sections can be numbered separately, so long as there is an overall pagination covering the whole
581 submission) with a table of contents, appropriate indices, appendices, cross-references, and tabs
582 differentiating sections.

583 1. *PSG Teleconferences*

584
585 A meeting package for a PSG teleconference generally should include the following information:

- 586
587 (1) Pre-assigned ANDA number or ANDA number.
588
589 (2) Month and year the current PSG was published.
590
591 (3) Signature page of the relevant in vivo BE study protocol signed by the study sponsor
592 and/or contract research organization, if applicable.⁵⁶
593
594 (4) RLD and application number.
595
596
597

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

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- 598
599 (5) Established name.
600
601 (6) Dosage form, route of administration, strength(s), and dosing regimen (frequency and
602 duration).
603
604 (7) A background section that includes the following:
605
606 • A brief history of the development program.
607
608 • The status of product development.
609
610 • A brief statement of the purpose and objectives of the teleconference, including a
611 brief background of the issues underlying the agenda, a description of how the
612 applicant's study differs from the recommendations in the PSG, and if applicable, a
613 statement indicating that the applicant's *in vivo* study is impacted by the new or
614 revised PSG.
615
616 • Summary of prior correspondence, meeting requests, and meetings with FDA
617 regarding the specific drug product that the teleconference request is regarding.
618
619 (8) The title page, protocol summary, and the signature page of the relevant *in vivo* study
620 protocol signed by the study sponsor and/or the contract research organization, if
621 applicable.
622
623 (9) The requested format⁵⁷—teleconference⁵⁸ or written response only.⁵⁹ For requested
624 teleconferences, the request package should also include the following information:
625
626 • A proposed agenda outlining how the 60-minute time allotted for the PSG
627 teleconference should be apportioned to each agenda item.
628
629 • Suggested dates and times (e.g., morning or afternoon) for the teleconference that are
630 within the time frame of the meeting type being requested (see section IV). Non-
631 available dates and times should also be included.
632

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.

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- 633 • A list of all individuals, with their titles and affiliations, who will attend the requested
634 meeting from the applicant’s organization, including consultants and interpreters.⁶⁰

2. *Pre-Submission PSG Meetings*

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

- 638 (1) Pre-assigned ANDA number.
639
640 (2) Month and year the current PSG was published.
641
642 (3) In vivo BE study protocol signature date, if applicable.
643
644 (4) Title and study number of the study impacted by the recommendations in the PSG.
645
646 (5) RLD and application number.
647
648 (6) Established Name.
649
650 (7) Dosage form, route of administration, strength(s), and dosing regimen (frequency and
651 duration).
652
653 (8) A background section that includes the following:
654
655 • A brief history of the development program.
656 • The status of product development, including status of the in vivo study.
657 • A brief summary of the PSG teleconference discussion.
658
659 (9) A brief statement of the purpose and objectives of the meeting. This statement should
660 include a brief background of the issues underlying the agenda and a description of how
661 the applicant’s study differs from the recommendations in the PSG.
662
663 (10) The specific alternative approach to establishing BE, with justification, rationale, and
664 data to support discussion.
665
666
667
668

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.

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

- 672
- 673 • A proposed agenda outlining how the 60-minute time allotted for the pre-submission
674 PSG meeting should be apportioned to each proposed question.
 - 675
 - 676 • Suggested dates and times (e.g., morning or afternoon) for the meeting that are within
677 the time frame of the meeting type being requested (see section IV). Non-available
678 dates and times should also be included.
 - 679
 - 680 • A list of all individuals, with their titles and affiliations, who will attend the requested
681 meeting from the applicant's organization, including consultants and interpreters.⁶³
682

3. Post-Submission PSG Meetings

683
684
685 A meeting package for a post-submission PSG meeting generally should include the following
686 information:

- 687
- 688 (1) ANDA number.
 - 689
 - 690 (2) Month and year the current PSG was published.
 - 691
 - 692 (3) In vivo BE study protocol signature date, if applicable.
 - 693
 - 694 (4) RLD and application number.
 - 695
 - 696 (5) Established Name.
 - 697
 - 698 (6) Dosage form, route of administration, strength(s), and dosing regimen (frequency and
699 duration).
 - 700
 - 701 (7) A background section that includes the following:
702
 - 703 • A brief history of the development program.
 - 704
 - 705 • The status of product development.

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.

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- 732
- 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 format⁶⁴—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

733

734

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

736 teleconference.

737

738 For pre-submission PSG meetings and post-submission PSG meetings, if FDA is not providing a

739 written response only to the applicant, FDA intends to provide preliminary written comments to

740 the applicant’s point of contact 5 calendar days before the meeting or teleconference.

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.

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741
742 Communications before the meeting between applicants and FDA, including preliminary written
743 comments, can serve as a foundation for discussion or as the final meeting responses if the
744 meeting is canceled. Nevertheless, preliminary written comments should not be construed as
745 final unless there is agreement between the applicant and FDA that additional discussion is not
746 necessary for any question (i.e., when the meeting is canceled because the applicant is satisfied
747 with FDA’s preliminary written comments), or the applicant and FDA agree a particular question
748 is considered resolved, allowing extra time for discussion of other questions during the meeting.
749 After receiving the preliminary written comments, the applicant should provide an updated
750 agenda with its list of questions for discussion in order of priority, no later than 48 hours before
751 the scheduled meeting. Preliminary written comments communicated by FDA should not
752 generate the submission of new questions, and new questions will not be entertained at the
753 meeting.

754

755

X. PROCEDURES FOR CONDUCT OF MEETINGS

757

A. Introductions and Agenda

759

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

764

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

769

B. End of Meeting Summary

771

772 Before the end of the meeting, FDA attendees and the applicant attendees should summarize the
773 important discussion points, agreements, clarifications, and action items. Generally, the
774 applicant will be asked to present the summary to ensure that there is mutual understanding of
775 the meeting outcomes and action items. FDA staff can add or further clarify any important
776 points not covered in the summary, and these items can be added to the meeting minutes. The
777 summary can be done at the end of the meeting or after discussion of each question.

778

C. Presentations

780

781 Presentations by applicants are not generally needed because the information necessary for
782 review and discussion should be part of the meeting package. If an applicant plans to make a
783 presentation, the presentation should be discussed ahead of time with the FDA point of contact to
784 ensure that FDA has the presentation materials ahead of the meeting, if possible. All
785 presentations should be kept brief to maximize the time available for discussion.

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787 The length of the meeting will not be increased to accommodate a presentation. If a presentation
788 contains more than a small amount of content distinct from clarifications or explanations of
789 previous data or contains data that were not included in the original meeting package submitted
790 to FDA for review, FDA staff may not be able to provide comments on the new information.

791
792 FDA does not expect that applicant attendees of a PSG teleconference will provide any
793 presentations.

794
795

796 **XI. DOCUMENTATION AND MEETING MINUTES**

797
798 Documentation of meeting outcomes (responses to the questions and outcomes of any
799 discussions regarding the responses), agreements, and disagreements is critical to ensuring that
800 this information is preserved for meeting participants and for future reference. FDA minutes are
801 the official record of the meeting. FDA intends to issue the official, finalized minutes to the
802 applicant within 30 days after the PSG teleconference, pre-submission PSG meeting, or post-
803 submission PSG meeting.

804
805

806 **XII. RESOLUTION OF DISPUTE ABOUT MEETING MINUTES**

807
808 On occasion, there may be disputes regarding the accuracy and sufficiency of the minutes of a
809 PSG teleconference, pre-submission PSG meeting, or post-submission PSG meeting. An
810 applicant requesting additional clarification of the meeting minutes issued by FDA should
811 contact the assigned FDA point of contact. FDA recommends that the applicant submit its
812 concerns about the meeting minutes in writing to FDA within 10 calendar days of receipt of the
813 official meeting minutes. This process addresses issues with the meeting minutes only.

814
815

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

819
820

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

827
828

829 The applicant's concerns will be taken under consideration by the assessment discipline and
830 senior management if senior management were present at the meeting. If the minutes are
831 deemed to accurately and sufficiently reflect the meeting discussion, the FDA point of contact
832 will convey this decision to the applicant and the minutes will stand as the official
833 documentation of the meeting. If, after discussions with the prospective ANDA applicant or
834 ANDA applicant, FDA deems it necessary to change the official minutes, the changes will be

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832 documented in an addendum to the official minutes. The addendum will also document any
833 continued objections.⁶⁶

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