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# **Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff**

## **Good Review Practice**

### ***DRAFT GUIDANCE***

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For questions regarding this draft document, contact (CDER) Rachel Hartford 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 2015  
Procedural**

# **Best Practices for Communication Between IND Sponsors and FDA During Drug Development Guidance for Industry and Review Staff**

## **Good Review Practice**

*Additional copies are available from:*

*Office of Communications, Division of Drug Information  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor  
Silver Spring, MD 20993-0002*

*Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353; Email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>*

*and/or*

*Office of Communication, Outreach, and Development  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 71, rm. 3128  
Silver Spring, MD 20993-0002*

*Phone: 800-835-4709 or 240-402-8010; Email: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)  
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1 **Best Practices for Communication Between IND Sponsors and**  
2 **FDA During Drug Development**  
3 **Guidance for Industry and Review Staff<sup>1</sup>**  
4

5 **Good Review Practice**  
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7  
8

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10 This draft guidance, when finalized, will represent the current thinking of the Food and Drug  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

16  
17  
18  
19 **I. INTRODUCTION**  
20

21 The purpose of this guidance is to describe best practices and procedures for timely, transparent,  
22 and effective communications between investigational new drug application (IND) sponsors<sup>2</sup> and  
23 FDA at critical junctures in drug<sup>3</sup> development, which may facilitate earlier availability of safe  
24 and effective drugs to the American public. This guidance describes:  
25

- 26 • FDA's philosophy regarding timely interactive communication with IND sponsors as a  
27 core activity
- 28
- 29 • The scope of appropriate interactions between the review team and the sponsor
- 30
- 31 • The types of advice appropriate for sponsors to seek from FDA in pursuing their drug  
32 development program
- 33
- 34 • General expectations for the timing of FDA response to IND sponsor inquiries  
35

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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 the purposes of this guidance, all references to *sponsors* include both sponsors and their authorized officials as described in 21 CFR 312.3 and 21 CFR 312.23(a)(1)(ix).

<sup>3</sup> For the purposes of this guidance, all references to *drugs* or *drug products* include human drug products, including biological drug products, regulated by CBER and CDER, unless otherwise specified.

## ***Contains Nonbinding Recommendations***

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- 36       • Best practices and communication methods to facilitate interactions between the FDA  
37       review team and the IND sponsor during drug development  
38  
39       • Expectations for appropriate methods, including the frequency, of such communications  
40

41 This guidance does not apply to communications or inquiries from industry trade organizations,  
42 consumer or patient advocacy organizations, other government agencies, or other stakeholders  
43 not pursuing a development program under an IND.  
44

45 Although this guidance describes FDA’s current best communication practices, it should be  
46 appreciated that a quality improvement process is dynamic and will continue to evolve over time  
47 with further feedback from sponsors and review staff. Thus, as additional best practices are  
48 identified or established, this guidance may be updated.  
49

50 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.  
51 Instead, guidances describe the FDA’s current thinking on a topic and should be viewed only as  
52 recommendations, unless specific regulatory or statutory requirements are cited. The use of the  
53 word *should* in FDA guidances means that something is suggested or recommended, but not  
54 required. Although guidance documents do not legally bind FDA, review staff may depart from  
55 guidance documents only with appropriate justification and supervisory concurrence.  
56  
57

## **II. BACKGROUND**

58  
59  
60 On July 9, 2012, the President signed the Food and Drug Administration Safety and Innovation  
61 Act of 2012, which includes the Prescription Drug User Fee Amendments of 2012 (PDUFA V).  
62 As directed by Congress in the Food and Drug Administration Amendments Act of 2007, FDA  
63 developed the proposed enhancements for PDUFA V in consultation with drug industry  
64 representatives, patient and consumer advocates, health care professionals, and other public  
65 stakeholders. These goals are described in “PDUFA Reauthorization Performance Goals and  
66 Procedures; Fiscal Years 2013 through 2017.”<sup>4</sup> Under the PDUFA V goals, CDER and CBER  
67 agreed to develop a dedicated drug development communication and training staff within CDER  
68 and augment the manufacturers assistance staff in CBER, focused on enhancing communication  
69 between FDA and sponsors during drug development. CDER’s Enhanced Communication Team  
70 (ECT) liaison staff and CBER’s Ombudsman serve as a secondary point of communication  
71 within FDA for sponsors who are encountering challenges communicating with the review  
72 team.<sup>5</sup>  
73

74 CDER and CBER also agreed to publish this joint guidance for industry and review staff on best  
75 practices for communication between IND sponsors and FDA during drug development. CDER  
76 and CBER gathered review staff best practices and incorporated input from interested parties

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<sup>4</sup> <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>

<sup>5</sup> See the Enhanced Communication Web page at  
<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm>.

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77 (i.e., those who responded to a notice published in the *Federal Register*<sup>6</sup> or who provided input  
78 directly to CDER's ECT) to inform the writing of this guidance.

79  
80 The IND phase of drug development is the time during which human trials of investigational  
81 drugs are conducted. From FDA's perspective, the IND phase of drug development spans the  
82 time from the first IND-related submission (including a pre-IND meeting request or an original  
83 IND) to the submission of a marketing application. The IND phase may also extend beyond  
84 initial approval or licensure to include additional trials relevant to the drug's development and  
85 labeling. From the sponsor's perspective, drug development is not limited to the IND phase  
86 because it also includes drug discovery and early work-up of compounds before IND submission  
87 and may include clinical trials conducted in other countries outside a U.S. IND.<sup>7</sup>  
88

89 Each year, sponsors and FDA engage in thousands of formal and informal communications,  
90 including meetings and teleconferences, during the IND phase of drug development. Because  
91 these communications are often opportunities to share information and provide critical advice  
92 (e.g., trial design, dose selection, nonclinical study requirements, manufacturing and facility  
93 issues), it is important that interactions be conducted efficiently and consistently, with clear,  
94 concise, and timely communication.  
95

96

### **97 III. FDA'S PHILOSOPHY REGARDING COMMUNICATION WITH IND 98 SPONSORS 99**

100 Ideally, IND sponsors and FDA work collaboratively during the drug development process,  
101 having a shared public health goal of early availability of safe, effective, and high-quality drugs  
102 to the American public. In this process, IND sponsors and FDA have distinct roles and primary  
103 areas of responsibility.  
104

- 105 • Sponsors' primary responsibilities are managing the overall development of their drug  
106 (i.e., supporting well-designed and well-conducted nonclinical and clinical trials for  
107 approval while ensuring patient safety), determining the nature and timing of regulatory  
108 submissions to the IND, soliciting input and guidance from FDA during the course of  
109 their development program, and providing well-organized and complete IND submissions  
110 (including amendments and supplementary information) to FDA for review.  
111
- 112 • FDA's primary responsibilities with respect to INDs are, during all phases of an  
113 investigation, to ensure the safety and rights of subjects, and, during phase 2 and phase 3,  
114 to help ensure that the quality of the scientific evaluation of drugs is adequate to permit

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<sup>6</sup> 79 FR 64397; October 29, 2014

<sup>7</sup> For more information on the use of information relating to foreign clinical trials in INDs and applications for marketing approval submitted to FDA, see the guidance for industry and FDA staff *FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND: Frequently Asked Questions*. We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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115 an evaluation of the drug's effectiveness and safety.<sup>8</sup> FDA also has the important  
116 responsibility of enforcing requirements related to good clinical practice (GCP) and  
117 human subject protections (HSP). FDA reviews IND submissions and takes regulatory  
118 actions (e.g., clinical hold) as appropriate. FDA review staff also play an active role  
119 during drug development by providing advice and feedback to sponsors on specific trials  
120 and overall development programs based on their review of IND submissions and in  
121 meetings conducted between sponsors and FDA. Finally, FDA promotes the  
122 advancement of regulatory science by authoring FDA and international guidances,  
123 conducting and participating in public workshops and public/private consortia,  
124 collaborating with academia, publishing in medical and trade journals, and presenting  
125 scientific and regulatory topics at professional conferences.

126  
127 FDA believes that the timely review of IND submissions with appropriate feedback to sponsors  
128 can result in greater efficiency of the drug development process. At the sponsor's request, FDA  
129 will, if possible, provide advice on specific matters relating to an IND. Examples include giving  
130 advice on the adequacy of technical data to support an investigational plan, the design of a  
131 clinical trial, and whether proposed investigations are likely to produce the data and information  
132 needed to meet requirements for a marketing application.<sup>9</sup> Because the complexity and  
133 importance of material submitted to an IND will vary by therapeutic indication and development  
134 stage, the review divisions retain the flexibility to determine the extent of review and feedback  
135 provided for each submission. For drugs developed under expedited programs, such as  
136 breakthrough therapy and fast track, sponsors receive more intensive guidance on an efficient  
137 drug development program with increased interactions and communications with FDA, including  
138 meetings.<sup>10</sup>

139  
140 FDA believes that scientific and regulatory recommendations provided during drug development  
141 meetings with sponsors may result in more efficient and robust development programs. This  
142 philosophy is articulated in 21 CFR 312.47, 21 CFR 312.82, FDA's meetings guidances,<sup>11</sup>  
143 CDER's Manuals of Policies and Procedures (MAPPs), and CBER's Standard Operating Policy  
144 and Procedures (SOPPs). Sponsors can request meetings with FDA at any time during drug  
145 development, and FDA strongly encourages sponsors to request the critical milestone meetings  
146 identified in the references cited above. FDA's decision to grant or deny meeting requests is  
147 resource-dependent and is based on the maturity of the drug's development at the time of the  
148 meeting request, taking into consideration the potential utility of the meeting. The procedures

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<sup>8</sup> 21 CFR 312.22

<sup>9</sup> 21 CFR 312.41(b)

<sup>10</sup> See CDER MAPP 6025.6 *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics* (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>).

<sup>11</sup> See the guidances for industry *Formal Meetings Between the FDA and Sponsors or Applicants* and *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants*. See also 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).



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149 for requesting and conducting effective meetings between IND sponsors and FDA are fully  
150 described in the meetings guidances.

151  
152 Timelines established by statute and/or regulation apply to the review of certain submission  
153 types (e.g., initial IND submissions) and CDER and CBER strive to review and provide timely  
154 feedback for other types of submissions that lack such required review timelines (e.g., a new  
155 phase 2 protocol under an active IND), as resources allow. CDER has documented its good  
156 review practices and principles during the IND phase of drug development in a MAPP.<sup>12</sup>  
157 Incorporation of the principles outlined in the MAPP into IND review processes is resource-  
158 dependent and intended to improve safety oversight and facilitate effective communication  
159 between IND sponsors and FDA during drug development. The MAPP lists timelines for certain  
160 IND submissions, including recommended timelines where there is no required timeline (e.g.,  
161 some safety-related submissions, drug development submissions without regulatory timelines  
162 where communication to the sponsor is often critical and recommended, and other submissions  
163 where communication with the sponsor may be needed). Although FDA review staff continually  
164 strive to meet the recommended review timelines for IND submissions described in the MAPP,  
165 they must balance this work with other critical public health responsibilities, including new drug  
166 application/biologics license application (NDA/BLA) review and oversight of drug safety.

167  
168 FDA may at any time during the course of an IND communicate with the sponsor orally or in  
169 writing about deficiencies in the IND or about FDA's need for more data or information. Unless  
170 the communication is accompanied by a clinical hold order under 21 CFR 312.42, FDA  
171 communications with a sponsor under 21 CFR 312.41 are solely advisory and do not require any  
172 modification in the planned or ongoing clinical investigations or response to FDA.<sup>13</sup>

173  
174

#### **IV. SCOPE OF INTERACTIONS BETWEEN THE SPONSOR AND THE REVIEW TEAM**

175  
176  
177  
178 The review division regulatory project manager (RPM) is the *primary* point of contact for  
179 communications between IND sponsors and FDA during the life cycle of drug development. As  
180 a co-leader of the FDA review team, the review division RPM has comprehensive knowledge of  
181 the drug and its regulatory history. The RPM is also the primary contact for facilitating the  
182 timely resolution of technical, scientific, and regulatory questions, conflicts, or communication  
183 challenges between the sponsor and the review team.

184  
185 During drug development there are circumstances under which it is appropriate for sponsors to  
186 directly contact FDA project managers other than the review division RPM in CDER. These  
187 other project managers include the following.  
188

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<sup>12</sup> See CDER MAPP 6030.9 *Good Review Practice: Good Review Management Principles and Practices for Effective IND Development and Review*.

<sup>13</sup> 21 CFR 312.41(c)

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- 189 • CDER’s Office of Pharmaceutical Quality regulatory business project managers manage  
190 meeting requests, regulatory submissions, and other inquiries that are solely related to  
191 chemistry, manufacturing, and controls, including facility and product quality issues.  
192
- 193 • CDER’s Office of Surveillance and Epidemiology safety regulatory project managers  
194 manage sponsor requests for proprietary name review.  
195
- 196 • CDER’s Formal Dispute Resolution Project Manager manages sponsor requests for  
197 resolving scientific and/or medical disputes that cannot be resolved at the division level.<sup>14</sup>  
198

199 There are also limited circumstances where sponsors may need to use certain FDA points of  
200 contact for responses to basic or procedural drug development questions not directly linked to an  
201 existing or planned development program. These may be in specific functional areas and serve  
202 as an alternative means to obtain general information or address issues that arise in the context of  
203 the regulatory process. The circumstances, contacts, and resources are described in detail in  
204 section VIII., Additional Contacts.  
205

206 CDER and CBER are aware that at times sponsors wish to communicate directly with reviewers  
207 assigned to their IND to expedite the exchange of information and to facilitate timely progress in  
208 their drug development program. Such communications are strongly discouraged and sponsors  
209 should not directly contact FDA reviewers. It is critical that sponsor inquiries be directed to the  
210 review division RPM to ensure that requests are appropriately communicated to and considered  
211 by the review team members, including supervisors as appropriate. CDER and CBER strive to  
212 provide timely and accurate advice and feedback to sponsors that represent the review team’s  
213 current thinking on the issue, and this is best accomplished by adhering to the communication  
214 procedures described above. Direct contact by sponsors with review team members may  
215 interrupt their work on other critical public health assignments and may lead to responses that  
216 have not been vetted by the appropriate members of the review team and supervisors, resulting in  
217 the possibility that the feedback and advice provided are not accurate and complete and are not  
218 properly documented in the IND file. Sponsors are advised that such informal responses may not  
219 accurately or comprehensively capture FDA’s thinking.  
220

221 In rare cases, however, and with supervisory approval, it may be appropriate for FDA review  
222 team members to communicate directly with sponsors regarding minor issues related to their  
223 drug development program. In all such cases, the FDA review team member will document the  
224 conversation in a memorandum to the IND file and to provide a copy of that record to the RPM  
225 for sharing with the rest of the FDA review team. Decisions to allow such limited direct contact  
226 between IND sponsors and FDA reviewers will be made on a case-by-case basis by FDA  
227 management, not the IND sponsor, and represent an exception to usual best practices, not the  
228 norm.  
229

230 Independent consultants in the pharmaceutical field, whether working on behalf of a specific  
231 IND sponsor or on their own behalf, who have basic drug development questions should use

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<sup>14</sup> 21 CFR 10.75

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232 existing FDA resources (e.g., Web pages, guidances, MAPPs, SOPPs, interactive media,  
233 presentations) and/or the contacts listed in section VIII., Additional Contacts, if needed.  
234 Independent consultants working on behalf of a specific sponsor who seek advice regarding the  
235 sponsor's drug development program should be authorized by the sponsor before initiating  
236 contact with FDA staff on behalf of the sponsor and should follow the procedures outlined above  
237 (i.e., direct requests to the review division RPM).<sup>15</sup>  
238

239 If sponsors encounter challenges in obtaining timely feedback to inquiries to the review division  
240 RPM, they should contact the RPM's next level supervisor (e.g., the review division's chief of  
241 the project management staff (CPMS) in CDER, review division's branch chief in CBER). This  
242 generally results in timely resolution of the issue. In some cases, sponsors may wish to  
243 communicate with review team supervisors or division or office management officials when  
244 sponsors continue to encounter challenges in obtaining timely feedback. Such requests generally  
245 should be directed to the review division CPMS/branch chief so they can be communicated  
246 appropriately to the requested official and a mutually agreeable time can be arranged for a  
247 conversation by phone. It is helpful if the sponsor provides the CPMS/branch chief with  
248 background information on the purpose of the request to assist in determining the proper official  
249 to handle the call and also to allow the FDA official to conduct any preparations needed in  
250 advance of the call to make most efficient use of the allotted time. All such communications will  
251 be documented by either the CPMS/branch chief or the designated FDA official to the IND file  
252 and shared, as appropriate, with other review team members.  
253

254 To streamline communications and have a mutual understanding of the preferences and  
255 expectations for IND sponsor/FDA communications during drug development, it is  
256 recommended that sponsors and FDA project managers, particularly the review division RPM  
257 responsible for managing their application, establish a mutually agreeable communication  
258 strategy. The informal communication strategy can be established early in the development  
259 program (i.e., around the time of IND submission) and adjusted at any time when there are  
260 outstanding issues (e.g., feedback on a new protocol) or modifications to the development  
261 program that might warrant more frequent or possibly less frequent contacts. A communication  
262 strategy might include the preferred method(s) (e.g., email versus telephone) and frequency of  
263 communications and/or approaches for managing information requests and responses (e.g., one  
264 request at a time versus bundled requests). As part of a communication strategy, sponsors and  
265 FDA should share contact information for alternative back-ups (e.g., the CDER review division  
266 CPMS or the CBER alternative project management staff) and the mutual expectations for the  
267 timing of responses to inquiries (see section VI., General Expectations for Timing of  
268 Communications).  
269

270 For breakthrough therapy-designated drugs, a formal communication plan is established at the  
271 initial comprehensive multidisciplinary meeting between FDA and the sponsor. The plan  
272 includes the expectations on the timing and format of interactions and information exchange. As  
273 is the case for all drug development plans, the review division RPM is the primary point of

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<sup>15</sup> 21 CFR 312.23(a)(1)(viii) describes the information to provide in an IND when a sponsor has transferred any obligations for the conduct of any clinical study to a contract research organization.

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274 contact for communications between FDA and sponsors for drugs developed under the  
275 breakthrough therapy program and other expedited programs.<sup>16</sup>

276  
277

### **V. TYPES OF ADVICE THAT ARE APPROPRIATE FOR SPONSORS TO SEEK**

279

280 During the life cycle of drug development, sponsors routinely solicit feedback from FDA on both  
281 scientific and regulatory issues. The breadth and frequency of advice sought can vary according  
282 to the experience of the sponsor, as well as the novelty and development stage of the proposed  
283 drug. During the IND phase of development, sponsors often solicit advice at critical junctures in  
284 their development program. These topics include, but are not limited to the following:

285

- 286 • Regulatory (e.g., plans for submission of proprietary name requests, plans to defer or  
287 waive specific studies, development plans with other FDA centers (e.g., the Center for  
288 Devices and Radiological Health) for combination products), applicability of an  
289 expedited program
- 290
- 291 • Clinical/statistical (e.g., planned clinical trials to support effectiveness, validity of  
292 outcomes and endpoints, trial size, enrichment designs)
- 293
- 294 • Safety (e.g., safety issues identified in nonclinical studies and early clinical trials, size of  
295 the overall safety database, concerns related to particular populations, postapproval  
296 pharmacovigilance plans, risk evaluation and mitigation strategies, plans for human  
297 factors studies, issues related to evaluation of abuse potential)
- 298
- 299 • Clinical pharmacology and pharmacokinetics (e.g., dose selection, use in specific  
300 populations, drug-drug interactions)
- 301
- 302 • Nonclinical pharmacology, pharmacokinetics, and toxicology (e.g., genetic toxicology,  
303 reproductive and developmental toxicology, carcinogenicity, mechanism of action)
- 304
- 305 • Product quality (e.g., proposed shelf life and stability studies, delivery systems,  
306 characterization of drug substance/product, facility compliance with good manufacturing  
307 practices, comparability of lots used in clinical trials and commercial lots)
- 308
- 309 • Pediatrics (e.g., proposed pediatric development plan, dosing)

310

311 Because FDA resources are limited, sponsors are strongly encouraged to first seek answers to  
312 their scientific and regulatory questions from the multitude of resources available to them, such  
313 as the FDA resources described in section VII.I., Resources for Sponsors. Sponsors also can  
314 employ an independent consultant for assistance in conceiving strategic drug development and  
315 regulatory plans. In doing so, this allows both sponsors and FDA to conserve their respective  
316 resources to address the more complex and challenging drug development issues.

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<sup>16</sup> See the guidance for industry *Expedited Programs for Serious Conditions — Drugs and Biologics*.

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When soliciting feedback from FDA, sponsors should keep in mind the following:

- FDA policy positions are typically documented and described in FDA guidances, MAPPs, and SOPPs.
- Complex scientific/technical drug development questions should be directed to the FDA project manager, typically the review division RPM, via either a submission or through the formal meeting request process.
- General questions that cannot be answered by using existing resources can be directed to an FDA project manager, to the designated enhanced communication staff within each FDA center, or to CDER's Division of Drug Information, (see section VIII., Additional Contacts). Depending on the nature and complexity of the question(s), FDA will either respond to the question(s) or redirect the sponsor to an alternative pathway for receiving a response (e.g., other FDA subject matter expert, formal meeting request process).

### **VI. GENERAL EXPECTATIONS FOR TIMING OF COMMUNICATIONS**

FDA recognizes that timely and effective communication with sponsors during the IND phase of drug development provides sponsors with information they seek to inform the design of studies and trials, as well as product quality information, intended to support approval of a future marketing application. As such, FDA staff strive to respond to sponsor questions promptly while balancing FDA public health priorities and their other workload responsibilities, noting that responses to safety-related inquiries will be prioritized higher than other inquiries in alignment with FDA's previously stated primary responsibilities with respect to INDs.

During the course of these collaborative interactions, sponsors sometimes pose questions to FDA that they perceive as being simple or clarifying questions with the expectation that only minimal time will be needed for an FDA response. However, what appear to the sponsor to be simple or clarifying questions are often more complex and necessitate significant review and communication among review team members, including conducting an internal meeting(s), before an answer can be provided. For example, questions that involve interpretation of regulations and statutes, or application of existing FDA policy to novel circumstances, are often complex (*not simple*) and therefore demand additional vetting and response time. Similarly, questions involving combination products usually demand significant time to solicit and consider feedback from multiple FDA centers. In all cases, FDA takes a thoughtful and measured approach to answering sponsor questions efficiently and comprehensively, particularly those questions that are likely to have an important impact on critical decision points in development programs or that represent FDA views related to the evidence that will be used to support marketing.

Complex scientific/technical, policy, or regulatory questions are best posed to FDA in either requests for formal meetings or in formal submissions. Traditionally, FDA has taken a

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362 collaborative approach to responding to questions included in meeting packages and in  
363 submissions according to their respective prespecified timelines as follows:

- 364
- 365 • **Meetings.** Communications that involve sharing results and information at critical  
366 milestones during drug development or are necessary for a stalled development program  
367 to proceed are best addressed in formal meetings between FDA and sponsors (e.g., face-  
368 to-face meeting, teleconference, or written response only (WRO)). Timelines for FDA  
369 sending feedback to sponsors via the formal meeting process are described in Prescription  
370 Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA) agreements<sup>17</sup> and in  
371 FDA's formal meetings guidances.<sup>18</sup> This FDA feedback includes: preliminary  
372 comments, final meeting minutes, and responses to questions posed in WRO requests.  
373
  - 374 • **Submissions.** Hundreds of supporting documents might be submitted to an IND during  
375 its life cycle that require varying degrees of review and for which communication with  
376 the sponsor may be needed. Some submissions have regulatory-mandated timelines for  
377 reviewing and providing feedback to the sponsor that are described by statute or  
378 regulation (e.g., some safety-related submissions, complete response to clinical hold<sup>19</sup>)  
379 while other submissions have FDA-established goals for review and feedback (e.g., in a  
380 MAPP). These latter submission types include some safety-related submissions, drug  
381 development submissions without regulatory timelines where communication to the  
382 sponsor is often critical and recommended (e.g., a new protocol or protocol amendment),  
383 and other submissions where communication with the sponsor may be needed.  
384

385 For all other sponsor inquiries, received via telephone, email, or in a submission (i.e., a  
386 submission without a review timeline described in a MAPP), that include specific questions for  
387 which sponsors are seeking FDA feedback, FDA project managers will strive to *acknowledge*  
388 such communications via telephone or email within 3 business days of receipt by the FDA  
389 project manager. FDA's acknowledgment will:

- 390
- 391 • Include the response itself, if available within the acknowledgment time frame;
  - 392
  - 393 • Include an estimated time frame for division response to question(s);
  - 394
  - 395 • Inform the sponsor that its question(s) involve consultation with other FDA parties (e.g.,  
396 policy questions where legal input is necessary, questions about combination products  
397 where other centers are involved) and therefore an estimated response time frame will be  
398 forthcoming;

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<sup>17</sup> See <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm> or  
<http://www.fda.gov/forindustry/userfees/biosimilaruserfeeactsufa/default.htm>.

<sup>18</sup> See the guidances for industry *Formal Meetings Between the FDA and Sponsors or Applicants* and *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants*. See also the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

<sup>19</sup> See 21 CFR 312.42(e).

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- Recommend that the sponsor submit a formal meeting request (e.g., face to face, teleconference, or WRO); or
- Recommend that the sponsor contact another specialized functional area in FDA (e.g., Import/Export, orphan products or rare diseases, pediatric therapeutics)

Similarly, sponsors should:

- Acknowledge receipt of FDA’s information requests (written or otherwise)
- Provide the project manager with an estimated response time

Because sponsor delays in responding, or lack of response, to FDA information requests can negatively affect later development, it is equally important for sponsors to respond completely and promptly to FDA requests.

Note that although FDA strives to adhere to all established or estimated response timelines, FDA may not always be able to meet these timelines. If unexpected complex issues arise during the review of an IND submission, FDA will provide an answer when it is fully formed, rather than adhering to a timeline when doing so may not provide useful information to a sponsor. The timing of FDA response may also be negatively affected if the review team experiences an unexpected shift in work priorities or team staffing. In these cases, the FDA project manager will try to keep sponsors apprised of changes to the estimated response timeline. When sponsors encounter delays in obtaining FDA response to questions for which they have solicited feedback, the following approach should be taken sequentially:

- Contact the appropriate FDA project manager, typically the review division RPM, for a status update after the expected amount of time (e.g., the timelines described in a MAPP) for FDA response has passed;

*Or*

Contact the appropriate FDA project manager, typically the review division RPM, for a status update after the estimated response time has passed (i.e., the estimated FDA-response date communicated to the sponsor previously)

- Contact the appropriate FDA project manager’s next level supervisor for assistance in eliciting a response from the project manager
- Contact the appropriate division or office management officials for assistance in eliciting a response from the project manager
- Contact CDER’s ECT or CBER’s Ombudsman for assistance in eliciting a response from the project manager

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### 445 **VII. BEST PRACTICES AND COMMUNICATION METHODS**

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447 Effective and timely communication between FDA and sponsors promotes understanding of  
448 mutual goals and is invaluable to the drug development process. Central to this is the ability to  
449 communicate clearly, both orally and in writing, inside and outside the formal meeting format. It  
450 is also important that FDA and sponsors have a common understanding of terms and phrasing  
451 used in communications with each other, and that they are used consistently by both parties. In  
452 FDA communications related to INDs:

453

454 • As a best practice, FDA staff will use words such as *shall, must, required, or requirement*  
455 to convey a statutory or regulatory requirement.

456

457 • As a best practice, FDA staff will use the following words to communicate advice (e.g.,  
458 on trial design), comments, or current thinking often include the following terminology:  
459 *advisable, critical, important, may be appropriate, should, consider, discourage,*  
460 *encourage, prefer, recommend, suggest, or urge.* Because FDA has the advantage of  
461 viewing the spectrum of drug development across sponsors, indications, and drug classes,  
462 FDA is able to communicate advice to sponsors with that expertise in mind, while  
463 upholding commercial confidentiality.

464

465 The IND phase of drug development is typically a multiyear process, and FDA staff recognize  
466 that new data will become available and that scientific advances and changes in clinical practice  
467 may occur during this time. Because sponsors are ultimately responsible for managing the  
468 overall development program for their proposed drug, sponsors should closely monitor for  
469 advances in the field and/or changes in FDA guidance, and inquire if those changes may  
470 necessitate changes in prior FDA recommendations for their development program. Although  
471 FDA reviewers consider new information and revise recommendations as needed, they try to  
472 support and adhere to their prior critical recommendations where appropriate. Changes in  
473 recommendations are expected to be based on new scientific or safety information or advances in  
474 clinical practice that make earlier FDA recommendations outdated, inappropriate, or unethical.  
475 In such cases, review staff via the project manager should inform sponsors in writing of these  
476 changes and the rationale behind the changes.

477

478 Both FDA and sponsors use various communication methods for focusing discussions to  
479 effectively exchange information and resolve issues. Because there are different business  
480 cultures, communication styles, preferences, and documentation needs, there is no single best  
481 communication method. Rather, there are best practices that enhance each method. For  
482 example, telephone communication between a sponsor and the FDA project manager may be  
483 more effective than email for time-sensitive matters. A best practice would be to follow up after  
484 the phone call with a written communication (e.g., email, submission, correspondence) so that  
485 there is documentation of decisions, agreements, or action items that arose during the contact.

486

487 The best practices and communication methods described within this section are intended to  
488 identify means of exchanging information in ways that permit efficient, timely, and targeted  
489 review of sponsors' questions. They were developed by gathering the experiences of CDER and  
490 CBER staff and by incorporating input from interested parties. Communication via any of these



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491 methods (except meetings where numerous attendees participate) should be conducted via the  
492 FDA project manager, typically the review division RPM, rather than FDA reviewers, team  
493 leaders, or senior management to ensure that the advice is appropriately vetted and documented.  
494

### **A. Meetings Between FDA and Sponsors**

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496  
497 Meetings are useful in resolving questions and issues raised during the life cycle of drug  
498 development. There are important reasons for sponsors to discuss development plans with FDA.  
499 FDA can provide valuable scientific and regulatory advice, resulting in more efficient and robust  
500 development programs. FDA can also help sponsors define adequate evidence of effectiveness,  
501 safety, and product quality. It is critical to efficient drug development for sponsors to ascertain  
502 FDA's views on the applicable statutory and evidentiary requirements well in advance of  
503 submission of an application.  
504

505 Meetings between FDA and a sponsor at critical junctures in drug development can be especially  
506 helpful in minimizing wasteful expenditures of time and resources and thus in speeding the drug  
507 development and evaluation process. These milestone meetings include pre-IND, end-of-phase 1  
508 (EOP1), end-of-phase 2 (EOP2), and pre-NDA/BLA meetings.  
509

- 510 • Pre-IND meetings are valuable for understanding proof of concept and initiating dialogue  
511 for drug development in its early stages. They can prevent clinical hold issues from  
512 arising and aid sponsors in developing a complete IND submission. FDA encourages  
513 sponsors to request a pre-IND meeting for the following: a drug not previously  
514 approved/licensed, a new molecular entity (NME), a planned marketing application  
515 intended to be submitted under the 505(b)(2) regulatory pathway, drugs for which it is  
516 critical to public health to have an effective and efficient drug development plan (e.g.,  
517 counter-terrorism), drugs with substantial early development outside the United States, a  
518 planned human factors development program, and drugs with adequate and well-  
519 controlled trials to support a new indication. However, a sponsor of any IND can request  
520 a pre-IND meeting. Because of limitations of FDA resources, it is common for review  
521 divisions to use the WRO meeting procedures for pre-IND meetings; however, in  
522 selected circumstances a face-to-face meeting or teleconference may be granted.  
523
- 524 • EOP1 meetings are useful to review and reach agreement on the design of phase 2  
525 controlled clinical trials and to discuss issues related to the proposed drug development  
526 program, including pediatric study plans, as appropriate. Because of limited resources,  
527 FDA has traditionally encouraged sponsors to request an EOP1 meeting only for drugs  
528 intended to treat life-threatening and severely debilitating illnesses, particularly situations  
529 where approval based on phase 2 trials or accelerated approval may be appropriate.<sup>20</sup>  
530
- 531 • EOP2 meetings are of considerable importance in planning later studies and in  
532 determining the safety of proceeding to phase 3. EOP2 meetings evaluate the phase 3  
533 plan and protocols, the adequacy of current studies and plans to assess pediatric safety

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<sup>20</sup> See 21 CFR part 312, subpart E.

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534 and effectiveness, the human factors validation plan, and identify any additional  
535 information necessary to support a marketing application for the uses under investigation.  
536 FDA encourages sponsors to request an EOP2 meeting for NMEs or major new uses of  
537 marketed drugs. However, a sponsor of any IND can request an EOP2 meeting.  
538

- 539 • Pre-NDA/BLA meetings are helpful in acquainting FDA reviewers with the format and  
540 content of the planned application, including labeling and risk management activities (if  
541 applicable), presentation and organization of data, dataset structure, acceptability of data  
542 for submission, as well as the projected submission date of the application. They are also  
543 intended to uncover major issues, identify studies intended to establish the drug's safety  
544 and effectiveness, discuss the status of pediatric studies, and discuss appropriate  
545 statistical analysis methods, or results of analyses. FDA encourages sponsors to request  
546 pre-NDA/BLA meetings for all planned marketing applications, particularly applications  
547 to be reviewed under the PDUFA V Program for Enhanced Review Transparency and  
548 Communication for NME NDAs and Original BLAs.<sup>21</sup>  
549

550 Feedback to sponsors via the formal meeting process is provided in three main formats: face-to-  
551 face meetings, teleconferences, and WRO responses. Detailed information about meeting  
552 requests, packages, scheduling, preparation, conduct, and documentation (meeting minutes) are  
553 described in other guidances.<sup>22</sup> The timelines are described in PDUFA and BsUFA agreements.  
554

555 The following represent meeting-related best practices for the various meeting formats.  
556

- 557 • **Meeting Requests**

- 558
  - 559 – Before requesting a meeting with FDA, sponsors should use the expansive sources of  
560 drug development information that are publically available. See section VII.I.,  
561 Resources for Sponsors.
  - 562
  - 563 – Sponsors are encouraged to request feedback via formal meetings with FDA at the  
564 major drug development milestones described above. FDA typically grants meeting  
565 requests at these major milestones.
  - 566
  - 567 – Sponsors should only submit milestone meeting requests when drug development has  
568 progressed to the point where a full discussion of issues germane to that development  
569 stage is possible. Premature meeting requests are often denied by FDA.
  - 570

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<sup>21</sup> As part of its commitments in PDUFA V, FDA established a new review program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative drugs reviewed by FDA. This new review program applies to all NME NDAs/original BLAs that are received from October 1, 2012, through September 30, 2017. See <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327030.htm>.

<sup>22</sup> See the guidances for industry *Formal Meetings Between the FDA and Sponsors or Applicants* and *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants*. See also the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

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- 571 – In lieu of a traditional meeting with FDA (i.e., face-to-face or teleconference),  
572 sponsors also can seek feedback through WRO requests, specifically for pre-IND  
573 feedback and feedback that would otherwise have been requested in a Type C  
574 meeting request.<sup>23</sup> To conserve resources, FDA may also exercise discretion in  
575 converting a traditional meeting request for a pre-IND or Type C meeting to WRO  
576 responses. The number of questions posed in a WRO request should be no more than  
577 what would be reasonably expected to be addressed in a traditional meeting's allotted  
578 duration.
- 579
- 580 – Sponsors should outline the purpose of the meeting in the meeting request.
- 581
- 582 – Sponsor's meeting requests should include their preferred dates and requested FDA  
583 attendees. FDA project managers should take these preferences into consideration  
584 when scheduling meetings.
- 585
- 586 – Sponsors should try to anticipate future needs and, to the extent practical, combine  
587 discussion of drug development issues into the fewest possible meetings.
- 588
- 589 • **Meeting Packages.** Premeeting preparation is critical for achieving a successful meeting  
590 with productive discussion and exchange of information.
- 591
- 592 – Sponsors should submit meeting packages for all meeting formats, including WRO,  
593 within the timelines described in PDFUA and BsUFA agreements. FDA grants and  
594 schedules meetings expecting that appropriate information to support the discussion  
595 will be submitted with sufficient time for review and preparatory discussion. Thus,  
596 the meeting or WRO may be cancelled if the meeting packages are not received  
597 within the specified timelines.
- 598
- 599 – Sponsors should submit a limited number of clearly worded and targeted questions  
600 that directly address concerns about the drug and development program. The number  
601 of questions in a meeting package should not exceed what can be reasonably  
602 discussed within the duration of allotted meeting time.
- 603
- 604 – Sponsors should provide sufficient data to support the questions being asked. If the  
605 meeting package is determined to be inadequate or too voluminous, the meeting may  
606 be rescheduled.
- 607
- 608 – Sponsors' meeting packages should be well-organized and tabbed to enhance the  
609 readability of the background information both before and during the meeting.
- 610
- 611 – FDA project managers should send preliminary responses to sponsor questions before  
612 the meeting so that the meeting time can be dedicated to unresolved issues for which  
613 more discussion is needed. In the preliminary responses, FDA should provide high-

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<sup>23</sup> Ibid.

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614 level recommendations for important issues identified during the review of the  
615 meeting package, even if questions concerning those issues were not explicitly posed  
616 by the sponsor.  
617

- 618 • **Meeting Conduct**  
619

- 620 – Sponsor presentations generally are not needed because the information necessary for  
621 review and discussion should have been included in the meeting package. Instead,  
622 valuable meeting time should be preserved for a focused discussion of issues  
623 identified in the meeting package, particularly those that are still unresolved after  
624 FDA’s preliminary responses have been sent to the sponsor or that have been raised  
625 in FDA’s responses.  
626

- 627 – Meeting facilitators should keep the discussion focused on the questions posed by the  
628 sponsor in the meeting package, as well as relevant FDA preliminary responses,  
629 taking into account the total time available for discussion of the questions. During  
630 the course of the meeting, sponsors should generally not ask substantive questions  
631 that were not included in the meeting package, or present new data or information  
632 that was not previously provided to FDA or requested by FDA in their preliminary  
633 comments. Such questions and presentation of new data generally are best addressed  
634 in a subsequent communication or meeting request to FDA.  
635

- 636 – Pre-IND and pre-NDA/BLA meetings should include a discussion of what constitutes  
637 a complete application to ensure there is mutual understanding and agreement on the  
638 contents of a complete application.  
639

- 640 – Sponsors and/or FDA attendees should summarize important discussion points,  
641 agreements, clarifications, and actions items either at the end of the meeting or after  
642 the discussion of each question. It is helpful for the sponsor to provide an overall  
643 summary of the discussion at the end of the meeting to ensure that there is mutual  
644 understanding of meeting outcomes and action items.  
645

- 646 • **Meeting Minutes.** FDA’s documentation of meeting outcomes, agreements,  
647 disagreements, and action items is critical to ensuring that this information is preserved  
648 for meeting attendees and future reference, because the FDA minutes are the official  
649 record of the meeting.  
650

- 651 – FDA minutes of meetings with IND sponsors are not intended to represent a  
652 transcript of the meeting but rather are intended to summarize the important elements  
653 of the discussion while also identifying any agreements, disagreements, and action  
654 items that were identified during the meeting.  
655

- 656 – FDA project managers will use established meeting minutes templates to ensure that  
657 all important meeting information is captured.  
658

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- 659 – FDA project managers will issue meeting minutes, or provide responses to WRO  
660 requests, according to the timelines described in PDUFA and BsUFA agreements.  
661  
662 – If there is a significant difference in the sponsor’s and FDA’s understanding of the  
663 content of the meeting minutes, sponsors should seek resolution by notifying FDA of  
664 their understanding of the discrepancy.  
665

### **B. Written Correspondence From FDA**

666 FDA project managers will use established letter templates to ensure consistency and accuracy in  
667 regulatory communications. Project managers should send a courtesy copy of written FDA  
668 correspondence to sponsors via secure email when such communications are time-sensitive or  
669 communicate actions (e.g., clinical hold). Project managers should send the courtesy copy via  
670 fax, if secure email has not been established by the sponsor.  
671  
672

### **C. Submissions From Sponsors**

673  
674 During the life cycle of IND drug development, sponsors submit an array of regulatory  
675 submissions to FDA that require varying degrees of review, response, and/or feedback. The  
676 regulations under 21 CFR part 312, subparts B and C,<sup>24</sup> describe types of submissions that are  
677 required to be submitted by sponsors during the IND phase of drug development. Some are  
678 administrative in nature (e.g., investigator information, meeting request, request for inactivation,  
679 annual reports), others focus on patient safety (e.g., IND safety reports, response to clinical hold  
680 deficiencies), and others describe clinical and nonclinical trial plans (e.g., protocols and protocol  
681 amendments, pediatric study plans, information amendments including drug quality  
682 amendments) for which sponsors may seek FDA comment and advice. Detailed information  
683 about the review of IND submissions, including FDA-established or regulatory-mandated review  
684 timelines, is described in a CDER MAPP.<sup>25</sup>  
685  
686

687 Sponsors must adhere to required timelines for their submissions (e.g., IND safety reports,  
688 annual reports).<sup>26</sup> In addition, FDA regulations describe the timing requirements for submitting  
689 a new protocol as an amendment to an IND that is already in effect or for when a new  
690 investigator is added to carry out a previously submitted protocol.<sup>27</sup> When several submissions  
691 of new protocols or protocol changes are anticipated during a short period, the sponsor is  
692 encouraged, to the extent feasible, to include these all in a single submission.<sup>28</sup> Information  
693

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<sup>24</sup> See, for example, 21 CFR 312.23, 312.30, 312.31, 312.32, 312.33, and 312.42.

<sup>25</sup> CDER MAPP 6030.9 *Good Review Practice: Good Review Management Principles and Practices for Effective IND Development and Review*.

<sup>26</sup> 21 CFR part 312

<sup>27</sup> 21 CFR 312.30(b)

<sup>28</sup> 21 CFR 312.30(e)

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694 amendments to the IND should be submitted as necessary but, to the extent feasible, not more  
695 often than every 30 days.<sup>29</sup>

696  
697 FDA regulations describe general principles of, as well as content and format requirements for,  
698 INDs.<sup>30</sup> Complete and well-organized sponsor submissions, in a format appropriate for scientific  
699 review, can increase the efficiency of FDA review. FDA Form 1571 is an administrative form  
700 that should accompany most IND submissions to indicate the content and purpose.<sup>31</sup> All IND  
701 submissions should include an overall summary sufficient to allow FDA staff to understand the  
702 regulatory and developmental context of the submission. The summary, which usually  
703 comprises the first page of the submission, should list the objectives of the submission, and  
704 include any questions the sponsor would like addressed in writing. Questions to FDA should be  
705 framed within the regulatory context to allow reviewers to understand why the issue is important.

706  
707 FDA encourages sponsors to identify issues or areas of concern in their submissions by  
708 describing them fully and soliciting feedback on specific areas of concern where further  
709 progression in drug development depends largely on receiving FDA feedback. Sponsors run the  
710 risk of not receiving timely FDA feedback, and therefore conducting an inefficient or inadequate  
711 development program that may increase the length of time to approval, if they omit important  
712 information, do not identify the regulatory intent of the submission, or provide insufficient detail.

713

### **D. Acknowledging Receipt of Communications**

714

715  
716 FDA project managers will send written acknowledgment of receipt of certain submissions that  
717 have review timelines (e.g., charging request, request for fast track designation). They will also  
718 strive to acknowledge receipt of questions received from sponsors via telephone calls, emails,  
719 and other submissions within 3 business days of receipt by the project manager. The  
720 acknowledgment may include: the response itself, an estimated response time frame, notification  
721 that the question(s) have been consulted to other offices/centers with an undetermined response  
722 time frame, a recommendation to submit the questions via a formal meeting request, or  
723 redirection to another specialized functional area in FDA (e.g., Import/Export).

724

725 Sponsors should likewise acknowledge receipt of FDA information requests and provide an  
726 estimated response time.

727

### **E. Email Between FDA and Sponsors**

728

729  
730 Use of secure email allows transparent and complete communication between FDA and sponsors  
731 although it is not a substitute for formal submissions (e.g., new INDs and amendments); formal  
732 submissions should be submitted to the respective center's document room (paper submissions)  
733 or via the electronic gateway, as applicable. FDA communication via unsecure email cannot

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<sup>29</sup> 21 CFR 312.31(c)

<sup>30</sup> 21 CFR 312.22, 312.23

<sup>31</sup> See 21 CFR 312.23(a)(1).

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734 include commercial confidential information (e.g., trade secrets, manufacturing, or patient  
735 information). Therefore, sponsors should establish secure email with FDA to allow for informal  
736 communications that may include commercial confidential information.<sup>32</sup>  
737

738 Sponsors should contact the Office of Information Management (OIM) to request secure email.<sup>33</sup>  
739 OIM provides requestors with general industry standard practices and instructions on how to  
740 obtain FDA digital certificates but does not otherwise provide outside support. If a digital  
741 certificate has expired, sponsors should send a signed message with the current digital signature  
742 to the email address provided on the Electronic Regulatory Submission and Review Web page.  
743

### **F. General Telephone Calls Between FDA and Sponsors**

744  
745  
746 General or administrative questions are suitable for informal communications between sponsors  
747 and FDA project managers via telephone. However, when complex, regulatory, or technical  
748 issues are discussed during the course of a telephone conversation between the sponsor and the  
749 FDA project manager, the caller should follow-up with a written communication (e.g., email,  
750 sponsor submission, FDA correspondence) to document the discussion and/or respond to  
751 information requested during the conversation. Telephone calls, even when documented in the  
752 administrative record, are not a substitute for formal submissions such as a formal meeting  
753 request, IND amendment, or a request for a special protocol assessment. Depending on the  
754 nature of the questions presented during the conversation, the sponsor may be referred to the  
755 formal meeting process for a fuller discussion of the issue(s) with additional review staff and  
756 management.  
757

758 Both FDA project managers and sponsors should provide mutual names and telephone numbers  
759 for communicating time-sensitive issues (e.g., notification of clinical hold). This contact  
760 information should be included in out-of-office messages, whenever appropriate.  
761

### **G. Faxes Between FDA and Sponsors**

762  
763  
764 A fax can be used when secure email has not been established between FDA and sponsors  
765 although it is not a substitute for formal submissions (e.g., new INDs and amendments); formal  
766 submissions should be submitted to the respective center's document room (paper submissions)  
767 or via the electronic gateway, as applicable. Before transmitting the fax, sponsors and FDA  
768 project managers should contact their respective counterparts to arrange for confirmation of  
769 receipt. Given the volume of communications received by FDA, this reduces the possibility that  
770 faxes will be overlooked. To facilitate accurate and timely routing, a coversheet should be  
771 included with the fax. Faxes should be sent to FDA during official business hours (8:00 a.m. to  
772 4:30 p.m. EST/EDT) Monday through Friday (except Federal government holidays).

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<sup>32</sup> Sponsors that are unable to establish secure email should contact the appropriate review division to discuss acceptable alternative arrangements for communication.

<sup>33</sup> See the Electronic Regulatory Submission and Review Web page for contact information (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm2007043.htm>).

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### **H. Use of Out-of-Office Messages by FDA and Sponsors**

IND sponsors and FDA staff should alert others to their unavailability by using email and voicemail out-of-office messages. The messages should include an expected return time and contact information for other staff that may be able to assist in the interim, particularly for time-sensitive communications (e.g., notification of clinical hold). FDA project managers should also include contact information for their division's CPMS in CDER or the alternative project management staff in CBER.

### **I. Resources for Sponsors**

To disseminate a broad range of information in a manner that can be easily and rapidly accessed by interested parties, FDA develops and maintains Web pages, portals, and databases, and participates in interactive media as a means of providing self-service tools for its stakeholders, including IND sponsors. Sponsor use of these tools allows for more effective utilization of limited FDA resources in providing advice on scientific and regulatory issues that fall outside of established guidance, policy, and procedures.

#### *1. FDA Guidances*

FDA uses guidance documents to explain its current thinking on policy, scientific, and/or regulatory issues.<sup>34</sup> FDA guidances are useful for industry and other stakeholders and FDA staff that may refer to them to address such matters as the design, manufacturing, and testing of regulated products; scientific issues; content and evaluation of applications for product approvals; and inspection and enforcement policies. In general, FDA guidances do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. However, stakeholders can use an alternative approach if the approach satisfies the requirements of applicable laws and regulations. For available guidances, see the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

#### *2. FDA Policy and Procedures*

CDER's MAPPs document CDER internal policies and procedures. MAPPs are made available to the public to make CDER a more transparent organization. A listing of CDER MAPPs can be found at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

CBER's SOPPs document CBER internal policies and procedures. SOPPs are made available to the public to make CBER a more transparent organization. CBER's SOPPs are organized by area of activity. A listing of CBER SOPPs can be found at

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<sup>34</sup> See 21 CFR 10.115.



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817 [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Proce-](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm)  
818 [duresSOPPs/default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm).

819

### 820 3. *FDA Basics for Industry*

821

822 The FDA Web site contains two Web pages that provide basic information for industry.

823

824 The FDA Basics for Industry Web page is a portal to information frequently requested by  
825 industry about the regulatory process and to resources on understanding how to work with the  
826 FDA. It is intended to improve communication between FDA and industry by providing basic  
827 information about the regulatory process in a user-friendly format. The FDA Basics for Industry  
828 Web page can be found at <http://www.fda.gov/FDABasicsforIndustry>.

829

830 The Investigator-Initiated Investigational New Drug (IND) Applications Web page includes links  
831 to information for investigators about submitting INDs to FDA and can be found at  
832 [http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm)  
833 [ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm343349.htm).

834

### 835 4. *FDA Interactive Media*

836

837 FDA uses interactive media to broadcast emerging science, new policies, procedures, guidances,  
838 MAPPs, SOPPs, and public advisory committee meetings or workshops that affect drug  
839 development. When appropriate, FDA uses interactive media channels to disseminate  
840 information that can inform drug development for sponsors. To stay informed, sponsors and  
841 review staff should subscribe to interactive media. A listing of interactive media resources can  
842 be found at <http://www.fda.gov/NewsEvents/InteractiveMedia/default.htm>.

843

### 844 5. *FDA Presentations*

845

846 CDER's Presentation Library provides access to information about FDA policies and procedures  
847 presented to external audiences at meetings, conferences, and workshops sponsored or co-  
848 sponsored by FDA. The information covers a range of topics, including, for example, user fees,  
849 drug advertising and marketing, genomics, drug quality, and nonprescription drugs. Materials  
850 and overviews from some of these meetings are listed in the presentations library at  
851 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/uc-](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm)  
852 [m074833.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm).

853

854 CBER's Web-based outreach program provides presentations about the work each of the CBER  
855 offices performs. A listing of available presentations can be found at  
856 <http://www.fda.gov/BiologicsBloodVaccines/InternationalActivities/ucm273267.htm>.

857

### 858 6. *FDA Labeling and Approvals*

859

860 CDER's Drugs@FDA database contains information about FDA-approved brand name and  
861 generic prescription and nonprescription human drugs and the biological therapeutic products  
862 regulated by CDER. It includes most of the approvals since 1939 and the majority of patient

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863 information, labels, approval letters, reviews, and other information for drug products approved  
864 since 1998. The database can be used to view approval history and find: all drugs with a  
865 specific active ingredient, consumer information, therapeutically equivalent drugs for an  
866 innovator or generic, generic drugs for an innovator, and labels for approved drugs. The  
867 database can be found at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

868

869 CBER's Biologics Products & Establishments Web page contains searchable information and  
870 supporting documents for approved NDAs regulated by CBER, licensed biological products  
871 (except for therapeutic biological products regulated by CDER), premarket approvals,  
872 humanitarian device exemptions, and cleared 510(k) submissions. It includes a complete list of  
873 licensed products and establishments and an FDA Online Label Repository. The Web page also  
874 contains information regarding 510(k) blood establishment computer software, donor screening  
875 assays for infectious agents and HIV diagnostic assays, a complete list of vaccines licensed for  
876 immunization and distribution in the United States, and reports including the User Fee Billable  
877 Biologic Products and Potencies Approved Under Section 351 of the PHS Act report. This Web  
878 page can be found at <http://www.fda.gov/BiologicsBloodVaccines/ucml21134.htm>.

879

880 The FDA Pediatric Labeling Information Database is a searchable list that highlights key  
881 pediatric information from the studies submitted in response to pediatric legislative initiatives.  
882 For information on new pediatric information that has been added to product labeling since  
883 September 9, 2007, see  
884 <http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=labelingdatabase>.

885

### 7. *FDA Rules and Regulations*

887

888 FDA publishes regulations and other notices in the *Federal Register*, the Federal government's  
889 official publication for notifying the public of many kinds of agency actions. FDA's Rules &  
890 Regulations Web page contains information about the notice and comment rulemaking process,  
891 the review of proposed and final rules, and related resources. See  
892 <http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm>.

893

### 8. *Code of Federal Regulations*

895

896 The Code of Federal Regulations (CFR) is the codification of the general and permanent rules  
897 published in the *Federal Register* by the departments and agencies of the Federal government.  
898 Final rules are integrated into the CFR by the Office of the Federal Register and Government  
899 Publishing Office staff. Regulations under 21 CFR part 312 contain the procedures and  
900 requirements governing the use of investigational new drugs, including procedures and  
901 requirements for the submission to, and review by, FDA of INDs.<sup>35</sup> See  
902 <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>.

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<sup>35</sup> 21 CFR 312.1

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904 The Electronic Code of Federal Regulations (e-CFR) is a current, daily updated version of the  
905 CFR.<sup>36</sup> It is not an official legal edition of the CFR. The e-CFR is an unofficial editorial  
906 compilation of CFR material and *Federal Register* amendments. The Office of the Federal  
907 Register updates the material in the e-CFR on a daily basis. Generally, the e-CFR is current  
908 within 2 business days. See <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>.  
909  
910

### **VIII. ADDITIONAL CONTACTS**

912  
913 As stated in section IV., Scope of Interactions Between the Sponsor and the Review Team, the  
914 review division RPM is the primary point of contact between sponsors and FDA during drug  
915 development, and reviewers, team leaders, and senior management generally should not be  
916 contacted directly. However, in certain limited circumstances, sponsors can directly contact  
917 other FDA project managers (see examples in section IV) or FDA staff who: (1) serve as  
918 resources in specific functional areas (e.g., product quality, pediatrics, orphan drugs or rare  
919 diseases, combination products, GCP, import/export, product jurisdiction) for the purposes of  
920 obtaining direct answers to simple regulatory, procedural, or administrative questions related to  
921 those functional areas; (2) serve as an alternative means to obtain general information (e.g.,  
922 CDER's Division of Drug Information (DDI), Small Business and Industry Assistance (SBIA),  
923 and ECT; CBER's Manufacturers Assistance and Technical Training Branch (MATTB); CDER  
924 or CBER Ombudsmen); or (3) address issues that arise in the context of the regulatory process  
925 (e.g., ombudsmen).  
926

927 Inquiries sent to any of the specific functional areas or general contacts listed herein should not  
928 include questions that are integral to an existing or planned drug development plan (e.g.,  
929 questions concerning clinical trial design, amount of data needed to support future phases of  
930 development or approval, nonclinical study requirements). Those types of questions should  
931 always be directed to the appropriate project manager, typically the review division RPM,  
932 because those questions are best answered by review staff who have properly considered the  
933 question within the context of the sponsor's overall development plan, as well as having vetted  
934 their advice with appropriate review team members and documented the advice or decisions  
935 rendered to the sponsor. By using these additional contacts and resources appropriately,  
936 sponsors may receive timely and comprehensive responses to basic or procedural questions in  
937 these functional areas that they can apply in parallel with the scientific, technical, and regulatory  
938 advice they receive directly from the review division RPM during the course of their drug  
939 development program. Responses to other basic or procedural drug development questions not  
940 tied to an existing or planned development program (e.g., IND exemptions, expanded access,  
941 adverse event reporting, FDA forms) can be directed to DDI/MATTB if not listed separately  
942 here.  
943

944 When sponsors do choose to contact one of these resources via email, the review division RPM  
945 should be copied on the email when the questions and subsequent responses may have bearing  
946 on review division activities or communications related to the question(s) at hand. Similarly,  
947 when one of the FDA resources is responding directly to a sponsor question, the review division

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<sup>36</sup> See the Electronic Code of Federal Regulations Web page at <http://www.ecfr.gov/cgi-bin/ECFR?page=userinfo>.

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948 RPM and/or respective FDA project manager, when known and when appropriate, should be  
949 copied. This ensures that the project manager, and therefore review team members, are aware of  
950 pertinent information or advice conveyed to sponsors. When contacting an ombudsman, the  
951 sponsor can request that the ombudsman consider its communications confidential; therefore, the  
952 FDA project manager(s) may or may not be copied on inquiries and responses between these two  
953 parties.  
954

### **A. CDER**

#### ***1. Controlled Substance Staff***

958  
959 The Controlled Substance Staff (CSS) promotes the public health through the medical science-  
960 based assessment of the abuse potential of investigative and marketed drugs. CSS accomplishes  
961 this by providing consultation services to CDER review divisions as FDA's experts in the area of  
962 drug abuse and dependence and also serving as liaison to the Drug Enforcement Administration  
963 for FDA's role in the drug scheduling process under the Controlled Substances Act. CSS  
964 responds to inquiries about the drug scheduling process and the study of abuse potential in  
965 animal and human studies.  
966

967 See the Controlled Substance Staff Web page at  
968 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/uc](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm180753.htm)  
969 [m180753.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm180753.htm).

#### ***2. Division of Drug Information***

970  
971 The DDI responds to a broad variety of public inquiries. It is staffed with a team of pharmacists  
972 and other health professionals who provide expert advice and guidance regarding all aspects of  
973 CDER activities to U.S. and international consumers, health care professionals, insurance  
974 companies, regulated industry, academia, law enforcement, FDA, and other government  
975 agencies.  
976  
977

978  
979 The DDI can be contacted for responses to questions not related to a specific development  
980 program in a functional area that is not already listed within this section (e.g., FDA forms,  
981 adverse event reporting, IND exemptions).  
982

983 Contact information can be found on the Division of Drug Information (DDI) Web page at  
984 <http://www.fda.gov/aboutDDI>.  
985

#### ***3. Division of Pediatric and Maternal Health***

986  
987  
988 The Division of Pediatric and Maternal Health (DPMH) oversees quality initiatives that promote  
989 and necessitate the study of drug and biological products in the pediatric population, and  
990 improve pregnancy and lactation-related information in product labeling. DPMH collaborates  
991 with stakeholders both inside and outside FDA to develop clinically relevant, evidence-based  
992 labeling and other communications that facilitate informed use of medicines in children and  
993 women of childbearing potential.

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995 Pediatric email: [pedsdrugs@fda.hhs.gov](mailto:pedsdrugs@fda.hhs.gov)

996 Maternal health email: [cdcr.pmhs@fda.hhs.gov](mailto:cdcr.pmhs@fda.hhs.gov)

997

### 998 4. *Enhanced Communication Team*

999

1000 The ECT is composed of individuals in the Office of New Drugs (OND) who are experienced  
1001 and knowledgeable about the drug review process, interact regularly with the staff in review  
1002 divisions, and are skilled in facilitating communications between sponsors and FDA staff. ECT  
1003 is a point of contact for general questions about the drug development process or for clarification  
1004 on which OND review division to contact with questions. ECT is also a secondary point of  
1005 communication for sponsors who are encountering challenges in communicating with the review  
1006 team for their IND. When sponsors encounter such challenges, ECT facilitates eliciting review  
1007 division responses to sponsor questions as described in section VI., General Expectations for  
1008 Timing of Communications.

1009

1010 In addition to the tasks described above, ECT is responsible for identifying and disseminating  
1011 best practices for enhanced communication to CDER staff involved in the review of INDs. Also,  
1012 in collaboration with CDER's training staff, ECT develops and provides training programs for  
1013 both CDER staff and IND sponsors on best practices for communication.

1014

1015 Contact information can be found on the Enhanced Communication Web page at  
1016 <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm327281.htm>.

1017

### 1018 5. *Import/Export*

1019

1020 The Import Operations Branch is the focal point for human drug import and export compliance  
1021 issues.

1022

1023 Contact information for general imports compliance questions and export certificate and  
1024 compliance questions can be found on the Import Operations Branch Web page at  
1025 <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/default.htm>.

1026

### 1027 6. *Ombudsman*

1028

1029  
1030 The CDER Ombudsman serves as a point of contact for informal advice or referrals and also  
1031 provides an alternative means to address issues that arise in the context of the regulatory process.  
1032 The Ombudsman receives questions and investigates complaints from regulated industry, law  
1033 firms, and consultants, and informally resolves disputes between those entities and CDER.  
1034 These disputes can be of a regulatory, scientific, or administrative nature.

1035

1036 In addition, the Ombudsman can assist with resolution of scientific differences of opinion among  
1037 staff. The Ombudsman performs these duties while adhering to the ombudsman principles of  
1038 confidentiality, neutrality, and informality. Every effort is made to respond to all complaints in a

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1039 timely and effective manner. Upon request, communication with the Ombudsman will be  
1040 considered confidential.

1041  
1042 Contact information can be found on the CDER Ombudsman Web page at  
1043 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/Co](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm)  
1044 [ntactCDER/CDEROmbudsman/default.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm).

### 1045 1046 7. *Rare Diseases Program*

1047  
1048 The Rare Diseases Program (RDP) facilitates, supports, and accelerates the development of  
1049 CDER-regulated drug and biologic products for the benefit of patients and families affected by  
1050 rare disorders. The RDP coordinates development of CDER policy, procedures, and training  
1051 related to rare disease drug development to promote consistency and innovation in review.  
1052 Through collaborative work with external and internal rare disease stakeholders, RDP promotes  
1053 evidence-based science as the basis for rare disease drug development. RDP is CDER's focal  
1054 point to the rare disease drug development community for effective interactions with CDER.

1055  
1056 Contact information can be found on the Rare Diseases Program Web page at  
1057 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/uc](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm221248.htm)  
1058 [m221248.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm221248.htm).

### 1059 1060 8. *Small Business and Industry Assistance Program*

1061  
1062 The SBIA Program promotes productive interaction with regulated industry by providing timely  
1063 and accurate information relating to development and regulation of human drug products  
1064 primarily to domestic and international small businesses; however, such assistance is available to  
1065 everyone.

1066  
1067 Contact information can be found on the CDER Small Business and Industry Assistance (CDER  
1068 SBIA) Web page at  
1069 <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm>.

## 1070 1071 **B. CBER**

### 1072 1073 1. *Manufacturers Assistance and Technical Training Branch*

1074  
1075 The MATTB provides assistance and training to industry, including large and small  
1076 manufacturers and trade associations, and responds to general information requests for  
1077 information received via email and telephone regarding CBER policies and procedures.

1078  
1079 Assistance is available in numerous areas including: clinical investigator information, adverse  
1080 event reporting procedures, electronic submissions guidance and requirements, and information  
1081 on how to submit an IND to administer an investigational product to humans.

1082

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1083 Contact information can be found on the Manufacturers Assistance (CBER) Web page at  
1084 [http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/manufacturingques  
1085 s/default.htm](http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/manufacturingquestions/default.htm).

1086

### 1087 **2. *Ombudsman***

1088

1089 The CBER Ombudsman provides an alternative means to obtain information or address issues  
1090 that arise in the context of the regulatory process. The Ombudsman receives questions and  
1091 investigates complaints from regulated industry, law firms, and consultants, and works  
1092 informally to resolve disputes between those entities and CBER. The Ombudsman may be  
1093 engaged by the regulated industry to address issues of a regulatory, scientific, or administrative  
1094 nature. In addition, the Ombudsman can assist with resolution of scientific differences of  
1095 opinion among staff within FDA. The Ombudsman performs these duties while adhering to the  
1096 ombudsman principles of confidentiality, neutrality, and informality. Every effort is made to  
1097 respond to all complaints in a timely and effective manner. Upon request, communication with  
1098 the Ombudsman will be considered confidential.

1099

1100 The CBER Ombudsman serves as a point of contact for informal advice or referrals, including  
1101 product jurisdiction information, and also manages the administrative process for formal dispute  
1102 resolution requests.

1103

1104 Contact information can be found on the CBER Ombudsman Web page at  
1105 [http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/uc  
1106 m122881.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122881.htm).

1107

### 1108 **C. *Office of Special Medical Programs***

1109

1110 The Office of Special Medical Programs (OSMP) serves as the FDA focal point for special  
1111 programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature.  
1112 OSMP oversees and provides executive leadership to five program area offices and is comprised  
1113 of the following: (1) Advisory Committee Oversight and Management Staff; (2) Office of  
1114 Combination Products; (3) Office of Good Clinical Practice; (4) Office of Orphan Products  
1115 Development; and (5) Office of Pediatric Therapeutics.

1116

1117 Contact information can be found on the Office of Special Medical Programs Web page at  
1118 [http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofsciencea  
1119 ndhealthcoordination/default.htm](http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/default.htm).

1120

1121 The following sections describe the five OSMP offices in further detail.

1122

#### 1123 **1. *Advisory Committee Oversight and Management Staff***

1124

1125 The Advisory Committee Oversight and Management Staff (ACOMS) works in close  
1126 collaboration with all FDA centers to provide consistent operations and seek continuous  
1127 improvements in the FDA advisory committee program. ACOMS ensures that all FDA  
1128 committee management activities are consistent with the provisions of the Federal Advisory

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1129 Committee Act, departmental policies, and related regulations and statutes. ACOMS provides  
1130 guidance and assistance on the establishment, staffing, and management of public advisory  
1131 committees to obtain the best possible expert scientific advice to assist FDA in meeting its public  
1132 health mission.

1133  
1134 Contact information can be found on the Advisory Committees Web page at  
1135 <http://www.fda.gov/AdvisoryCommittees/default.htm>.

### *2. Office of Combination Products*

1138  
1139 The Office of Combination Products (OCP) oversees the regulatory life cycle of combination  
1140 products and serves as the focal point for resolving combination product issues. A combination  
1141 product is a product composed of any combination of a drug and a device; a biological product  
1142 and a device; a drug and a biological product; or a drug, device, and a biological product.<sup>37</sup> OCP  
1143 ensures the prompt assignment of combination products to FDA centers, the timely and effective  
1144 premarket review of such applications, and consistent and appropriate postmarketing regulation  
1145 of these products. When a product's classification and/or assignment is unclear or in dispute,  
1146 OCP is also responsible for: classifying the product as a drug, medical device, biological  
1147 product, or combination product, and assigning the product to the appropriate FDA center; or in  
1148 the case of a combination product, assigning it to the FDA center that will have primary  
1149 responsibility for its regulation. In addition, OCP develops guidances and regulations to foster  
1150 greater clarity, efficiency, and effectiveness of the regulatory process for combination products.  
1151 OCP routinely provides responses to requests for assistance from regulated industry and FDA  
1152 staff relating to premarketing review and postmarketing regulation of combination products.

1153  
1154 Contact information can be found on the Office of Combination Products Web page at  
1155 <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/officeofscienceandhealthcoordination/ucm2018184.htm>.

### *3. Office of Good Clinical Practice*

1159  
1160 The Office of Good Clinical Practice (OGCP) is the focal point within FDA for HSP and GCP  
1161 issues arising in clinical trials regulated by FDA. OGCP develops FDA-wide HSP/GCP policy  
1162 for informed consent, institutional review boards, and clinical trial conduct, advises FDA staff  
1163 and the research community on HSP/GCP issues, and coordinates FDA's Bioresearch  
1164 Monitoring program, working with FDA's product centers and the Office of Regulatory Affairs.  
1165 OGCP develops and conducts training and outreach programs, both internally and externally.

1166  
1167 Contact information can be found on the Office of Good Clinical Practice Web page at  
1168 <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191.htm>.

1170

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<sup>37</sup> See 21 CFR 3.2(e).



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### 1171 4. *Office of Orphan Products Development*

1172  
1173 The Office of Orphan Products Development (OOPD) advances the evaluation and development  
1174 of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the  
1175 diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000 people in  
1176 the United States, or that affect more than 200,000 persons but are not expected to recover the  
1177 costs of developing and marketing a treatment drug. OOPD provides incentives for sponsors to  
1178 develop products for rare diseases. They work on rare disease issues with the medical and  
1179 research communities, professional organizations, academia, governmental agencies, industry,  
1180 and rare disease patient groups. OOPD regularly participates in meetings with these stakeholders  
1181 who seek input on orphan-drug designation requests, humanitarian use device designation  
1182 requests, rare pediatric disease designation requests, funding opportunities through the Orphan  
1183 Products Grants Program and the Pediatric Device Consortium Grants Program, and other  
1184 orphan product patient-related issues.

1185  
1186 Contact information can be found on the Developing Products for Rare Diseases & Conditions  
1187 Web page at  
1188 <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm>.

### 1189 5. *Office of Pediatric Therapeutics*

1191  
1192 The Office of Pediatric Therapeutics works to ensure timely access to medical products proven  
1193 to be safe and effective for children. It is comprised of four distinct yet interrelated programs:  
1194 scientific activities, ethics, safety, and international activities. The Office of Pediatric  
1195 Therapeutics provides consultative services in ethics and neonatology, coordinates the monthly  
1196 international Pediatric Cluster, administers the congressionally mandated postmarketing safety  
1197 reviews for pediatric products, and provides scientific data and reports on pediatric product  
1198 development activities.

1199  
1200 Contact information can be found on the Pediatrics Web page at  
1201 <http://www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/default.htm>.

1202

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**REFERENCES**

- 1203  
1204  
1205 **Related Guidances**<sup>38</sup>  
1206  
1207 Draft guidance for industry *Investigational New Drug Applications Prepared and Submitted by*  
1208 *Sponsor-Investigators*<sup>39</sup>  
1209  
1210 Guidance for industry *Expedited Programs for Serious Conditions — Drugs and Biologics*  
1211  
1212 Guidance for industry *Formal Meetings Between the FDA and Biosimilar Biological Product*  
1213 *Sponsors or Applicants*  
1214  
1215 Guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants*  
1216  
1217 Guidance for industry *IND Meetings for Human Drugs and Biologics; Chemistry,*  
1218 *Manufacturing, and Controls Information*  
1219  
1220 Guidance for review staff and industry *Good Review Management Principles and Practices for*  
1221 *PDUFA Products*  
1222  
1223 **Related CDER MAPPs**<sup>40</sup>  
1224  
1225 MAPP 4515.1 *Email Best Practices*  
1226  
1227 MAPP 6025.1 *Good Review Practices*  
1228  
1229 MAPP 6025.6 *Good Review Practice: Management of Breakthrough Therapy-Designated*  
1230 *Drugs and Biologics*  
1231  
1232 MAPP 6030.9 *Good Review Practice: Good Review Management Principles and Practices for*  
1233 *Effective IND Development and Review*  
1234

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<sup>38</sup> Guidances can be found on the FDA Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

<sup>39</sup> When final, this guidance will represent the FDA’s current thinking on this topic.

<sup>40</sup> MAPPs can be found on the Manual of Policies and Procedures Web page at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

***Contains Nonbinding Recommendations***

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1235 **Related CBER SOPPs**<sup>41</sup>

1236

1237 SOPP 8101.1 *Scheduling and Conduct of Regulatory Review Meetings with Sponsors and*  
1238 *Applicants*

1239

1240 SOPP 8104 *Documentation of Telephone Contacts with Regulated Industry*

1241

1242 SOPP 8113 *Handling of Regulatory Faxes in CBER*

1243

1244 SOPP 8119 *Use of Email for Regulatory Communications*

1245

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<sup>41</sup> SOPPS can be found on the Biologics Procedures (SOPPs) Web page at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/default.htm>.