
Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (CDER) Sandra Benton at 301-796-1042, or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

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

**August 2023
Procedural
Revision 1**

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Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry¹

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. INTRODUCTION

This guidance provides recommendations to industry on formal meetings between the Food and Drug Administration (FDA) and sponsors or applicants relating to the development and review of biosimilar or interchangeable biosimilar products² regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

This guidance does not apply to meetings associated with the development of products intended for submission in, or with the review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act), biologics license applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act),³ or submissions for devices under the FD&C Act.⁴ For the purposes of this guidance, *formal meeting* includes any meeting that is requested by a sponsor or applicant (hereafter referred to as *requester(s)*) following the procedures provided in this guidance and

¹ This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research at the Food and Drug Administration.

² In this guidance, the following terms are used to describe biological products licensed under section 351(k) of the PHS Act: (1) “biosimilar” or “biosimilar product” refers to a product that FDA has determined to be biosimilar to the reference product (see sections 351(i)(2) and 351(k)(2) of the PHS Act) and (2) “interchangeable biosimilar” or “interchangeable product” refers to a biosimilar product that FDA has determined to be interchangeable with the reference product (see sections 351(i)(3) and 351(k)(4) of the PHS Act).

³ For information on meetings for new drug applications and 351(a) BLAs, see the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (December 2017). When final, this guidance will represent the FDA’s current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

⁴ For information on meetings for medical device submissions, see the guidance for industry *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program* (June 2023).

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31 includes meetings conducted in any format (i.e., in-person, virtual (videoconference),
32 teleconference, or written response only (WRO)).

33
34 This guidance discusses the principles of good meeting management practices (GMMPs) and
35 describes standardized procedures for requesting, preparing, scheduling, conducting, and
36 documenting such formal meetings.⁵

37
38 This draft guidance for industry revises and replaces the draft guidance of the same name issued
39 in June 2018. This revision includes:

- 40
- 41 • Changes to the data expectations in Biosimilar Initial Advisory (BIA) meeting requests
- 42
- 43 • Addition of Biological Product Development (BPD) Type 2a meeting
- 44
- 45 • Changes to when the meeting background package is submitted for BPD Type 4 meeting
- 46
- 47 • Changes to the description of the available meeting formats
- 48
- 49 • Addition of an option for a request for clarification
- 50

51 FDA also made certain clarifying and editorial changes. Editorial changes were made primarily
52 for clarification.

53
54 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
55 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
56 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
57 the word *should* in Agency guidances means that something is suggested or recommended, but
58 not required.

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61 **II. BACKGROUND**

62
63 Each year, FDA review staff participate in many meetings with requesters who seek advice
64 relating to the development and review of a biosimilar or interchangeable biosimilar product.
65 Because these meetings often represent critical points in the regulatory and development process,
66 it is important that there are efficient, consistent procedures for the timely and effective conduct
67 of such meetings. The GMMPs in this guidance are intended to provide consistent procedures
68 that will promote well-managed meetings and to ensure that such meetings are scheduled within
69 a reasonable time, conducted efficiently, and documented appropriately.

70

⁵ The previous guidance for industry *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* published November 18, 2015, has been withdrawn.

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71 As part of the reauthorization of the Biosimilar User Fee Act (BsUFA), the FDA has committed
72 to specific performance goals that include meeting management goals for formal meetings that
73 occur between the FDA and requesters.⁶
74

75

III. MEETING TYPES⁷

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77
78 There are six types of formal meetings that occur between requesters and FDA staff to discuss
79 development and review of a biosimilar or interchangeable biosimilar product: BIA, BPD Type
80 1, BPD Type 2a, BPD Type 2b, BPD Type 3, and BPD Type 4.
81

82

A. BIA Meeting

83

84 A BIA meeting is an initial assessment limited to a general discussion regarding whether
85 licensure under section 351(k) of the PHS Act may be feasible for a particular product, and if so,
86 general advice on the expected content of the development program as it relates to the
87 biosimilarity assessment. This meeting type does not involve substantive review of summary
88 data or full study reports. Although the FDA encourages requesters to provide analytical data
89 from at least one lot of the proposed biosimilar or interchangeable biosimilar product compared
90 to the U.S.-licensed reference product, the data are not required as long as the requester provides
91 sufficient information with the meeting request to enable the FDA to make a preliminary
92 determination as to whether licensure under section 351(k) of the PHS Act may be feasible for a
93 particular product and to provide meaningful advice. The meeting request should include the
94 following, as appropriate:
95

96

- Identification of reference product.

97

- The indications intended to be sought for licensure.

98

99

- A comparative analytical assessment plan, including preliminary identification of the critical quality attributes and planned characterization methods.

100

101

- If a requester seeks to use a non-U.S.-licensed comparator product during development, the proposed bridging strategy to justify the relevance of the data generated with the non-U.S.-licensed comparator product.

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⁶ See BsUFA III goals letter titled “Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027” available on the FDA website at <https://www.fda.gov/media/152279/download>.

⁷ The meeting types and goal dates are described in the BsUFA III goals letter and apply to formal meetings between FDA staff and requesters of BsUFA meetings; they do not apply to meetings with CDER Office of Generic Drugs, CDER Office of Compliance, or CDER Office of Prescription Drug Promotion.

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- 110 • A conceptual description of the planned clinical pharmacokinetics and/or
111 pharmacodynamic study or studies, including proposed endpoints.
112
- 113 • A conceptual plan that includes initial considerations regarding the need for a
114 comparative clinical study. If the requester plans to conduct a comparative clinical safety
115 and efficacy study, this conceptual plan should include the patient population and
116 proposed endpoints.
117
- 118 • Any guidance already received from other health authorities on product development.
119
- 120 • Identification to the FDA of the regulatory status in other jurisdictions.
121

122 Extensive analytical, nonclinical, and/or clinical data are not expected to be provided based on
123 the expected stage of development of the proposed biosimilar or interchangeable biosimilar
124 product. If the requester is seeking targeted advice on the adequacy of any comparative data or
125 extensive advice for any aspect of a planned or ongoing biosimilar or interchangeable biosimilar
126 product development program, a different meeting type should be requested.
127

B. BPD Type 1 Meeting

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129
130 A BPD Type 1 meeting is a meeting that is necessary for an otherwise stalled development
131 program to proceed or a meeting to address an important safety issue. Examples of a BPD Type
132 1 meeting include the following:
133

- 134 • Meetings to discuss clinical holds in which (1) the requester seeks input on how to
135 address the hold issues; or (2) a response to hold issues has been submitted and reviewed
136 by the FDA, but the FDA and the requester agree that the development is stalled and a
137 new path forward should be discussed.
138
- 139 • Meetings that are requested after receipt of an FDA nonagreement special protocol
140 assessment letter in response to protocols submitted under the special protocol
141 assessment procedures as described in the guidance for industry *Special Protocol*
142 *Assessment* (April 2018).
143
- 144 • Meetings to discuss an important safety issue, when such an issue is identified and the
145 FDA and requester agree that the issue should be discussed.
146
- 147 • Dispute resolution meetings as described in 21 CFR 10.75 and 312.48 and in the
148 guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals*
149 *Above the Division Level* (May 2019).
150
- 151 • Post-action meetings requested after an FDA regulatory action other than an approval
152 (i.e., issuance of a complete response letter).
153
- 154 • Meetings requested within 30 days of FDA issuance of a refuse-to-file letter to discuss
155 whether the FDA should file the application.

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C. BPD Type 2a Meeting

A BPD Type 2a meeting is a meeting focused on a narrow set of issues (e.g., often one, but not more than two issues and associated questions), requiring input from no more than three disciplines or review divisions. To request a BPD Type 2a meeting, requesters must first have had a BIA or another BPD meeting type with the FDA.⁸ Examples of such discussion issues could include the following:

- Immunogenicity testing strategy following prior FDA recommendations or feedback.
- A request for feedback on an updated study design when the revisions are based on prior FDA feedback.
- Defined chemistry, manufacturing, and controls (CMC) postapproval commitments (e.g., related to analytical methods) discussing the approach in advance of conducting the study to ensure the approach is in line with the FDA’s expectations.

D. BPD Type 2b Meeting

A BPD Type 2b⁹ meeting is a meeting to discuss a specific issue (e.g., ranking of quality attributes; CMC such as control strategy; study design or endpoints; postapproval changes) or questions for which the FDA will provide targeted advice regarding an ongoing development program. This meeting type may include substantive review of summary data but does not include review of full study reports.

E. BPD Type 3 Meeting

A BPD Type 3 meeting is an in-depth data review and advice meeting regarding an ongoing development program. This meeting type includes substantive review of full study reports (e.g., detailed and robust analytical similarity data or clinical study reports), FDA advice regarding similarity between the proposed biosimilar or interchangeable biosimilar product and the reference product, and FDA advice regarding the need for additional studies, including design and analysis.

- Examples of a BPD Type 3 meeting submission include the following:
 - Comprehensive analytical similarity data sufficient for the FDA to make a preliminary evaluation of analytical similarity. The level of analytical data provided

⁸ Section I.H. of the BsUFA III goals letter.

⁹ A BPD Type 2b meeting under BsUFA III has the same scope as a BPD Type 2 meeting under BsUFA II; accordingly, FDA considers a BPD Type 2b meeting to be broader in scope than a BPD Type 2a meeting.

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195 should be similar to what the requester intends to submit in a 351(k) BLA (e.g., full
196 study reports and/or datasets that support the full study reports).

197

198 — Full study report(s) for a clinical study or studies.

199

200 • Based on the data and/or datasets and results reported in the full study reports, the FDA
201 encourages the requester to provide an update on the development plan of the proposed
202 biosimilar or interchangeable biosimilar product. Examples of topics the requester can
203 address as part of a BPD Type 3 meeting in addition to the in-depth data submitted
204 include the following:

205

206 — Proposal for any additional planned studies

207

208 — Proposal for justification of extrapolation

209

210 **F. BPD Type 4 Meeting**

211

212 A BPD Type 4 meeting is a presubmission meeting to discuss the format and content of a
213 complete original application under the Program for Enhanced Review Transparency and
214 Communication for Original 351(k) BLAs (also known as *the Program*)¹⁰ or supplement
215 submitted under 351(k) of the PHS Act for a biosimilar or interchangeable biosimilar product.
216 The purpose of this meeting is to discuss the format and content of the planned submission and
217 other items, including the following:

218

219 • Identification of those studies that the requester is relying on to support a demonstration
220 of biosimilarity or interchangeability

221

222 • Discussion of any potential review issues identified based on the information provided

223

224 • Identification of the status of pediatric assessments or investigations to adequately
225 address the Pediatric Research Equity Act

226

227 • Acquainting FDA reviewers with the general information to be submitted in the
228 marketing application (including technical information)

229

230 • Discussion of the best approach to the presentation and formatting of data in the
231 marketing application

232

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234 **IV. BsUFA FEES ASSOCIATED WITH THE BPD PROGRAM**

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236 Under the BsUFA user fee provisions of the FD&C Act, BPD fees are assessed for products in
237 the BPD program. BPD fees include the initial BPD fee, the annual BPD fee, and the
238 reactivation fee. No fee is associated with a BIA meeting. For more information about BsUFA

¹⁰ See BsUFA III goals letter.

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239 fees, including the assessment of BPD fees and the consequences for failure to pay any required
240 BPD fees, refer to the guidance for industry *Assessing User Fees Under the Biosimilar User Fee*
241 *Amendments of 2022* (July 2023).

242
243

V. MEETING FORMATS

244

245
246 There are four meeting formats: in-person, virtual (videoconference), teleconference, and WRO
247 as follows:

248

1. Face-to-Face:

249

250
251 a. **In-person:** The majority of attendees participate in person at the FDA.

252

253 b. **Virtual (videoconference):** Attendees participate from various remote locations via a
254 **video and audio connection** (e.g., with cameras on and screen sharing).

255

256 2. **Teleconference:** Attendees participate from various remote locations via an **audio only**
257 **connection** (e.g., telephone).

258

259 3. **Written response only (WRO):** WRO responses are sent to requesters in lieu of
260 meetings conducted in one of the three formats described above. Requesters may request
261 this meeting format for BIA, BPD Type 2a, and BPD Type 2b meetings.

262

263

VI. MEETING REQUESTS

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265
266 To make the most efficient use of FDA resources, before seeking a meeting, requesters should
267 consult the information publicly available from the FDA that relates to biosimilar or
268 interchangeable biosimilar product development.¹¹

269

270 To promote efficient meeting management, requesters should anticipate future needs and, to the
271 extent practical, combine related product development issues into the fewest possible meetings.

272

273 To request a meeting, submit a written request to the FDA via the respective center's document
274 room (paper submissions) or via the electronic gateway, as appropriate. Written meeting
275 requests must be made in accordance with any applicable electronic submission requirements.¹²
276 Meeting requests must be addressed to the appropriate review division or office to qualify for

¹¹ See the guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* (December 2017).

¹² See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014) and *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).

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277 meeting management performance goals,¹³ and if previously assigned, are expected to be
278 submitted to the pre-investigational new drug application (pre-IND) file or application (e.g.,
279 investigational new drug application (IND), BLA). The FDA considers meeting requests sent by
280 fax or email to be courtesy copies only and are not substitutes for formal submissions.

281
282 The requester should submit a meeting request for the development of a proposed biosimilar or
283 interchangeable biosimilar product with multiple indications that span multiple review divisions
284 to the division that has regulatory oversight of the reference product.

285
286 Requesters are not required to request meetings in sequential order (e.g., BIA, BPD Type 2a,
287 BPD Type 2b, BPD Type 3, then BPD Type 4). However, to request a Type 2a meeting,
288 requesters must first have had a BIA or another BPD meeting type with FDA.¹⁴ The meeting
289 type requested depends on the stage of the development program and/or the advice sought. The
290 FDA will grant one BIA meeting for the development program of a particular biosimilar or
291 interchangeable biosimilar product and, generally, one BPD Type 4 meeting for each application
292 or supplement, as appropriate. The FDA will, as appropriate, grant as many BPD Type 2a, BPD
293 Type 2b, and BPD Type 3 meetings as are requested and considered necessary to support the
294 development and review of a biosimilar or interchangeable biosimilar product.

295
296 The meeting request should include adequate information for the FDA to assess the potential
297 utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

298
299 The meeting request should include the following information:

- 300
- 301 1. Application number (if previously assigned).
 - 302
 - 303 2. Development-phase code name of product (if pre-licensure).
 - 304
 - 305 3. Proper name (if post-licensure).
 - 306
 - 307 4. Structure (if applicable).
 - 308
 - 309 5. Proper and proprietary names of the reference product.
 - 310
 - 311 6. Proposed indication(s) or context of product development.
 - 312
 - 313 7. Pediatric study plans (if applicable).
 - 314
 - 315 8. Human factors engineering plan (if applicable).
 - 316
 - 317 9. Combination product information (e.g., constituent parts, including details of the device
318 constituent part, intended packaging, planned human factors studies) (if applicable).
 - 319

¹³ BsUFA III goals letter.

¹⁴ BsUFA III goals letter.

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320 The meeting request must include the following information for the performance goals
321 (described in section I.H., Meeting Management Goals, of the BsUFA III goals letter) to apply:
322

- 323 1. Meeting type being requested (i.e., BIA meeting, BPD Type 1, Type 2a, Type 2b, Type 3,
324 or Type 4 meeting). The rationale for requesting the meeting type should also be
325 included.
326
- 327 2. Proposed meeting format (i.e., in-person, virtual (videoconference), teleconference, or
328 WRO).
329
- 330 3. Brief statement of the purpose of the meeting. This statement should include a brief
331 background of the issues underlying the proposed agenda. It also can include a brief
332 summary of completed or planned studies or data that the requester intends to discuss at
333 the meeting, the general nature of the critical questions to be asked, and where the
334 meeting fits in overall development plans. Although the statement should not provide the
335 details of study designs or completed studies, it should provide enough information to
336 facilitate understanding of the issues, such as a small table that summarizes major results.
337
- 338 4. List of specific objectives or outcomes the requester expects from the meeting.
339
- 340 5. Proposed agenda, including estimated times needed for discussion of each agenda item.
341
- 342 6. List of questions, grouped by FDA discipline. For each question there should be a brief
343 explanation of the context and purpose of the question.
344
- 345 7. List of planned attendees from the requester's organization, which should include their
346 names and titles. The list should also include names, titles, and affiliations of consultants
347 and interpreters (if applicable).
348
- 349 8. List of requested FDA attendees and/or discipline representative(s). Requests for
350 attendance by FDA staff who are not otherwise essential to the application's review may
351 affect the ability to hold the meeting within the specified time frame of the meeting type
352 being requested. Therefore, when attendance by nonessential FDA staff is requested, the
353 meeting request should provide a justification for such attendees and state whether a later
354 meeting date is acceptable to the requester to accommodate the inclusion of nonessential
355 FDA attendees.
356
- 357 9. Suggested dates and times (e.g., morning, afternoon) for the meeting that are within or
358 beyond the appropriate scheduling time frame of the meeting type being requested (see
359 Table 2 in section VII.B., Meeting Granted). Dates and times when the requester is not
360 available should also be included.
361

362 When submitting a meeting request, the requester should define the specific areas of input
363 needed from the FDA. A well-written meeting request that includes the above components can
364 help the FDA understand and assess the utility and timing of the meeting related to product
365 development or review. The list of planned attendees and the list of requested FDA attendees

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366 can be useful in providing or preparing for the input needed at the meeting. However, during the
367 time between the request and the meeting, the planned attendees can change. If there are
368 changes, an updated list of attendees with their titles and affiliations should be provided to the
369 appropriate FDA contact at least 1 week before the meeting.

370
371 The objectives and agenda provide overall context for the meeting topics, but it is the list of
372 questions that is most critical to understanding the kind of information or input needed by the
373 requester and to focus the discussion should the meeting be granted. Each question should be
374 precise and include a brief explanation of the context and purpose of the question. The questions
375 submitted within a single meeting request should be limited to those that can be reasonably
376 answered within the allotted meeting time, taking into consideration the complexity of the
377 questions submitted. Similar considerations regarding the complexity of questions submitted
378 within a WRO should be applied.

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VII. ASSESSING AND RESPONDING TO MEETING REQUESTS

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383 Although requesters must request a specific meeting type and format,¹⁵ the FDA assesses each
384 meeting request, including WRO requests for BIA, BPD Type 2a, and BPD Type 2b meetings,
385 and determines whether or not the request should be granted, the appropriate meeting type, and
386 the appropriate meeting format. The FDA honors requests for BPD Type 2b, BPD Type 3, and
387 BPD Type 4 meetings except in the most unusual circumstances. However, the FDA may
388 determine that a different type of meeting is more appropriate and may grant a different type of
389 meeting than is requested.¹⁶ Additionally, if the FDA determines that the WRO format is not
390 appropriate for a requested WRO meeting or that the face-to-face (i.e., in-person, virtual
391 (videoconference)) or teleconference format is not appropriate for a requested face-to-face or
392 teleconference meeting, the FDA will notify the requester that the meeting has been denied, as
393 described in section VII.A., Meeting Denied. However, if an in-person, virtual
394 (videoconference) or teleconference meeting format is requested for a BPD Type 2a meeting, but
395 the FDA determines that a written response to the questions would be the most appropriate
396 format, the FDA will notify the requester as described in section VII.B. Meeting Granted.

397

398 The meeting request must be accompanied by the meeting package for BIA, BPD Type 1, BPD
399 Type 2a, BPD Type 2b, and BPD Type 3 meetings (see section VIII.C., Meeting Package
400 Content, for additional information regarding the content of the meeting package).¹⁷ This
401 ensures that the FDA has adequate information to assess the potential utility of the meeting and
402 prepare for the meeting. If the meeting package is not submitted to the review division as
403 described above, the FDA will consider the meeting request incomplete and will generally deny
404 the meeting request.

¹⁵ BsUFA III goals letter.

¹⁶ If FDA grants a meeting of a different type than requested, this may require the payment of a biosimilar biological product development fee as described in section 744H of the FD&C Act before the meeting will be conducted. If a biosimilar biological product development fee is required under section 744H, and the sponsor does not pay the fee within the timeframe required under section 744H, the meeting will be cancelled.

¹⁷ BsUFA III goals letter.

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A. Meeting Denied

If a meeting request is denied, the FDA will notify the requester in writing according to the timelines described in Table 1. These notifications include an explanation of the reason for the denial. Denials are based on substantive reason, not merely on the absence of a minor element of the meeting request or a minor element of the meeting package. For example, the FDA may deny a meeting request because it is premature for the stage of product development, is clearly unnecessary, or is not appropriate for the format requested (e.g., WRO versus in-person/virtual (videoconference)/teleconference for BIA, BPD Type 2a, or BPD Type 2b meetings) or the meeting package does not provide an adequate basis for the meeting discussion.

The FDA may also deny requests for meetings that do not have substantive information related to the elements described in section VI., Meeting Requests. FDA will consider a subsequent request to schedule the meeting as a new request (i.e., a request that is assigned a new set of time frames described below in section VII.B., Meeting Granted).

B. Meeting Granted

If a meeting request is granted, the FDA will notify the requester in writing according to the timelines described in Table 1. For in-person, teleconference, virtual (videoconference) meetings, these notifications include the date, time, conferencing arrangements and/or location of the meeting, and expected FDA participants. For BIA, BPD Type 2a, and BPD Type 2b WRO meetings, these notifications include the date the FDA intends to send the written response (see Table 3 for FDA WRO response timelines).

For the BPD Type 2a meeting, although the requester may request an in-person, virtual (videoconference), or teleconference format, the FDA may determine that a written response to the requester’s questions would be the most appropriate means for providing feedback and advice to the requester. When it is determined that the meeting request can be appropriately addressed through a written response, the FDA will notify the requester of the meeting format change in writing and this notification will include the date the FDA intends to send the written response in the Agency’s response to the meeting request (see Table 3 for FDA WRO response timelines). If the requester believes an in-person, virtual (videoconference), or teleconference BPD Type 2a meeting is valuable and warranted, then the requester may provide rationale in a follow-up correspondence explaining why that meeting format is valuable and warranted, and the FDA will reconsider this request. If the FDA agrees to grant the in-person, virtual (videoconference), or teleconference format, the Agency will strive to schedule the meeting to occur within 60 days of FDA’s receipt of the meeting request.

For in-person, virtual (videoconference), or teleconference meeting formats, the FDA schedules the meeting on the next available date at which all expected FDA staff are available to attend. However, the meeting should be scheduled consistent with the type of meeting requested (see Table 2 for FDA meeting scheduling time frames). If the requested date for any meeting type is greater than the specified time frame, the meeting date should be within 14 calendar days of the requested date.

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451 **Table 1: FDA Meeting Request Response Timelines**

| Meeting Type | Response Time (calendar days from receipt of meeting request) |
|---------------------|--|
| BIA | 21 days |
| BPD 1 | 14 days |
| BPD 2a | 21 days |
| BPD 2b | 21 days |
| BPD 3 | 21 days |
| BPD 4 | 21 days |

452
453 **Table 2: FDA Meeting Scheduling Time Frames**

| Meeting Type | Meeting Scheduling (calendar days from receipt of meeting request) |
|---------------------|---|
| BIA | 75 days |
| BPD 1 | 30 days |
| BPD 2a | 60 days |
| BPD 2b | 90 days |
| BPD 3 | 120 days |
| BPD 4 | 60 days |

454
455 **Table 3: FDA WRO Response Timelines**

| Meeting Type | WRO Response Time (calendar days from receipt of WRO meeting request) |
|---------------------|--|
| BIA | 75 days |
| BPD 2a | 60 days |
| BPD 2b | 90 days |

456
457
458 **VIII. MEETING PACKAGE**
459

460 Premeeting preparation is critical for achieving a productive discussion or exchange of
461 information. Preparing the meeting background package should help the requester focus on
462 describing its principal areas of interest. The meeting package should provide information
463 relevant to the discussion topics and enable the FDA to prepare adequately for the meeting.
464

465 **A. Timing of Meeting Package Submission**
466

467 As discussed in section VII., Assessing and Responding to Meeting Requests, if the meeting
468 package is not submitted with the meeting request for BIA, BPD Type 1, BPD Type 2a, BPD
469 Type 2b, and BPD Type 3 meetings, the meeting request is considered incomplete and the FDA

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470 generally will deny the meeting. For BPD Type 4 meetings, the background package must be
471 received no later than 14 calendar days after the FDA’s receipt of the meeting request.¹⁸
472

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

473
474
475 Requesters must submit a meeting package to the appropriate review division or office¹⁹ and, if
476 previously assigned, is expected to be submitted to the relevant pre-IND file or application(s)
477 (e.g., IND, BLA). Meeting packages are expected to be submitted via the appropriate center’s
478 document room (paper submission) or electronic gateway, as applicable. Submissions must be
479 made in accordance with any applicable electronic submission requirements.²⁰
480

481 Occasionally, to facilitate the meeting process, CDER staff may request, in addition to the
482 electronic format, a limited number of meeting packages in paper format (desk copies). The
483 number of desk copies of a meeting package will vary based on the meeting. The CDER project
484 manager will advise on the number of desk copies needed for the meeting attendees. CBER
485 neither requests nor accepts paper copies (desk copies) of meeting packages that have been
486 submitted in electronic format.
487

C. Meeting Package Content

488
489
490 The meeting package should provide information relevant to the product, stage of development,
491 and meeting type requested (see section III., Meeting Types), in addition to any supplementary
492 information needed to develop responses to issues raised by the requester or review division.
493 The meeting package should contain sufficient details to meet the intended meeting objectives.
494 For example, inclusion of raw data in addition to the derived conclusions may be appropriate in
495 some situations. Similarly, merely describing a result as *significant* does not provide the review
496 division with enough information to give advice or identify important problems the requester
497 may have missed. FDA guidances identify and address many issues related to biosimilar or
498 interchangeable biosimilar product development, and requestors should consider these when
499 planning, developing, and providing information needed to support a meeting with the FDA.²¹ If
500 a product development plan adopts an alternative approach from that recommended in FDA
501 guidance, the alternative approach should be recognized and explained. Known or expected
502 difficult design and evidence issues should be raised for discussion (e.g., selection of study
503 populations, doses, or endpoints different from those studied for the reference product’s
504 licensure; extrapolation of data and information).
505

¹⁸ BsUFA III goals letter.

¹⁹ *Id.*

²⁰ See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014) and *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020).

²¹ See the FDA Biosimilars Industry Information and Guidance web page, available at <https://www.fda.gov/drugs/biosimilars/industry-information-and-guidance>.

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506 To facilitate FDA review, the meeting package content should be organized according to the
507 proposed agenda. The meeting package should be a sequentially paginated document with a
508 table of contents, appropriate indices, appendices, and cross references. It should be tabbed or
509 bookmarked to enhance reviewers' navigation across different sections within the package, both
510 in preparation for and during the meeting. Meeting packages generally should include the
511 following information in the order listed below:

- 512
- 513 1. Application number (if previously assigned).
- 514
- 515 2. Development-phase code name of product (if pre-licensure).
- 516
- 517 3. Proper name (if post-licensure).
- 518
- 519 4. Structure (if applicable).
- 520
- 521 5. Proper and proprietary names of the reference product.
- 522
- 523 6. Proposed indication(s) or context of product development.
- 524
- 525 7. Dosage form, route of administration, dosing regimen (frequency and duration), strength,
526 and presentation(s).
- 527
- 528 8. Pediatric study plans (if applicable).
- 529
- 530 9. Human factors engineering plan (if applicable).
- 531
- 532 10. Combination product information (e.g., constituent parts, including details of the device
533 constituent part, intended packaging, planned human factors studies) (if applicable).
- 534
- 535 11. List of planned attendees, including titles and affiliations, from the requester's
536 organization, including consultants and interpreters (if applicable).
- 537
- 538 12. Background section that includes the following:
 - 539
 - 540 a. Brief history of the development program and relevant communications with the FDA
541 before the meeting.
 - 542
 - 543 b. Substantive changes in product development plans (e.g., manufacturing changes, new
544 study population or endpoint) (when applicable).
 - 545
 - 546 c. Status of product development (e.g., CMC; nonclinical; clinical, including any
547 development outside the United States, as applicable).
 - 548
- 549 13. Brief statement summarizing the purpose of the meeting.
- 550
- 551 14. Proposed agenda, including estimated times needed for discussion of each agenda item.

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- 552
553 15. List of questions for discussion, grouped by FDA discipline and with a brief summary for
554 each question to explain the need or context for the question. Questions regarding
555 combination product issues should be grouped together.
556
557 16. Data to support discussion organized by FDA discipline and question. The level of detail
558 of the data should be appropriate to the meeting type requested and the stage of product
559 development.
560

IX. PRELIMINARY RESPONSES

561
562
563 Communications before the meeting between requesters and the FDA, including preliminary
564 responses, can serve as a foundation for discussion or as the final meeting responses.
565 Nevertheless, preliminary responses should not be construed as *final* unless there is agreement
566 between the requester and the FDA that additional discussion is not necessary for any question
567 (i.e., when the meeting is canceled because the requester is satisfied with the FDA's preliminary
568 responses), or a particular question is considered resolved, allowing time for discussion of the
569 other questions during the meeting. Preliminary responses communicated by the FDA are not
570 intended to generate the submission of new information or new questions. If a requester
571 nonetheless provides new data or a revised or new proposal, the FDA may not be able to provide
572 comments on the new information, and the requester may need to submit a new meeting request
573 for the FDA to provide feedback on the new information.
574
575

576 The FDA holds internal meetings, including meetings with relevant committees within CDER or
577 CBER, to discuss the content of meeting packages and to gain internal alignment on the
578 preliminary responses. The FDA will send the requester its preliminary responses to the
579 questions in the meeting package no later than 5 calendar days before the in-person, virtual
580 (videoconference), or teleconference meeting date for BPD Type 2b and BPD Type 3 meetings.
581 For all other meeting types, the FDA intends to send the requester its preliminary responses to
582 the questions no later than 2 calendar days before the in-person, virtual (videoconference), or
583 teleconference meeting.
584
585

X. RESCHEDULING MEETINGS

586
587 Occasionally, circumstances arise that necessitate the rescheduling of a meeting. If a meeting
588 needs to be rescheduled, it should be rescheduled as soon as possible after the original meeting
589 date. A new meeting request should not be submitted. Requesters and the FDA should take
590 reasonable steps to avoid rescheduling meetings. For example, if an attendee becomes
591 unavailable, a substitute can be identified, or comments on the topic that the attendee would have
592 addressed can be forwarded to the requester following the meeting. It is at the discretion of the
593 review division whether the meeting should be rescheduled depending on the specific
594 circumstances.
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597 The following situations are examples of when the FDA may reschedule a meeting. This list
598 includes representative examples and is not intended to be an exhaustive list.

- 599
- 600 • The review team determines that additional information is needed to address the
601 requester’s questions or other important issues, and it is possible to identify the additional
602 information needed and arrange for its timely submission.
 - 603
 - 604 • Essential attendees are no longer available for the scheduled date and time because of an
605 unexpected or unavoidable conflict or an emergency situation.
 - 606
 - 607 • Before preliminary responses to the questions are sent by the FDA, the requester sends
608 the FDA additional questions or data that are intended for discussion at the meeting and
609 require additional review time.
 - 610
 - 611 • Attendance by additional FDA personnel not originally anticipated or requested is critical
612 and their unavailability precludes holding the meeting on the original date.
 - 613
 - 614

XI. CANCELING MEETINGS

615

616 Failure to pay required BPD fees for a product within the required time frame may result in the
617 cancellation by the FDA of a scheduled BPD meeting.²² For more information on BPD fees,
618 refer to the guidance for industry *Assessing User Fees Under the Biosimilar User Fee*
619 *Amendments of 2022* (July 2023). If the requester pays the required BPD fee after the meeting
620 has been canceled because of nonpayment, the goal time frame for the FDA’s response to a
621 meeting request will be calculated from the date on which the FDA received the payment, not the
622 date on which the requester originally submitted the meeting request.²³

623

624 Occasionally, other circumstances arise that necessitate the cancellation of a meeting. If a
625 meeting is canceled for reasons other than nonpayment of a required BPD fee, the FDA
626 considers a subsequent request to schedule a meeting to be a new request and the goal time frame
627 for the FDA’s response is calculated from the date of the subsequent request. Requesters and the
628 FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no longer
629 necessary). Cancellation is at the discretion of the review division and depends on the specific
630 circumstances.

631

632

633 The following situations are examples of when a meeting may be canceled. This list includes
634 representative examples and is not intended to be an exhaustive list.

- 635
- 636 • The requester determines that preliminary responses to its questions are sufficient for its
637 needs and additional discussion is not necessary (see section IX., Preliminary Responses).
638 In this case, the requester should contact the FDA regulatory project manager to request
639 cancellation of the meeting. The FDA then considers whether it agrees that the meeting

²² See section 744H(a)(1)(E)(i) of the FD&C Act.

²³ BsUFA III goals letter.

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640 should be canceled. Some meetings can be valuable because of the discussion they
641 generate and the opportunity for the division to ask about relevant matters, even if the
642 preliminary responses to the requester’s questions seem sufficient. If the FDA agrees that
643 the meeting can be canceled, the reason for cancellation is documented and the
644 preliminary responses represent the final responses and the official record.
645

- 646 • The FDA determines that the meeting package is inadequate or, for BPD Type 4
647 meetings, the meeting package is not received by the FDA within 14 calendar days of the
648 meeting request. Meetings are scheduled on the condition that the requester has
649 submitted appropriate information to support the discussion. Adequate planning by the
650 requester should avoid this problem.

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XII. MEETING CONDUCT

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Meetings will be chaired by an FDA staff member and begin with introductions and an overview of the agenda. Attendees should not make audio or visual recordings of discussions at meetings described in this guidance.

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In general, presentations by requesters are not needed because the information necessary for review and discussion should be part of the meeting package. If a requester plans to make a presentation, the presentation should be discussed ahead of time with the FDA project manager to determine if a presentation is warranted and to ensure that the FDA has the presentation materials ahead of the meeting, if possible. All presentations should be kept brief to maximize the time available for discussion. The FDA will not extend the length of a meeting to accommodate a presentation. If a presentation contains more than a small amount of content, distinct from clarifications or explanations of previous data, that was not included in the original meeting package submitted for review, FDA staff may not be able to provide commentary.

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Either a representative of the FDA or the requester should summarize the important discussion points, agreements, clarifications, and action items. Summation can be done at the end of the meeting or after the discussion of each question. Generally, the requester is asked to present the summary to ensure that there is mutual understanding of meeting outcomes and action items. FDA staff can add or further clarify any important points not covered in the summary and these items can be added to the meeting minutes.

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At BPD Type 4 meetings for original applications reviewed under the Program, the requester and the FDA should also summarize agreements regarding the content of a complete application and any agreements reached on delayed submission of certain minor application components.

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XIII. MEETING MINUTES

Because the FDA’s minutes are the official records of meetings, the FDA’s documentation of meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this

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685 information is preserved for meeting attendees and future reference. The FDA will issue the
686 official, finalized minutes to the requester within 30 calendar days after the meeting.

687

688 The following are general considerations regarding meeting minutes:

689

690 • FDA minutes will outline the important agreements, disagreements, issues for further
691 discussion, and action items from the meeting in bulleted format. This information does
692 not need to be in great detail. The minutes are not intended to represent a transcript of
693 the meeting.

694

695 • FDA project managers will use established templates to ensure that all important meeting
696 information is captured.

697

698 • The FDA may communicate additional information in the final minutes that was not
699 explicitly communicated during the meeting (e.g., pediatric requirements, data standards)
700 or that provides further explanation of discussion topics. The FDA's final minutes will
701 distinguish this additional information from the discussion that occurred during the
702 meeting.

703

704 • In cases of a WRO, the WRO will serve as the meeting minutes.

705

706 The following steps should be taken when a requester disagrees that the minutes are an accurate
707 account of the meeting:

708

709 1. The requester should contact the FDA project manager and describe the concern. If, after
710 contacting the FDA project manager, the requester still disagrees with the content of the
711 minutes, the requester should submit a description of the specific disagreements to the
712 application.

713

714 2. The review division and the meeting chair will take the concerns under consideration, and
715 the FDA will act in one of two ways:

716

717 • If the minutes are deemed to accurately and sufficiently reflect the meeting
718 discussion, the FDA project manager will convey this decision to the requester and
719 the minutes will stand as the official documentation of the meeting.

720

721 • If the FDA deems it necessary, the FDA will document changes in an addendum to
722 the official minutes. The addendum will also document any remaining requester
723 objections.

724

725 For all meeting types, to ensure the sponsor's understanding of FDA feedback from meeting
726 discussions or a WRO, sponsors may submit clarifying questions to the Agency. Only questions
727 of a clarifying nature will be permitted (i.e., to confirm something in minutes or a WRO issued
728 by FDA) rather than raising new issues or new proposals. The FDA will develop criteria and
729 parameters for permissible requests, and the FDA may exercise discretion about whether
730 requests are in scope. The clarifying questions should be sent in writing as a "Request for

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731 Clarification” to the FDA within 20 calendar days following receipt of meeting minutes or a
732 WRO. For questions that meet the criteria, the FDA will issue a response in writing within 20
733 calendar days of receipt of the clarifying questions. The FDA’s response will reference the
734 original meeting minutes or WRO.

735
736 To request information on additional issues that were not addressed at the meeting, the requester
737 should submit a new meeting request or a submission containing specific questions for FDA
738 feedback.

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REFERENCES

Related guidances¹

Draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* (December 2017)²

Draft guidance for review staff and industry *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* (September 2018)³

Guidance for industry and review staff *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* (December 2017)

Guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the Division Level* (May 2019)

Guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2022* (July 2023)

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020)

Guidance for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* (December 2014)

Guidance for industry *Special Protocol Assessment* (April 2018)

Related Center for Biologics Evaluation and Research Standard Operating Policies and Procedures (SOPPs)⁴

SOPP 8101.1 *Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products* (March 2023)

¹ Guidances are updated periodically. To make sure you have the most recent version of a guidance, check the FDA’s guidance web pages at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

² When final, this guidance will represent the FDA’s current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

³ When final, this guidance will represent the FDA’s current thinking on this topic.

⁴ SOPPs can be found on the Biologics Procedures (SOPPs) web page at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-procedures-sopps>.