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# **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## ***DRAFT GUIDANCE***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) Neel Patel at 301-796-0970 or (CBER) the 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)**

**June 2018  
Procedural**

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

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## **Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products Guidance for Industry<sup>1</sup>**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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**

19 This guidance provides recommendations to industry on formal meetings between the Food and  
20 Drug Administration (FDA) and sponsors or applicants relating to the development and review  
21 of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation  
22 and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This  
23 guidance does not apply to meetings associated with the development of products intended for  
24 submission in, or with the review of, new drug applications or abbreviated new drug applications  
25 under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act), biologics license  
26 applications (BLAs) under section 351(a) of the Public Health Service Act (PHS Act), or  
27 submissions for devices under the FD&C Act.<sup>2</sup> For the purposes of this guidance, *formal*  
28 *meeting* includes any meeting that is requested by a sponsor or applicant (hereafter referred to as  
29 *requester(s)*) following the procedures provided in this guidance and includes meetings  
30 conducted in any format (i.e., face to face, teleconference/videoconference, or written response  
31 only (WRO)).  
32

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<sup>1</sup> This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

<sup>2</sup> 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*. 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 Drugs or Biologics guidance web pages at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> and <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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33 This guidance discusses the principles of good meeting management practices (GMMPs) and  
34 describes standardized procedures for requesting, preparing, scheduling, conducting, and  
35 documenting such formal meetings.<sup>3</sup>

36  
37 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.  
38 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only  
39 as recommendations, unless specific regulatory or statutory requirements are cited. The use of  
40 the word *should* in Agency guidances means that something is suggested or recommended, but  
41 not required.

42

43

### **II. BACKGROUND**

44

45  
46 Each year, FDA review staff participate in many meetings with requesters who seek advice  
47 relating to the development and review of a biosimilar or interchangeable product. Because  
48 these meetings often represent critical points in the regulatory and development process, it is  
49 important that there are efficient, consistent procedures for the timely and effective conduct of  
50 such meetings. The GMMPs in this guidance are intended to provide consistent procedures that  
51 will promote well-managed meetings and to ensure that such meetings are scheduled within a  
52 reasonable time, conducted efficiently, and documented appropriately.

53

54 As part of the reauthorization of the Biosimilar User Fee Act (BsUFA),<sup>4</sup> the FDA has committed  
55 to specific performance goals that include meeting management goals for formal meetings that  
56 occur between the FDA and requesters.<sup>5</sup>

57

58

### **III. MEETING TYPES<sup>6</sup>**

59

60  
61 There are five types of formal meetings that occur between requesters and FDA staff to discuss  
62 development and review of a biosimilar or interchangeable product: Biosimilar Initial Advisory  
63 (BIA), Biosimilar Biological Product Development (BPD) Type 1, BPD Type 2, BPD Type 3,  
64 and BPD Type 4.

65

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<sup>3</sup> The previous guidance for industry *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants* published November 18, 2015, has been withdrawn.

<sup>4</sup> The Biosimilar User Fee Act of 2012 (BsUFA I) added sections 744G and 744H to the FD&C Act, authorizing FDA to collect user fees for a 5-year period from persons that develop biosimilar biological products. BsUFA was reauthorized for a 5-year period in 2017 under Title IV of the FDA Reauthorization Act of 2017 (BsUFA II), enacted on August 18, 2017.

<sup>5</sup> See the BsUFA II goals letter titled “BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022” available on the FDA website at <https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf>.

<sup>6</sup> The meeting types and goal dates are described in the BsUFA II 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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66 Requesters are not required to request meetings in sequential order (i.e., BIA, BPD Type 2, BPD  
67 Type 3, then BPD Type 4). The meeting type requested depends on the stage of the development  
68 program and/or the advice being sought. Although the FDA would, in general, grant one BIA  
69 meeting and one BPD Type 4 meeting for a particular biosimilar or interchangeable product,  
70 requesters can request, as appropriate, as many BPD Type 2 and Type 3 meetings as needed to  
71 support the development and review of a biosimilar or interchangeable product.

72

### **A. BIA Meeting**

73

74  
75 A BIA meeting is an initial assessment limited to a general discussion regarding whether  
76 licensure under section 351(k) of the PHS Act may be feasible for a particular product, and if so,  
77 general advice on the expected content of the development program. This meeting type does not  
78 include any meeting that involves substantive review of summary data or full study reports.  
79 However, preliminary comparative analytical similarity data from at least one lot of the proposed  
80 biosimilar or interchangeable product compared to the U.S.-licensed reference product should be  
81 provided in the meeting package. The analytical similarity data should be sufficient to enable the  
82 FDA to make a preliminary determination as to whether licensure under section 351(k) of the  
83 PHS Act may be feasible for a particular product and to provide meaningful advice. A general  
84 overview of the development program, including synopses of results and findings from all  
85 completed studies and information about planned studies, also should be provided.

86

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

92

### **B. BPD Type 1 Meeting**

93

94  
95 A BPD Type 1 meeting is a meeting that is necessary for an otherwise stalled development  
96 program to proceed or a meeting to address an important safety issue. Examples of a BPD Type  
97 1 meeting include the following:

98

- 99 • Meetings to discuss clinical holds: (1) in which the requester seeks input on how to  
100 address the hold issues; or (2) in which a response to hold issues has been submitted, and  
101 reviewed by the FDA, but the FDA and the requester agree that the development is  
102 stalled and a new path forward should be discussed.
- 103 • Meetings that are requested after receipt of an FDA nonagreement Special Protocol  
104 Assessment letter in response to protocols submitted under the special protocol  
105 assessment procedures as described in the guidance for industry *Special Protocol*  
106 *Assessment*.<sup>7</sup>

107

108

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<sup>7</sup> We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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- 109 • Meetings to discuss an important safety issue, when such an issue is identified and the  
110 FDA and requester agree that the issue should be discussed.  
111
- 112 • Dispute resolution meetings as described in 21 CFR 10.75 and 312.48 and in the  
113 guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals*  
114 *Above the Division Level*.  
115
- 116 • Post-action meetings requested after an FDA regulatory action other than an approval  
117 (i.e., issuance of a complete response letter).  
118
- 119 • Meetings requested within 30 days of FDA issuance of a refuse-to-file letter to discuss  
120 whether the FDA should file the application.  
121

### **C. BPD Type 2 Meeting**

122  
123  
124 A BPD Type 2 meeting is a meeting to discuss a specific issue (e.g., ranking of quality attributes;  
125 chemistry, manufacturing, and controls such as control strategy; study design or endpoints; post-  
126 approval changes) or questions for which the FDA will provide targeted advice regarding an  
127 ongoing development program. This meeting type may include substantive review of summary  
128 data but does not include review of full study reports.  
129

### **D. BPD Type 3 Meeting**

130  
131  
132 A BPD Type 3 meeting is an in-depth data review and advice meeting regarding an ongoing  
133 development program. This meeting type includes substantive review of full study reports or an  
134 extensive data package (e.g., detailed and robust analytical similarity data), FDA advice  
135 regarding the similarity between the proposed biosimilar or interchangeable product and the  
136 reference product based on a comprehensive data package, and FDA advice regarding the need  
137 for additional studies, including design and analysis, based on a comprehensive data package.  
138

- 139 • Examples of a BPD Type 3 meeting submission include the following:  
140
  - 141 – Comprehensive analytical similarity data that permit the FDA to make a preliminary  
142 evaluation of analytical similarity during development. The level of analytical data  
143 provided should be similar to what the requester intends to submit in a 351(k) BLA  
144 (e.g., full study reports and/or datasets that support the full study reports).  
145
  - 146 – Full study report(s) for a clinical study or clinical studies.  
147
- 148 • Based on the data and/or datasets and results reported in the full study reports, the FDA  
149 encourages the requester to provide an update on the development plan of the proposed  
150 biosimilar or interchangeable product. Examples of topics the requester can address as  
151 part of a BPD Type 3 meeting in addition to the in-depth data submitted include the  
152 following:  
153
  - 154 – Proposal for any planned additional studies

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197

– Proposal for extrapolation

### **E. BPD Type 4 Meeting**

A BPD Type 4 meeting is a presubmission meeting to discuss the format and content of a complete application for an original biosimilar or interchangeable product application or supplement submitted under 351(k) of the PHS Act. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including the following:

- Identification of those studies that the sponsor is relying on to support a demonstration of biosimilarity or interchangeability
- Discussion of any potential review issues identified based on the information provided
- Identification of the status of ongoing or needed studies to adequately address the Pediatric Research Equity Act
- Acquainting FDA reviewers with the general information to be submitted in the marketing application (including technical information)
- Discussion of the best approach to the presentation and formatting of data in the marketing application

### **IV. BSUFA FEES ASSOCIATED WITH THE BPD PROGRAM**

Under the BsUFA user fee provisions of the FD&C Act, BPD fees are assessed for products in the BPD program. BPD fees include the initial BPD fee, the annual BPD fee, and the reactivation fee. No fee is associated with a BIA meeting. For more information about BsUFA fees, including the assessment of BPD fees and the consequences for failure to pay any required BPD fees, refer to the draft guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2017*.<sup>8</sup>

### **V. MEETING FORMATS**

There are three formats for formal meetings: face to face, teleconference/videoconference, and WRO as follows:

1. **Face to face** — Traditional face-to-face meetings are those in which the majority of attendees participate in person at the FDA.

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<sup>8</sup> When finalized, this guidance will represent the FDA’s current thinking on this topic.



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- 198 2. **Teleconference/Videoconference** — Teleconferences/videoconferences are meetings in  
199 which the attendees participate from various remote locations via an audio (e.g.,  
200 telephone) and/or video connection.  
201
- 202 3. **Written response only (WRO)** — WRO responses are sent to requesters in lieu of  
203 meetings conducted in one of the other two formats described above. Requesters may  
204 request this meeting format for BIA and BPD Type 2 meetings.  
205

### **VI. MEETING REQUESTS**

207  
208  
209 To make the most efficient use of FDA resources, before seeking a meeting, requesters should  
210 consult the information publicly available from the FDA that relates to biosimilar or  
211 interchangeable product development.<sup>9</sup>  
212

213 To promote efficient meeting management, requesters should try to anticipate future needs and,  
214 to the extent practical, combine related product development issues into the fewest possible  
215 meetings.  
216

217 To request a meeting, submit a written request to the FDA via the respective center's document  
218 room (paper submissions) or via the electronic gateway, as appropriate. Written meeting  
219 requests must be made in accordance with any applicable electronic submission requirements.<sup>10</sup>  
220 Requests should be addressed to the appropriate review division or office and, if previously  
221 assigned, submitted to the pre-investigational new drug application (pre-IND) file or application  
222 (e.g., investigational new drug application (IND), BLA). Meeting requests sent by fax or email  
223 are considered courtesy copies only and are not a substitute for a formal submission.  
224

225 A meeting request for the development of a proposed biosimilar or interchangeable product with  
226 multiple indications that span multiple review divisions should be submitted to the division that  
227 has regulatory oversight of the reference product.  
228

229 The meeting request should include adequate information for the FDA to assess the potential  
230 utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.  
231

232 The meeting request should include the following information:  
233

- 234 1. The application number (if previously assigned).  
235  
236 2. The development-phase code name of product (if pre-licensure).  
237

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<sup>9</sup> See the guidance for industry *Best Practices for Communication Between IND Sponsors and FDA During Drug Development*.

<sup>10</sup> See the guidances for industry *Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.

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- 238 3. The proper name (if post-licensure).  
239  
240 4. The structure (if applicable).  
241  
242 5. The reference product proper and proprietary names.  
243  
244 6. The proposed indication(s) or context of product development.  
245  
246 7. Pediatric study plans, if applicable.  
247  
248 8. Human factors engineering plan, if applicable.  
249  
250 9. Combination product information (e.g., constituent parts, including details of the device  
251 constituent part, intended packaging, planned human factors studies), if applicable.  
252

253 The meeting request must include the following information for the performance goals described  
254 in section I.I., Meeting Management Goals, of the commitment letter to apply:<sup>11</sup>  
255

- 256 1. The meeting type being requested (i.e., BIA meeting, BPD Type 1, 2, 3, or 4 meeting).  
257 The rationale for requesting the meeting type should also be included.  
258  
259 2. The proposed format of the meeting (i.e., face to face, teleconference/videoconference or  
260 WRO).  
261  
262 3. A brief statement of the purpose of the meeting. This statement should include a brief  
263 background of the issues underlying the agenda. It also can include a brief summary of  
264 completed or planned studies or data that the requester intends to discuss at the meeting,  
265 the general nature of the critical questions to be asked, and where the meeting fits in  
266 overall development plans. Although the statement should not provide the details of  
267 study designs or completed studies, it should provide enough information to facilitate  
268 understanding of the issues, such as a small table that summarizes major results.  
269  
270 4. A list of the specific objectives or outcomes the requester expects from the meeting.  
271  
272 5. A proposed agenda, including estimated times needed for discussion of each agenda item.  
273  
274 6. A list of questions, grouped by FDA discipline. For each question there should be a brief  
275 explanation of the context and purpose of the question.  
276  
277 7. A list of planned attendees from the requester's organization, which should include their  
278 names and titles. The list should also include the names, titles, and affiliations of  
279 consultants and interpreters, if applicable.  
280  
281 8. A list of requested FDA attendees and/or discipline representative(s). Note that requests  
282 for attendance by FDA staff who are not otherwise essential to the application's review

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<sup>11</sup> See BsUFA II goals letter.

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283 may affect the ability to hold the meeting within the specified time frame of the meeting  
284 type being requested. Therefore, when attendance by nonessential FDA staff is  
285 requested, the meeting request should provide a justification for such attendees and state  
286 whether or not a later meeting date is acceptable to the requester to accommodate the  
287 nonessential FDA attendees.  
288

289 9. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or  
290 beyond the appropriate scheduling time frame of the meeting type being requested (see  
291 Table 2 in section VII.B., Meeting Granted). Dates and times when the requester is not  
292 available should also be included.  
293

294 When submitting a meeting request, the requester should define the specific areas of input  
295 needed from the FDA. A well-written meeting request that includes the above components can  
296 help the FDA understand and assess the utility and timing of the meeting related to product  
297 development or review. The list of requester attendees and the list of requested FDA attendees  
298 can be useful in providing or preparing for the input needed at the meeting. However, during the  
299 time between the request and the meeting, the planned attendees can change. If there are  
300 changes, an updated list of attendees with their titles and affiliations should be provided to the  
301 appropriate FDA contact at least 1 week before the meeting.  
302

303 The objectives and agenda provide overall context for the meeting topics, but it is the list of  
304 questions that is most critical to understanding the kind of information or input needed by the  
305 requester and to focus the discussion should the meeting be granted. Each question should be  
306 precise and include a brief explanation of the context and purpose of the question. The questions  
307 submitted within a single meeting request should be limited to those that can be reasonably  
308 answered within the allotted meeting time, taking into consideration the complexity of the  
309 questions submitted. Similar considerations regarding the complexity of questions submitted  
310 within a WRO should be applied.  
311

312

## **VII. ASSESSING AND RESPONDING TO MEETING REQUESTS**

314

315 Although requesters should request a specific meeting type and format, the FDA assesses each  
316 meeting request, including WRO requests for BIA and BPD Type 2 meetings, and determines  
317 whether or not the request should be granted, the appropriate meeting type, and the appropriate  
318 meeting format. Requests for BPD Type 2, 3, and 4 meetings will be honored except in the most  
319 unusual circumstances. However, if the FDA determines that WRO format is not appropriate for  
320 a requested WRO meeting or that in-person format (i.e., face to face or  
321 teleconference/videoconference) is not appropriate for a requested in-person meeting, we will  
322 notify the requester that the meeting has been denied, as described in section VII.A., Meeting  
323 Denied.  
324

325

326 The meeting request should be accompanied by the meeting package (see section VIII.C.,  
327 Meeting Package Content, for additional information regarding the content of the meeting  
328 package). This ensures that the FDA has adequate information to assess the potential utility of  
the meeting and prepare for the meeting. If the meeting package is not submitted to the review

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329 division with the meeting request, the FDA will consider the meeting request incomplete and  
330 generally will deny the meeting request.

331

### **A. Meeting Denied**

333

334 If a meeting request is denied, the FDA will notify the requester in writing according to the  
335 timelines described in Table 1. The notification will include an explanation of the reason for the  
336 denial. Denials will be based on a substantive reason, not merely on the absence of a minor  
337 element of the meeting request or a minor element of the meeting package. For example, a  
338 meeting request can be denied because it is premature for the stage of product development, is  
339 clearly unnecessary, or is not appropriate for the format requested (e.g., face to  
340 face/videoconference/teleconference versus WRO) or the meeting package does not provide an  
341 adequate basis for the meeting discussion.

342

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

347

### **B. Meeting Granted**

348

349  
350 If a meeting request is granted, the FDA will notify the requester in writing according to the  
351 timelines described in Table 1. For face-to-face and teleconference/videoconference meetings,  
352 the notification will include the date, time, conferencing arrangements and/or location of the  
353 meeting, and expected FDA participants. For BIA and BPD Type 2 WRO meetings, the  
354 notification will include the date the FDA intends to send the written response (see Table 3 for  
355 FDA WRO response timelines).

356

357 For face-to-face and teleconference/videoconference meetings, the FDA will schedule the  
358 meeting on the next available date at which all expected FDA staff are available to attend;  
359 however, the meeting should be scheduled consistent with the type of meeting requested (see  
360 Table 2 for FDA meeting scheduling time frames). If the requested date for any meeting type is  
361 greater than the specified time frame, the meeting date should be within 14 calendar days of the  
362 requested date.

363

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

<b>Meeting Type</b>	<b>Response Time (calendar days from receipt of meeting request and meeting package)</b>
BIA	21 days
BPD 1	14 days
BPD 2	21 days
BPD 3	21 days
BPD 4	21 days

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367 **Table 2: FDA Meeting Scheduling Time Frames**

<b>Meeting Type</b>	<b>Meeting Scheduling (calendar days from receipt of meeting request and meeting package)</b>
BIA	75 days
BPD 1	30 days
BPD 2	90 days
BPD 3	120 days
BPD 4	60 days

368

369

370 **Table 3: FDA WRO Response Timelines**

<b>Meeting Type</b>	<b>WRO Response Time (calendar days from receipt of WRO meeting request and meeting package)</b>
BIA	75 days
BPD 2	90 days

371

372

373 **VIII. MEETING PACKAGE**

374

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

379

380 **A. Timing of Meeting Package Submission**

381

382 As discussed in section VII., Assessing and Responding to Meeting Requests, if the meeting  
383 package is not submitted with the meeting request for each meeting type, the meeting request  
384 will be considered incomplete and the FDA generally will deny the meeting.

385

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

387

388 Requesters should submit an archival meeting package to the appropriate review division or  
389 office or, if previously assigned, to the relevant pre-IND file or application(s) (e.g., IND, BLA)  
390 via the appropriate center’s document room (paper submission) or via the electronic gateway, as  
391 applicable. Submissions must be made in accordance with any applicable electronic submission  
392 requirements.<sup>12</sup>

393

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

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394 To facilitate the meeting process, CDER strongly suggests that copies of meeting packages  
395 provided in electronic format also be provided in paper (desk copies). The number of desk  
396 copies of a meeting package will vary based on the meeting. The CDER project manager will  
397 advise on the number of desk copies needed for the meeting attendees. CDER neither requests  
398 nor accepts paper copies (desk copies) of meeting packages that have been submitted in  
399 electronic format.

400

### **C. Meeting Package Content**

401

402  
403 The meeting package should provide information relevant to the product, stage of development,  
404 and meeting type requested (see section III., Meeting Types), in addition to any supplementary  
405 information needed to develop responses to issues raised by the requester or review division.  
406 The meeting package should contain sufficient detail to meet the intended meeting objectives.  
407 For example, inclusion of raw data in addition to the derived conclusions may be appropriate in  
408 some situations. Similarly, merely describing a result as *significant* does not provide the review  
409 division with enough information to give good advice or identify important problems the  
410 requester may have missed. FDA guidances identify and address many issues related to  
411 biosimilar or interchangeable product development and should be considered when planning,  
412 developing, and providing information needed to support a meeting with the FDA.<sup>13</sup> If a product  
413 development plan deviates from current guidances, or from current practices, the deviation  
414 should be recognized and explained. Known or expected difficult design and evidence issues  
415 should be raised for discussion (e.g., selection of study populations, doses, or endpoints different  
416 from those studied for the reference product's licensure; extrapolation of indications).

417

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

424

- 425 1. The application number (if previously assigned).
- 426
- 427 2. The development-phase code name of product (if pre-licensure).
- 428
- 429 3. The proper name (if post-licensure).
- 430
- 431 4. The structure (if applicable).
- 432
- 433 5. The reference product proprietary and proper names.
- 434
- 435 6. The proposed indication(s) or context of product development.
- 436

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<sup>13</sup> See the FDA Biosimilars guidance web page, available at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm>.

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- 437 7. The dosage form, route of administration, dosing regimen (frequency and duration), and  
438 presentation(s).  
439
- 440 8. Pediatric study plans, if applicable.  
441
- 442 9. Human factors engineering plan, if applicable.  
443
- 444 10. Combination product information (e.g., constituent parts, including details of the device  
445 constituent part, intended packaging, planned human factors studies), if applicable.  
446
- 447 11. A list of all individuals, with their titles and affiliations, who will attend the requested  
448 meeting from the requester's organization, including consultants and interpreters, if  
449 applicable.  
450
- 451 12. A background section that includes the following:  
452
- 453 a. A brief history of the development program and relevant communications with the  
454 FDA before the meeting  
455
  - 456 b. Substantive changes in product development plans (e.g., manufacturing changes, new  
457 study population or endpoint), when applicable  
458
  - 459 c. The current status of product development (e.g., chemistry, manufacturing, and  
460 controls; nonclinical; and clinical, including any development outside the United  
461 States, as applicable)  
462
- 463 13. A brief statement summarizing the purpose of the meeting.  
464
- 465 14. A proposed agenda, including estimated times needed for discussion of each agenda item.  
466
- 467 15. A list of questions for discussion grouped by FDA discipline and with a brief summary  
468 for each question to explain the need or context for the question. Questions regarding  
469 combination product issues should be grouped together.  
470
- 471 16. Data to support discussion organized by FDA discipline and question. The level of detail  
472 of the data should be appropriate to the meeting type requested and the stage of product  
473 development.  
474  
475

### **IX. PRELIMINARY RESPONSES**

476  
477  
478 Communications before the meeting between requesters and the FDA, including preliminary  
479 responses, can serve as a foundation for discussion or as the final meeting responses.  
480 Nevertheless, preliminary responses should not be construed as *final* unless there is agreement  
481 between the requester and the FDA that additional discussion is not necessary for any question  
482 (i.e., when the meeting is canceled because the requester is satisfied with the FDA's preliminary

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483 responses), or a particular question is considered resolved allowing time for discussion of the  
484 other questions during the meeting. Preliminary responses communicated by the FDA are not  
485 intended to generate the submission of new information or new questions. If a requester  
486 nonetheless provides new data or a revised or new proposal, the FDA may not be able to provide  
487 comments on the new information, and the requester may need to submit a new meeting request  
488 for the FDA to provide feedback on the new information.

489  
490 The FDA holds internal meetings, including meetings with the CDER or CBER Biosimilar  
491 Review Committee, to discuss the content of meeting packages and to gain internal alignment on  
492 the preliminary responses. The FDA will send the requester its preliminary responses to the  
493 questions in the meeting package no later than 5 calendar days before the face-to-face,  
494 videoconference, or teleconference meeting date for BPD Type 2 and BPD Type 3 meetings.  
495 For all other meeting types, the FDA intends to send the requester its preliminary responses no  
496 later than 2 calendar days before the face-to-face, videoconference, or teleconference meeting.

497  
498

### **X. RESCHEDULING MEETINGS**

500

501 Occasionally, circumstances arise that necessitate the rescheduling of a meeting. If a meeting  
502 needs to be rescheduled, it should be rescheduled as soon as possible after the original date. A  
503 new meeting request should not be submitted. Requesters and the FDA should take reasonable  
504 steps to avoid rescheduling meetings. For example, if an attendee becomes unavailable, a  
505 substitute can be identified, or comments on the topic that the attendee would have addressed can  
506 be forwarded to the requester following the meeting. It will be at the discretion of the review  
507 division whether the meeting should be rescheduled depending on the specific circumstances.

508

509 The following situations are examples of when a meeting may be rescheduled by FDA. This list  
510 includes representative examples and is not intended to be an exhaustive list.

511

512 • The review team determines that additional information is needed to address the  
513 requester's questions or other important issues, and it is possible to identify the additional  
514 information needed and arrange for its timely submission.

515

516 • Essential attendees are no longer available for the scheduled date and time because of an  
517 unexpected or unavoidable conflict or an emergency situation.

518

519 • Before preliminary responses are sent by the FDA, the requester sends the FDA  
520 additional questions or data that are intended for discussion at the meeting and require  
521 additional review time.

522

523 • It is determined that attendance by additional FDA personnel not originally anticipated or  
524 requested is critical and their unavailability precludes holding the meeting on the original  
525 date.

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### **XI. CANCELING MEETINGS**

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529  
530 Failure to pay required BPD fees for a product, within the required time frame, may result in the  
531 cancellation by FDA of a previously scheduled BPD meeting.<sup>14</sup> For more information on BPD  
532 fees, refer to the draft guidance for industry *Assessing User Fees Under the Biosimilar User Fee*  
533 *Amendments of 2017*.<sup>15</sup> If the requester pays the required BPD fee after the meeting has been  
534 canceled because of nonpayment, the goal time frame for FDA's response to a meeting request  
535 will be calculated from the date on which FDA received the payment, not the date on which the  
536 sponsor originally submitted the meeting request.<sup>16</sup>

537  
538 Occasionally, other circumstances arise that necessitate the cancellation of a meeting. If a  
539 meeting is canceled for reasons other than nonpayment of a required BPD fee, the FDA will  
540 consider a subsequent request to schedule a meeting to be a new request and the goal time frame  
541 for FDA's response will be calculated from the date of the subsequent request. Requesters and  
542 the FDA should take reasonable steps to avoid canceling meetings (unless the meeting is no  
543 longer necessary). Cancellation will be at the discretion of the review division and will depend  
544 on the specific circumstances.

545  
546 The following situations are examples of when a meeting may be canceled. This list includes  
547 representative examples and is not intended to be an exhaustive list.

- 548  
549
- 550 • The requester determines that preliminary responses to its questions are sufficient for its  
551 needs and additional discussion is not necessary (see section IX., Preliminary Responses).  
552 In this case, the requester should contact the FDA regulatory project manager to request  
553 cancellation of the meeting. The FDA will consider whether it agrees that the meeting  
554 should be canceled. Some meetings can be valuable because of the discussion they  
555 generate and the opportunity for the division to ask about relevant matters, even if the  
556 preliminary responses seem sufficient to answer the requester's questions. If the FDA  
557 agrees that the meeting can be canceled, the reason for cancellation will be documented  
558 and the preliminary responses will represent the final responses and the official record.
  - 559 • The FDA determines that the meeting package is inadequate. Meetings are scheduled on  
560 the condition that the requester has submitted appropriate information to support the  
561 discussion. Adequate planning by the requester should avoid this problem.
- 562  
563

### **XII. MEETING CONDUCT**

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

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<sup>14</sup> See section 744H(a)(1)(E)(i) of the FD&C Act.

<sup>15</sup> When finalized, this guidance will represent the FDA's current thinking on this topic.

<sup>16</sup> See BsUFA II goals letter.

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569  
570 Presentations by requesters generally are not needed because the information necessary for  
571 review and discussion should be part of the meeting package. If a requester plans to make a  
572 presentation, the presentation should be discussed ahead of time with the FDA project manager  
573 to determine if a presentation is warranted and to ensure that the FDA has the presentation  
574 materials ahead of the meeting, if possible. All presentations should be kept brief to maximize  
575 the time available for discussion. The length of the meeting will not be increased to  
576 accommodate a presentation. If a presentation contains more than a small amount of content,  
577 distinct from clarifications or explanations of previous data, that was not included in the original  
578 meeting package submitted for review, FDA staff may not be able to provide commentary.

579  
580 Either a representative of the FDA or the requester should summarize the important discussion  
581 points, agreements, clarifications, and action items. Summation can be done at the end of the  
582 meeting or after the discussion of each question. Generally, the requester will be asked to  
583 present the summary to ensure that there is mutual understanding of meeting outcomes and  
584 action items. FDA staff can add or further clarify any important points not covered in the  
585 summary and these items can be added to the meeting minutes.

586  
587 At BPD Type 4 meetings for original applications reviewed under the BsUFA Program for  
588 Enhanced Review Transparency and Communication for Original 351(k) BLAs (also known as  
589 *the Program*),<sup>17</sup> the requester and the FDA should also summarize agreements regarding the  
590 content of a complete application and any agreements reached on delayed submission of certain  
591 minor application components.

### **XIII. MEETING MINUTES**

592  
593  
594  
595  
596 Because the FDA's minutes are the official records of meetings, the FDA's documentation of  
597 meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this  
598 information is preserved for meeting attendees and future reference. The FDA will issue the  
599 official, finalized minutes to the requester within 30 calendar days after the meeting.

600  
601 The following are general considerations regarding meeting minutes:

- 602
- 603 • FDA minutes will outline the important agreements, disagreements, issues for further  
604 discussion, and action items from the meeting in bulleted format. This information does  
605 not need to be in great detail. The minutes are not intended to represent a transcript of  
606 the meeting.
  - 607
  - 608 • FDA project managers will use established templates to ensure that all important meeting  
609 information is captured.
  - 610
  - 611 • The FDA may communicate additional information in the final minutes that was not  
612 explicitly communicated during the meeting (e.g., pediatric requirements, data standards)

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<sup>17</sup> See BsUFA II goals letter.

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613 or that provides further explanation of discussion topics. The FDA's final minutes will  
614 distinguish this additional information from the discussion that occurred during the  
615 meeting.

616

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

619

- 620 • The requester should contact the FDA project manager and describe the concern
- 621
- 622 • If, after contacting the FDA project manager, the requester still disagrees with the content  
623 of the minutes, the requester should submit a description of the specific disagreements  
624 either:
  - 625
  - 626 – To the application; or
  - 627
  - 628 – If there is no application, in a letter to the division director, with a copy to the FDA  
629 project manager
  - 630
  - 631 • The review division and the office director, if the office director was present at the  
632 meeting, will take the concerns under consideration
  - 633
  - 634 – If the minutes are deemed to accurately and sufficiently reflect the meeting  
635 discussion, the FDA project manager will convey this decision to the requester and  
636 the minutes will stand as the official documentation of the meeting.
  - 637
  - 638 – If the FDA deems it necessary, changes will be documented in an addendum to the  
639 official minutes. The addendum will also document any remaining requester  
640 objections.

641

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

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**REFERENCES**

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**Related guidances<sup>1</sup>**

Draft guidance for industry *Assessing User Fees Under the Biosimilar User Fee Amendments of 2017*<sup>2</sup>

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

Guidance for review staff and industry *Good Review Management Principles and Practices for PDUFA Products*

**Related CBER SOPPs<sup>3</sup>**

SOPP 8101.1: *Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products*

SOPP 8404.1: *Procedures for Filing an Application When the Applicant Protests a Refusal to File Action (File Over Protest)*

**Other guidances**

Draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*<sup>4</sup>

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

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

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<sup>1</sup> We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs or Biologics guidance web pages at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> and <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<sup>2</sup> 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 Drugs or Biologics guidance web pages at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> and <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<sup>3</sup> SOPPs can be found on the Biologics Procedures (SOPPs) web page at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm>.

<sup>4</sup> When final, this guidance will represent the FDA’s current thinking on this topic.

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- 679 Guidance for industry *Special Protocol Assessment*  
680  
681 Guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals Above the*  
682 *Division Level*  
683