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

## *DRAFT GUIDANCE*

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For questions regarding this draft document, contact (CDER) Rachel Kichline at 301-796-0319 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)**

**December 2017  
Procedural**

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

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

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 drug or biological drug products (hereafter referred to as *products*) regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This guidance does not apply to abbreviated new drug applications, applications for biosimilar biological products, or submissions for medical devices. 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 includes meetings conducted in any format (i.e., face to face, teleconference/videoconference, or written response only (WRO)).

This guidance discusses the principles of good meeting management practices (GMMPs) and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting such formal meetings. The general principles in this guidance may be extended to other nonapplication-related meetings with external constituents, insofar as this is possible.<sup>2</sup>

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of

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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> The previous guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants* published May 19, 2009, and the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* published March 11, 2015, have been withdrawn.

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38 the word *should* in Agency guidances means that something is suggested or recommended, but  
39 not required.

40

41

### **42 II. BACKGROUND**

43

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

52

53 FDA review staff and requesters adhere to the meeting management goals that were established  
54 under reauthorizations of the Prescription Drug User Fee Act (PDUFA).<sup>3</sup> They are described  
55 individually throughout this guidance and summarized in the Appendix.

56

57

### **58 III. MEETING TYPES<sup>4</sup>**

59

60 There are four types of formal meetings under PDUFA that occur between requesters and FDA  
61 staff: Type A, Type B, Type B (end of phase (EOP)), and Type C.

62

#### **63 A. Type A Meeting**

64

65 Type A meetings are those that are necessary for an otherwise stalled product development  
66 program to proceed or to address an important safety issue. Examples of a Type A meeting  
67 include:

68

- 69 • Dispute resolution meetings as described in 21 CFR 10.75, 312.48, and 314.103 and in  
70 the guidance for industry and review staff *Formal Dispute Resolution: Sponsor Appeals*  
71 *Above the Division Level*.<sup>5</sup>

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<sup>3</sup> See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>.

<sup>4</sup> The meeting types and goal dates were negotiated under the Prescription Drug User Fee Act (PDUFA) and apply to formal meetings between FDA staff and requesters of PDUFA products; they do not apply to meetings with CDER Office of Generic Drugs, CDER Office of Compliance, or CDER Office of Prescription Drug Promotion. See the Prescription Drug User Fee Act (PDUFA) web page at <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>.

<sup>5</sup> We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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- Meetings to discuss clinical holds: (1) in which the requester seeks input on how to address the hold issues; or (2) in which a response to hold issues has been submitted, and reviewed by the FDA, but the FDA and the requester agree that the development is stalled and a new path forward should be discussed.
- Meetings that are requested after receipt of an FDA Nonagreement Special Protocol Assessment letter in response to protocols submitted under the special protocol assessment procedures as described in the guidance for industry *Special Protocol Assessment*.
- Post-action meetings requested within 3 months after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).
- Meetings requested within 30 days of FDA issuance of a refuse-to-file letter. To file an application over protest, applicants must avail themselves of this meeting (21 CFR 314.101(a)(3)).

Before submitting a Type A meeting request, requesters should contact the review division or office to discuss the appropriateness of the request.

### **B. Type B Meeting**

Type B meetings are as follows:

- Pre-investigational new drug application (pre-IND) meetings.
- Pre-emergency use authorization meetings.
- Pre-new drug application (pre-NDA)/pre-biologics license application (pre-BLA) meetings (21 CFR 312.47).
- Post-action meetings requested 3 or more months after an FDA regulatory action other than an approval (i.e., issuance of a complete response letter).
- Meetings regarding risk evaluation and mitigation strategies or postmarketing requirements that occur outside the context of the review of a marketing application.
- Meetings held to discuss the overall development program for products granted breakthrough therapy designation status. Subsequent meetings for breakthrough therapy-designated products will be considered either Type B or possibly Type A meetings if the meeting request meets the criteria for a Type A meeting.

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### 115 C. Type B (EOP) Meeting

116

117 Type B (EOP) meetings are as follows:

118

119 • Certain end-of-phase 1 meetings (i.e., for products that will be considered for marketing  
120 approval under 21 CFR part 312, subpart E, or 21 CFR part 314, subpart H, or similar  
121 products)

122

123 • End-of-phase 2 or pre-phase 3 meetings (21 CFR 312.47)

124

### 125 D. Type C Meeting

126

127 A Type C meeting is any meeting other than a Type A, Type B, or Type B (EOP) meeting  
128 regarding the development and review of a product, including meetings to facilitate early  
129 consultations on the use of a biomarker as a new surrogate endpoint that has never been  
130 previously used as the primary basis for product approval in the proposed context of use.

131

132

## 133 IV. MEETING FORMATS

134

135 There are three meeting formats: face to face, teleconference/videoconference, and WRO as  
136 follows:

137

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

140

141 (2) **Teleconference/Videoconference** — Teleconferences/videoconferences are meetings in  
142 which the attendees participate from various remote locations via an audio (e.g.,  
143 telephone) and/or video connection

144

145 (3) **Written response only** — WRO responses are sent to requesters in lieu of meetings  
146 conducted in one of the other two formats described above

147

148

## 149 V. MEETING REQUESTS

150

151 To make the most efficient use of FDA resources, before seeking a meeting, requesters should  
152 use the extensive sources of product development information that are publically available. To  
153 disseminate a broad range of information in a manner that can be easily and rapidly accessed by  
154 interested parties, the FDA develops and maintains web pages, portals, and databases, and  
155 participates in interactive media as a means of providing advice on scientific and regulatory  
156 issues that fall outside of established guidance, policy, and procedures.

157

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

160

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161 When a meeting is needed, a written request must be submitted to the FDA via the respective  
162 center's document room (paper submissions) or via the electronic gateway, as appropriate.<sup>6</sup>  
163 Requests should be addressed to the appropriate review division or office and, if previously  
164 assigned, submitted to the application (e.g., investigational new drug application (IND), new  
165 drug application (NDA), biologics license application (BLA)). Meeting requests sent by fax or  
166 email are considered courtesy copies only and are not a substitute for a formal submission.

167  
168 The meeting request should include adequate information for the FDA to assess the potential  
169 utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

170  
171 The meeting request should include the following information:

- 172  
173 1. The application number (if previously assigned).
- 174  
175 2. The product name.
- 176  
177 3. The chemical name, established name, and/or structure.
- 178  
179 4. The proposed regulatory pathway (e.g., 505(b)(1), 505(b)(2)).
- 180  
181 5. The proposed indication(s) or context of product development.
- 182  
183 6. The meeting type being requested (i.e., Type A, Type B, Type B (EOP), or Type C).
- 184  
185 7. Pediatric study plans, if applicable.
- 186  
187 8. Human factors engineering plan, if applicable.
- 188  
189 9. Combination product information (e.g., constituent parts, including details of the device  
190 constituent part, intended packaging, planned human factors studies), if applicable.
- 191  
192 10. Suggested dates and times (e.g., morning or afternoon) for the meeting that are consistent  
193 with the appropriate scheduling time frame for the meeting type being requested (see  
194 Table 2 in section VI.B., Meeting Granted). Dates and times when the requester is not  
195 available should also be included.
- 196  
197 11. A list of proposed questions, grouped by FDA discipline. For each question there should  
198 be a brief explanation of the context and purpose of the question.
- 199

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<sup>6</sup> See the 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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200 The meeting request must include the following information:<sup>7</sup>

- 201
- 202 1. The proposed meeting format (i.e., face to face, teleconference/videoconference, or
- 203 WRO).
- 204
- 205 2. The date the meeting background package will be sent by the requester (see section
- 206 VII.A., Timing of Meeting Package Submission). Note that meeting packages should be
- 207 included with the meeting request for all Type A meetings and those Type C meetings
- 208 where the objective is to facilitate early consultation on the use of a biomarker as a new
- 209 surrogate endpoint that has never been previously used as the primary basis for product
- 210 approval in the proposed context of use.
- 211
- 212 3. A brief statement of the purpose of the meeting. This statement should include a brief
- 213 background of the issues underlying the agenda. It also can include a brief summary of
- 214 completed or planned studies and clinical trials or data that the requester intends to
- 215 discuss at the meeting, the general nature of the critical questions to be asked, and where
- 216 the meeting fits in overall development plans. Although the statement should not provide
- 217 the details of trial designs or completed studies and clinical trials, it should provide
- 218 enough information to facilitate understanding of the issues, such as a small table that
- 219 summarizes major results.
- 220
- 221 4. A list of the specific objectives or outcomes the requester expects from the meeting.
- 222
- 223 5. A proposed agenda, including estimated times needed for discussion of each agenda item.
- 224
- 225 6. A list of planned attendees from the requester's organization, including their names and
- 226 titles. The list should also include the names, titles, and affiliations of consultants and
- 227 interpreters, if applicable.
- 228
- 229 7. A list of requested FDA attendees and/or discipline representative(s). Note that requests
- 230 for attendance by FDA staff who are not otherwise essential to the application's review
- 231 may affect the ability to hold the meeting within the specified time frame of the meeting
- 232 type being requested. Therefore, when attendance by nonessential FDA staff is
- 233 requested, the meeting request should provide a justification for such attendees and state
- 234 whether or not a later meeting date is acceptable to the requester to accommodate the
- 235 nonessential FDA attendees.
- 236

237 When submitting a meeting request, the requester should define the specific areas of input  
238 needed from the FDA. A well-written meeting request that includes the above components can  
239 help the FDA understand and assess the utility and timing of the meeting related to product  
240 development or review. The list of requester attendees and the list of requested FDA attendees  
241 can be useful in providing or preparing for the input needed at the meeting. However, during the  
242 time between the request and the meeting, the planned attendees can change. Therefore, an

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<sup>7</sup> See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>.

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243 updated list of attendees with their titles and affiliations should be included in the meeting  
244 package and a final list provided to the appropriate FDA contact before the meeting (see section  
245 VII.C., Meeting Package Content).

246  
247 The objectives and agenda provide overall context for the meeting topics, but it is the list of  
248 questions that is most critical to understanding the kind of information or input needed by the  
249 requester and to focus the discussion should the meeting be granted. Each question should be  
250 precise and include a brief explanation of the context and purpose of the question. The questions  
251 submitted within a single meeting request should be limited to those that can be reasonably  
252 answered within the allotted meeting time, taking into consideration the complexity of the  
253 questions submitted. Similar considerations regarding the complexity of questions submitted  
254 within a WRO should be applied.

255  
256

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

257  
258

259 Although requesters can request any meeting format for any meeting type, the FDA assesses  
260 each meeting request, including WRO requests, and determines whether or not the request  
261 should be granted, the final meeting type, and the appropriate meeting format. The FDA may  
262 determine that a WRO is the most appropriate means for providing feedback and advice for pre-  
263 IND and most Type C meetings, except for Type C meetings to discuss the use of a biomarker as  
264 a new surrogate endpoint when that endpoint has never been previously used as the primary basis  
265 for product approval, which will be conducted face to face. If the FDA decides that another  
266 meeting format is needed instead of sending responses by WRO, it will notify the requester as  
267 described in section VI.B., Meeting Granted.

268

269 Requests for Type B and Type B (EOP) meetings will be honored except in unusual  
270 circumstances. Generally, with the exception of products granted breakthrough therapy  
271 designation status, the FDA will not grant more than one of each of the Type B meetings for  
272 each potential application (e.g., IND, NDA, BLA) or combination of closely related products  
273 developed by the same requester (e.g., same active ingredient but different dosage forms being  
274 developed concurrently), but the FDA can do so when it would be beneficial to hold separate  
275 meetings to discuss unrelated issues. For example, it may be appropriate to conduct more than  
276 one end-of-phase 2 meeting with different review divisions for concurrent development of a  
277 product for unrelated claims or a separate meeting to discuss manufacturing development when  
278 the clinical development is on a different timeline.

279

#### **A. Meeting Denied**

280  
281

282 If a meeting request is denied, the FDA will notify the requester in writing according to the  
283 timelines described in Table 1. The FDA's letter will include an explanation of the reason for  
284 the denial. Denials will be based on a substantive reason, not merely on the absence of a minor  
285 element of the meeting request or meeting package items. For example, a meeting can be denied  
286 because it is premature for the stage of product development or because the meeting package  
287 does not provide an adequate basis for the meeting discussion. Thus, the FDA will generally  
288 deny requests for Type A meetings and Type C meetings to discuss the use of a biomarker as a

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289 new surrogate endpoint that has never been previously used as the primary basis for product  
290 approval that do not include an adequate meeting package in the original request (see section IX.,  
291 Rescheduling and Canceling Meetings, for the effect of inadequate meeting packages on other  
292 meeting types where the package is received after the meeting is granted). The FDA may also  
293 deny requests for meetings that do not have substantive required elements described in section  
294 V., Meeting Requests. A subsequent request to schedule the meeting will be considered as a new  
295 request (i.e., a request that merits a new set of time frames as described in section III., Meeting  
296 Types).

297  
298 **B. Meeting Granted**  
299

300 If a meeting request is granted, the FDA will notify the requester in writing according to the  
301 timelines described in Table 1. For face-to-face and teleconference/videoconference meetings,  
302 the FDA’s letter will include the date, time, conferencing arrangements and/or location of the  
303 meeting, as well as expected FDA participants. For WRO requests, the FDA’s letter will include  
304 the date the FDA intends to send the written responses (see Table 3 for FDA WRO response  
305 timelines). As shown in Tables 2 and 3, FDA WRO response timelines are the same as those for  
306 scheduling a meeting (face to face or teleconference/videoconference) of the same meeting type.  
307

308 For face-to-face and teleconference/videoconference meetings, the FDA will schedule the  
309 meeting on the next available date at which all expected FDA staff are available to attend;  
310 however, the meeting should be scheduled consistent with the type of meeting requested (see  
311 Table 2 for FDA meeting scheduling time frames). If the requested date for any meeting type is  
312 greater than the specified time frame, the meeting date should be within 14 calendar days of the  
313 requested date.  
314

315 **Table 1: FDA Meeting Request/WRO Request Response Timelines**

<b>Meeting Type (any format)</b>	<b>Response Time (calendar days from receipt of meeting request/WRO request)</b>
A	14 days
B	21 days
B (EOP)	14 days
C	21 days

316  
317 **Table 2: FDA Meeting Scheduling Time Frames**

<b>Meeting Type</b>	<b>Meeting Scheduling (calendar days from receipt of meeting request)</b>
A	30 days
B	60 days
B (EOP)	70 days
C	75 days

318

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

Meeting Type	WRO Response Time (calendar days from receipt of WRO request)
A	30 days
B	60 days
B (EOP)	70 days
C	75 days

320

321

322 **VII. MEETING PACKAGE**

323

324 Premeeting preparation is critical for achieving a productive discussion or exchange of  
 325 information. Preparing the meeting package should help the requester focus on describing its  
 326 principal areas of interest. The meeting package should provide information relevant to the  
 327 discussion topics and enable the FDA to prepare adequately for the meeting. In addition, the  
 328 timely submission of the meeting package is important for ensuring that there is sufficient time  
 329 for meeting preparation, accommodating adjustments to the meeting agenda, and accommodating  
 330 appropriate preliminary responses to meeting questions.

331

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

333

334 Requesters must submit the meeting package for each meeting type (including WRO) according  
 335 to the meeting package timelines described in Table 4.<sup>8</sup>

336

337 **Table 4: Requester Meeting Package Timelines**

Meeting Type	FDA Receipt of Meeting Package (calendar days)
A, C*	At the time of the meeting request
B	No later than 30 days before the scheduled date of the meeting or WRO response time
B (EOP)	No later than 50 days before the scheduled date of the meeting or WRO response time**
C	No later than 47 days before the scheduled date of the meeting or WRO response time***

338 \*For Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used as  
 339 the primary basis for product approval in a proposed context of use, the meeting package is due at the time of the  
 340 meeting request.

341 \*\* If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA receipt of the meeting request,  
 342 the requester’s meeting package will be due no sooner than 6 calendar days after FDA response time for issuing the  
 343 letter granting the meeting (see Table 1 in section VI.B., Meeting Granted).

344 \*\*\* If the scheduled date of a Type C meeting is earlier than 75 days from FDA receipt of the meeting request, the  
 345 meeting package will be due no sooner than 7 calendar days after FDA response time for issuing the letter granting  
 346 the meeting (see Table 1 in section VI.B., Meeting Granted).

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<sup>8</sup> See PDUFA Reauthorization Performance Goals and Procedures available at  
<https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm149212.htm>.

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

349

350 Requesters should submit the archival meeting package to the relevant application(s) (e.g., IND,  
351 NDA, or BLA) via the appropriate center's document room (paper submission) or via the  
352 electronic gateway, as applicable.<sup>9</sup>

353

354 To facilitate the meeting process, CDER strongly suggests that copies of meeting packages  
355 provided in electronic format also be provided in paper (desk copies). The number of desk  
356 copies of a meeting package will vary based on the meeting. The CDER project manager will  
357 advise on the number of desk copies needed for the meeting attendees. CDER neither requests  
358 nor accepts paper copies (desk copies) of meeting packages that have been submitted in  
359 electronic format.

360

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

361

362 The meeting package should provide *summary* information relevant to the product and any  
363 supplementary information needed to develop responses to issues raised by the requester or  
364 review division. It is critical that the entire meeting package content support the intended  
365 meeting objectives. The meeting package content will vary depending on the product,  
366 indication, phase of product development, and issues to be discussed. FDA and ICH guidances  
367 identify and address many issues related to product development and should be considered when  
368 planning, developing, and providing information needed to support a meeting with the FDA. If a  
369 product development plan deviates from current guidances, or from current practices, the  
370 deviation should be recognized and explained. Known difficult design and evidence issues  
371 should be raised for discussion (e.g., use of a surrogate endpoint, reliance on a single study, use  
372 of a noninferiority design, adaptive designs). Also, merely describing a result as *significant* does  
373 not provide the review division with enough information to give good advice or identify  
374 important problems the requester may have missed.

375

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

382

383 1. The application number (if previously assigned).

384

385 2. The product name.

386

387 3. The chemical name, established name, and/or structure.

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<sup>9</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 — General Considerations*.

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4. The proposed regulatory pathway (e.g., 505(b)(1), 505(b)(2)).
  5. The proposed indication(s) or context of product development.
  6. The dosage form, route of administration, and dosing regimen (frequency and duration).
  7. Pediatric study plans, if applicable.
  8. Human factors engineering plan, if applicable.
  9. Combination product information (e.g., constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable.
  10. A list of all individuals, with their titles and affiliations, who will attend the requested meeting from the requester's organization, including consultants and interpreters.
  11. A background section that includes the following:
    - a. A brief history of the development program and relevant communications with the FDA before the meeting
    - b. Substantive changes in product development plans (e.g., new indication, population, basis for a combination), when applicable
    - c. The current status of product development
  12. A brief statement summarizing the purpose of the meeting and identifying the type of milestone meeting, if applicable.
  13. A proposed agenda, including estimated times needed for discussion of each agenda item.
  14. A list of the final questions for discussion grouped by FDA discipline and with a brief summary for each question to explain the need or context for the question. Questions regarding combination products should be grouped together.
  15. Data to support discussion organized by FDA discipline and question. Protocols, full study reports, or detailed data generally are not appropriate for meeting packages; the summarized material should describe the results of relevant studies and clinical trials with some degree of quantification, and any conclusion about clinical trials that resulted. The trial endpoints should be stated, as should whether endpoints were altered or analyses changed during the course of the trial.

For example, for an end-of-phase 2 meeting, this section of the meeting package should include the following: a description and the results of controlled trials conducted to determine dose-response information; adequately detailed descriptors of planned phase 3

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435 trials identifying major trial features such as population, critical exclusions, trial design  
436 (e.g., randomization, blinding, and choice of control group, with an explanation of the  
437 basis for any noninferiority margin if a noninferiority trial is used), dose selection, and  
438 primary and secondary endpoints; and major analyses (including planned interim  
439 analyses and adaptive features, and major safety concerns).  
440

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### **VIII. PRELIMINARY RESPONSES**

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443  
444 Communications before the meeting between requesters and the FDA, including preliminary  
445 responses, can serve as a foundation for discussion or as the final meeting responses.  
446 Nevertheless, preliminary responses should not be construed as *final* unless there is agreement  
447 between the requester and the FDA that additional discussion is not necessary for any question  
448 (i.e., when the meeting is canceled because the requester is satisfied with the FDA's preliminary  
449 responses), or a particular question is considered resolved allowing extra time for discussion of  
450 the more complex questions during the meeting. Preliminary responses communicated by the  
451 FDA are not intended to generate the submission of new information or new questions. If a  
452 requester nonetheless provides new data or a revised or new proposal, the FDA may not be able  
453 to provide comments on the new information or it may necessitate the submission of a new  
454 meeting request by the requester.  
455

456 The FDA holds an internal meeting to discuss the content of meeting packages and to gain  
457 internal alignment on the preliminary responses. The FDA will send the requester its  
458 preliminary responses to the questions in the meeting package no later than 5 calendar days  
459 before the meeting date for Type B (EOP) and Type C meetings. The requester will notify the  
460 FDA no later than 3 calendar days following receipt of the FDA's preliminary responses for  
461 these meeting types of whether the meeting is still needed, and if it is, the requester will send the  
462 FDA a revised meeting agenda indicating which questions the requestor considers as resolved,  
463 and which questions the requestor will want to further discuss.<sup>10</sup> For all other meeting types, the  
464 FDA intends to send the requester its preliminary responses no later than 2 calendar days before  
465 the meeting.  
466

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### **IX. RESCHEDULING AND CANCELING MEETINGS**

468

469  
470 Occasionally, circumstances arise that necessitate the rescheduling or cancellation of a meeting.  
471 If a meeting needs to be rescheduled, it should be rescheduled as soon as possible after the  
472 original date. A new meeting request should not be submitted. However, if a meeting is  
473 canceled, the FDA will consider a subsequent request to schedule a meeting to be a new request  
474 (i.e., a request that merits a new set of time frames as described in section VI., Assessing and  
475 Responding to Meeting Requests). Requesters and the FDA should take reasonable steps to  
476 avoid rescheduling and canceling meetings (unless the meeting is no longer necessary). For  
477 example, if an attendee becomes unavailable, a substitute can be identified, or comments on the

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<sup>10</sup> See PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>.

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478 topic that the attendee would have addressed can be forwarded to the requester following the  
479 meeting. It will be at the discretion of the review division whether the meeting should be  
480 rescheduled or canceled depending on the specific circumstances.

481  
482 The following situations are examples of when a meeting can be rescheduled. Some of the  
483 examples listed also represent reasons that a meeting may be canceled by the FDA. This list  
484 includes representative examples and is not intended to be an exhaustive list.

- 485  
486 • The requester experiences a minor delay in submitting the meeting package. The  
487 requester should contact the FDA project manager to explain why it cannot meet the time  
488 frames for submission and when the meeting package will be submitted.
- 489  
490 • The review team determines that the meeting package is inadequate, or additional  
491 information is needed to address the requester's questions or other important issues for  
492 discussion, but it is possible to identify the additional information needed and arrange for  
493 its timely submission.
- 494  
495 • There is insufficient time to review the material because the meeting package is  
496 voluminous (see section VII.C., Meeting Package Content), despite submission within the  
497 specified time frames and the appropriateness of the content.
- 498  
499 • After the meeting package is submitted, the requester sends the FDA additional questions  
500 or data that are intended for discussion at the meeting and require additional review time.
- 501  
502 • It is determined that attendance by additional FDA personnel not originally anticipated or  
503 requested is critical and their unavailability precludes holding the meeting on the original  
504 date.
- 505  
506 • Essential attendees are no longer available for the scheduled date and time because of an  
507 unexpected or unavoidable conflict or an emergency situation.

508  
509 The following situations are examples of when a meeting can be canceled:

- 510  
511 • The meeting package is not received by the FDA within the specified time frames (see  
512 section VII.A., Timing of Meeting Package Submission) or is grossly inadequate.  
513 Meetings are scheduled on the condition that appropriate information to support the  
514 discussion will be submitted with sufficient time for review and preparatory discussion.  
515 Adequate planning should avoid this problem.
- 516  
517 • The requester determines that preliminary responses to its questions are sufficient for its  
518 needs and additional discussion is not necessary (see section VIII., Preliminary  
519 Responses). In this case, the requester should contact the FDA project manager to  
520 request cancellation of the meeting. The FDA will consider whether it agrees that the  
521 meeting should be canceled. Some meetings, particularly milestone meetings, can be  
522 valuable because of the broad discussion they generate and the opportunity for the  
523 division to ask about relevant matters (e.g., dose-finding, breadth of subject exposure,



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524 particular safety concerns), even if the preliminary responses seem sufficient to answer  
525 the requester’s questions. If the FDA agrees that the meeting can be canceled, the reason  
526 for cancellation will be documented and the preliminary responses will represent the final  
527 responses and the official record.

528  
529

### **X. MEETING CONDUCT**

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531  
532 Meetings will be chaired by an FDA staff member and begin with introductions and an overview  
533 of the agenda. FDA policy prohibits audio or visual recording of discussions at meetings.

534

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

545

546 Either a representative of the FDA or the requester should summarize the important discussion  
547 points, agreements, clarifications, and action items. Summation can be done at the end of the  
548 meeting or after the discussion of each question. Generally, the requester will be asked to  
549 present the summary to ensure that there is mutual understanding of meeting outcomes and  
550 action items. FDA staff can add or further clarify any important points not covered in the  
551 summary and these items can be added to the meeting minutes. At pre-NDA and pre-BLA  
552 meetings for applications reviewed under the PDUFA Program for Enhanced Review  
553 Transparency and Communication for NME NDAs and Original BLAs (also known as *the*  
554 *Program*),<sup>11</sup> the requester and the FDA should also summarize agreements regarding the content  
555 of a complete application and any agreements reached on delayed submission of certain minor  
556 application components.

557

558

### **XI. MEETING MINUTES**

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560  
561 Because the FDA’s minutes are the official records of meetings, the FDA’s documentation of  
562 meeting outcomes, agreements, disagreements, and action items is critical to ensuring that this  
563 information is preserved for meeting attendees and future reference. The FDA will issue the  
564 official, finalized minutes to the requester within 30 calendar days after the meeting.

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<sup>11</sup> See <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm>.

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566 The following are general considerations regarding meeting minutes:  
567

- 568 • FDA minutes will outline the important agreements, disagreements, issues for further  
569 discussion, and action items from the meeting in bulleted format. This information does  
570 not need to be in great detail. The minutes are not intended to represent a transcript of  
571 the meeting.  
572
- 573 • FDA project managers will use established templates to ensure that all important meeting  
574 information is captured.  
575
- 576 • The FDA may communicate additional information in the final minutes that was not  
577 explicitly communicated during the meeting (e.g., pediatric requirements, data standards,  
578 abuse liability potential) or that provides further explanation of discussion topics. The  
579 FDA's final minutes will distinguish this additional information from the discussion that  
580 occurred during the meeting.  
581

582 The following steps should be taken when there is a difference of understanding regarding the  
583 minutes:  
584

- 585 • Requesters should contact the FDA project manager if there is a significant difference in  
586 their and the FDA's understanding of the content of the final meeting minutes issued to  
587 the requesters  
588
- 589 • If after contacting the FDA project manager there are still significant differences in the  
590 understanding of the content, the requester should submit a description of the specific  
591 disagreements either:  
592
  - 593 – To the application; or
  - 594
  - 595 – If there is no application, in a letter to the division director, with a copy to the FDA  
596 project manager
  - 597
- 598 • The review division and the office director, if the office director was present at the  
599 meeting, will take the concerns under consideration  
600
  - 601 – If the minutes are deemed to accurately and sufficiently reflect the meeting  
602 discussion, the FDA project manager will convey this decision to the requester and  
603 the minutes will stand as the official documentation of the meeting.  
604
  - 605 – If the FDA deems it necessary, changes will be documented in an addendum to the  
606 official minutes. The addendum will also document any remaining requester  
607 objections, if any.  
608

609 For input on additional issues that were not addressed at the meeting, the requester should submit  
610 a new meeting request, a WRO request, or a submission containing specific questions for FDA  
611 feedback.

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**REFERENCES**

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**Related Guidances<sup>12</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 CDER MAPP<sup>13</sup>**

MAPP 6025.6 *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics*

**Related CBER SOPPs<sup>14</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)*

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<sup>12</sup> Guidances can be found on the FDA Drugs guidance web page at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<sup>13</sup> MAPPs can be found on the Manual of Policies and Procedures web page at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

<sup>14</sup> SOPPs can be found on the Biologics Procedures (SOPPs) web page at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm>.

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**APPENDIX:  
SUMMARY OF MEETING MANAGEMENT PROCEDURAL GOALS**

Table A is a summary of Prescription Drug User Fee Act meeting management procedural goals.

**Table A: Meeting Management Procedural Goals**

<b>Meeting Type</b>	<b>FDA Response to Request</b>	<b>FDA Receipt of Meeting Package</b>	<b>FDA Preliminary Responses to Requester (if applicable†)</b>	<b>Requester Response to FDA Preliminary Responses (if applicable†)</b>	<b>FDA Scheduled Meeting Date (days from receipt of request)</b>	<b>FDA Meeting Minutes to Requester (if applicable†)</b>
A	14 days	With meeting request	No later than 2 days before meeting	--	Within 30 days	30 days after meeting
B	21 days	No later than 30 days before meeting	No later than 2 days before meeting	--	Within 60 days	30 days after meeting
B (EOP)*	14 days	No later than 50 days before meeting**	No later than 5 days before meeting	No later than 3 days after receipt of preliminary responses	Within 70 days	30 days after meeting
C	21 days	No later than 47 days before meeting***	No later than 5 days before meeting	No later than 3 days after receipt of preliminary responses	Within 75 days	30 days after meeting

†Not applicable to written response only.

\* EOP = end of phase

\*\* If the scheduled date of a Type B (EOP) meeting is earlier than 70 days from FDA receipt of the meeting request, the requester’s meeting package will be due no sooner than 6 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted).

\*\*\* If the scheduled date of a Type C meeting is earlier than 75 days from FDA receipt of the meeting request, the meeting package will be due no sooner than 7 calendar days after FDA response time for issuing the letter granting the meeting (see Table 1 in section VI.B., Meeting Granted). Note that for Type C meetings that are requested as early consultations on the use of a new surrogate endpoint to be used as the primary basis for product approval in a proposed context of use, the meeting package is due at the time of the meeting request.