

1                   **Guidance for Industry**  
2                   **Advisory Committee Meetings —**  
3                   **Preparation and Public Availability**  
4                   **of Information Given to Advisory**  
5                   **Committee Members**

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10                   ***DRAFT GUIDANCE***

11                   **This guidance document is being distributed for comment purposes only.**

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14                   Comments and suggestions regarding this draft document should be submitted within 90  
15                   days of publication in the *Federal Register* of the notice announcing the availability of  
16                   the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food  
17                   and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All  
18                   comments should be identified with the docket number listed in the notice of availability  
19                   that publishes in the *Federal Register*.

20  
21                   For questions regarding this draft document contact the Office of Policy (Office of the  
22                   Commissioner) at 301-827-3360.

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34 **Advisory Committee Meetings —**  
35 **Preparation and Public Availability of**  
36 **Information Given to Advisory**  
37 **Committee Members**

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79 **Guidance for Industry<sup>1</sup>**  
80 **Advisory Committee Meetings — Preparation and Public**  
81 **Availability of Information Given to Advisory Committee**  
82 **Members**  
83

84  
85 This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's)  
86 current thinking on this topic. It does not create or confer any rights for or on any person and  
87 does not operate to bind FDA or the public. You can use an alternative approach if the approach  
88 satisfies the requirements of the applicable statutes and regulations. If you want to discuss an  
89 alternative approach, contact the FDA staff responsible for implementing this guidance. If you  
90 cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of  
91 this guidance.  
92

93  
94  
95 **I. INTRODUCTION**  
96

97 This document provides guidance to industry sponsors, applicants, and petitioners  
98 (referred to collectively as *sponsors*) who develop, prepare, or submit briefing materials  
99 that will be given to advisory committee members as background information before an  
100 open FDA advisory committee meeting.<sup>2</sup> This guidance will help sponsors develop,  
101 organize, and submit advisory committee briefing materials for public release and should  
102 help minimize the time and resources spent in preparing these materials for public  
103 availability. The guidance also describes the process FDA intends to follow when we  
104 make briefing materials available to the public. In addition, the Appendices provide  
105 recommended timelines for preparing and submitting briefing materials to us.<sup>3</sup>  
106

107 An important goal of this guidance is to help ensure that briefing materials are made  
108 available to the public as provided under section 10(b) of the Federal Advisory

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<sup>1</sup> This guidance has been prepared by a working group with members from across FDA.

<sup>2</sup> Most FDA advisory committee meetings are open to the public. However, sometimes a portion of a meeting will be closed to the public under 21 C.F.R. § 14.27. This guidance only applies to briefing materials prepared for open advisory committee meetings or for the open portions of such meetings.

<sup>3</sup> This draft guidance, which applies to all FDA open advisory committee meetings or open portions of such meetings, replaces three previously issued draft guidances: 1) Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research (CDER), Beginning on January 1, 2000 (December 1999); 2) Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research (CBER) (February 2001); and 3) Availability of Information Given to Advisory Committee Members in Connection with the Center for Devices and Radiological Health (CDRH) Open Public Panel Meetings (July 2001).

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109 Committee Act (FACA) (5 U.S.C. App. 2). The guidance includes recommendations on  
110 how to identify information that is exempt from public disclosure under the Freedom of  
111 Information Act (FOIA) (5 U.S.C. § 552).

112  
113 Our guidance documents do not establish legally enforceable responsibilities. Instead,  
114 guidances describe our current thinking on a topic and should be viewed only as  
115 recommendations, unless specific regulatory or statutory requirements are cited. The use  
116 of the word *should* in our guidances means that something is suggested or recommended,  
117 but not required.

118

119 **II. BACKGROUND**

120

121 **A. Relevant Statutes and Regulations**

122

123 As stated earlier, under section 10(b) of FACA, any materials made available to an  
124 advisory committee also must be made available to the public. The public availability of  
125 these materials, however, is subject to FOIA, and FOIA exempts certain types of  
126 information from public disclosure. We interpret FACA to require that, with respect to  
127 any open advisory committee meeting convened pursuant to FACA, whenever  
128 practicable and subject to any applicable FOIA exemptions, those materials that we  
129 provide to advisory committee members in connection with that meeting must be made  
130 available for public inspection and copying *before or at the time of* the advisory  
131 committee meeting.

132

133 Several FDA regulations (e.g., 21 CFR §§ 20.61, 20.63, 171.1, 314.430, 514.12, 601.51,  
134 and 860.5) protect information that is exempt from public disclosure under FOIA. We  
135 interpret our regulations to be consistent with FACA and intend to exercise our discretion  
136 under our regulations in a manner consistent with FACA and FOIA. This guidance  
137 should help ensure that information that is exempt from disclosure under FOIA will not  
138 be made publicly available.

139

140 **B. Advisory Committee Meetings – General Information**

141

142 We convene advisory committee meetings for a variety of different purposes. Some  
143 meetings discuss particular matters such as the approval or testing of products. Topics  
144 commonly discussed at this type of advisory committee meeting often involve marketing  
145 applications/submissions such as:

146

- 147
- 148 • New drug applications and application supplements;
  - 149 • New animal drug applications and application supplements;
  - 150 • Biologics license applications and application supplements;
  - 151 • Premarket approval applications for medical devices and their supplements;
  - Premarket notifications for medical devices; and

- Medical device classifications and reclassifications.

We also convene advisory committee meetings to discuss general matters, such as guidance documents, issues pertaining to trial design, post-approval monitoring, citizen’s petitions, and policy issues related to FDA-regulated products.

### III. MAKING BRIEFING MATERIALS AVAILABLE TO THE PUBLIC

#### A. Scope of Briefing Materials Subject to this Guidance

This guidance uses the term “briefing materials” to describe the package of information that we provide to advisory committee members before a meeting. The briefing materials usually contain information prepared by us and/or the sponsor (if the meeting involves an application or a particular product). Although interested persons (i.e., individuals or organizations who are not sponsors) may submit information to an advisory committee pursuant to 21 C.F.R. §§ 14.29 or 14.35(d), this guidance does not consider those submissions to be “briefing materials.”<sup>4</sup>

#### B. Timelines for Submitting and Making Briefing Materials Publicly Available

For an open advisory committee meeting for which the briefing materials may contain information that, under certain circumstances, could be considered to be exempt from public disclosure under FOIA, we intend to post a publicly available version of the briefing materials on our Web site at least *two full business days*<sup>5</sup> before the advisory committee meeting is scheduled to occur. With respect to meetings for which the briefing materials do not contain information that, under certain circumstances, could be considered exempt from public disclosure under FOIA, we will probably make the briefing materials available on our Web site more than two full business days before the advisory committee meeting is scheduled to occur. We anticipate that meetings subject to this timeline will normally address general matters such as guidance documents and policy issues related to FDA-regulated products.

Whether the briefing materials for a particular advisory committee meeting are subject to the timelines in the Appendices, or will probably be posted on our Web site more than two full business days before the advisory committee meeting is scheduled to occur, does not depend on whether they are fully releasable without redaction (see section IV.D). Rather, it depends on whether they contain information that, under certain circumstances, could be considered to be exempt from disclosure under FOIA. For example, if a sponsor prepares briefing materials for an advisory committee meeting on a pending application,

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<sup>4</sup> Information submitted by interested persons is considered to be publicly disclosable and must conform to the requirements of 21 CFR § 10.20. Failure to comply with the requirements will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply (21 CFR § 10.20(c)(6)).

<sup>5</sup> In this guidance, a “business day” is a day that we are officially open for business.

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192 the fact that the sponsor submits briefing materials that do not contain any information  
193 that it asserts is exempt from disclosure under FOIA) (see section IV.B) does not mean  
194 that those materials will be posted on our Web site earlier than they would have been if  
195 the sponsor included in them information that it does assert is exempt from disclosure  
196 under FOIA (see section IV.E). As another example, if we prepare briefing materials for  
197 an advisory committee meeting on a policy issue, and include publicly available  
198 information related to one or more specific products, we will probably make those  
199 briefing materials available on our Web site more than two full business days before the  
200 advisory committee meeting is scheduled to occur.

201

202 If an advisory committee meeting is scheduled to address more than one topic, separate  
203 briefing materials may be prepared for the different topics on the meeting agenda. For  
204 meetings that last more than one day, we intend to post the publicly available version of  
205 the briefing materials on our Web site at least two full business days before the topic to  
206 which the materials pertain will be discussed. For example, assume that two drugs, A  
207 and B, will be discussed on days 1 and 2 respectively. We would make the briefing  
208 materials on drug A available at least two full business days before the scheduled day 1  
209 of the advisory committee meeting and the briefing materials on drug B available at least  
210 two full business days before the scheduled day 2 of the advisory committee meeting.  
211 Please note that the timelines for sponsors to submit materials to us are linked to the first  
212 day of the meeting and not to the specific day on which a particular topic will be  
213 discussed. Thus, in our example, the sponsor for drug B would have the same deadline  
214 for submitting materials to us as the sponsor for drug A, even though the discussions for  
215 their drugs would occur on different days.

216

217 The Appendices to this guidance provide timelines for preparing and submitting briefing  
218 materials to us. Appendix A provides timelines for FDA-prepared briefing materials and  
219 sponsor-prepared briefing materials that are fully releasable to the public. Appendix B  
220 provides timelines for similar briefing materials that are not fully releasable. Please note  
221 that the timelines in the Appendices do not provide for formal predisclosure notification  
222 to sponsors pursuant to 21 CFR § 20.61(e) and (f). The predisclosure notification  
223 requirements in that regulation apply only where the disclosure is to be made in response  
224 to a specific request for our records. The disclosures contemplated here are not made in  
225 response to a request for our records, but to comply with FACA. Nevertheless, the  
226 timelines in the Appendices are at least as generous as the timeframes for notification  
227 under 21 CFR § 20.61.

228

229 This guidance does, however, constitute public notice under 21 CFR §14.35(d)(2) that a  
230 sponsor should submit information to us within the timelines listed in the Appendices if  
231 the sponsor wants the advisory committee to consider that information before the  
232 meeting. If we do not receive a sponsor's briefing materials within the applicable  
233 timeline in the Appendices, we do not intend to provide the sponsor's briefing materials  
234 to the members of the committee, and the committee will not consider the sponsor's  
235 materials before the meeting.

236

237 **C. Postponing the Public Release of Briefing Materials**

238

239 On occasion, the issue of whether certain information in the briefing materials should be  
240 made available to the public may need to be decided in court. If a federal court directs us  
241 to not release information in briefing materials, we will not release that information and  
242 may postpone the advisory committee meeting where the information would have been  
243 discussed until the matter is resolved.

244

245 **IV. PREPARING BRIEFING MATERIALS**

246

247 The contents of the briefing materials provided to advisory committee members for their  
248 review in advance of a meeting differ from meeting to meeting, and the type and amount  
249 of information included generally will depend on the type of product or issues to be  
250 discussed. Additionally, as indicated in the Appendices, the times by which sponsors  
251 should submit briefing materials differ depending on whether the materials contain  
252 information that the sponsor claims is exempt from disclosure under FOIA.

253

254 It is important to minimize the time we will need to spend reviewing briefing materials,  
255 consulting with sponsors, and redacting such materials. The more time we need to  
256 complete this process, the earlier the sponsors may need to submit materials for an  
257 advisory committee meeting. If the preparation of the materials occurs too far in advance  
258 of a meeting, the materials may not adequately address the issues that will be the subject  
259 of the meeting because those issues will not yet have been fully identified.

260

261 **A. General Recommendations on Preparing Briefing Materials**

262

263 For open advisory committee meetings that involve sponsor-prepared briefing materials,  
264 approximately *11 weeks* before the meeting is scheduled to occur, FDA intends to notify  
265 a sponsor that an advisory committee will consider an issue that is directly relevant to the  
266 sponsor. We will explain the meeting's focus to the sponsor and also may advise the  
267 sponsor about the information it may wish to include in its briefing materials. To  
268 facilitate the review and eventual posting of sponsor-prepared briefing materials, we  
269 strongly recommend that sponsors submit both paper and electronic versions of their  
270 materials. Sponsors should consult the appropriate FDA component about compatible  
271 electronic formats and consult the Designated Federal Official<sup>6</sup> for a given meeting to  
272 determine the appropriate number of paper copies.<sup>7</sup>

273

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<sup>6</sup> The Designated Federal Official is a federal employee who is responsible for the overall administrative management of an advisory committee.

<sup>7</sup> If an advisory committee meeting involves advisory committees from different agency components (e.g., a joint meeting of a Center for Biologics Evaluation and Research advisory committee and a Center for Drug Evaluation and Research advisory committee), sponsors should consult the relevant Designated Federal Officials of the two committees as to the Designated Federal Official coordinating the briefing material process.

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274 We emphasize that a sponsor’s submissions should include only information related to  
275 the issue being discussed by the committee. Statements or suggestions that could be  
276 viewed as misleading or promotional (e.g., statements that go beyond study conclusions  
277 or speculate about clinical or commercial implications not supported by the data) are  
278 inappropriate for inclusion in the briefing materials. In addition, statements or language  
279 that are defamatory, irrelevant, or intemperate are inappropriate for inclusion in briefing  
280 materials and should be avoided.

281

282 **B. Information in Briefing Materials That Typically Will Be Disclosable**  
283 **Under FOIA**

284

285 We generally will consider the following information in advisory committee briefing  
286 materials to be disclosable without redaction, unless the sponsor demonstrates that  
287 disclosure of the information is likely to cause substantial competitive harm:

288

- 289 • Summaries of clinical safety and effectiveness data;
- 290 • Summaries of non-clinical safety and effectiveness data;
- 291 • Summaries of adverse drug reaction data;
- 292 • Written discussion or analysis of safety or effectiveness data relevant to the  
293 topic of the meeting;
- 294 • A general description (such as that which would typically be included in  
295 product labeling) of product functions, mechanics, and/or engineering;
- 296 • A general description of physical characteristics and performance parameters;
- 297 • Clinical or preclinical protocols or summaries of protocols;
- 298 • Statistical protocols and analyses;
- 299 • Information that is proposed to be included in product labeling, such as  
300 indications and usage, dosage and administration, and safety information such  
301 as warnings and precautions;
- 302 • Literature references;<sup>8</sup>
- 303 • Any other information that has been previously publicly disclosed by the  
304 sponsor;
- 305 • Copies of the sponsor’s slides to be presented at the advisory committee  
306 meeting, if included in the briefing materials; and

---

<sup>8</sup> FDA does not post copyrighted materials on its Web site. If sponsors do wish to submit copyrighted materials, they should provide a bibliography of the copyrighted materials that can be posted.

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- 307           • Guidance documents.

308

309 The above list is neither exhaustive nor absolute.

310

311 With regard to certain topics discussed at advisory committee meetings (for example,  
312 issues relating to the approval of a pending New Drug Application (NDA), Biologics  
313 Licensing Application (BLA), Premarket Approval Application (PMA), 510(k), New  
314 Animal Drug Application (NADA), or a supplement to any of these), some of the  
315 information listed above might be considered confidential commercial information at  
316 earlier stages of the product development process. However, we believe it is appropriate  
317 to make this information available under 21 CFR §§ 20.82, 314.430(d)(1), 514.11(d),  
318 601.51(d)(1), 814.9(d)(1), and/or 171.1(h)(2) (whichever is applicable) at the time of an  
319 advisory committee meeting if the information is germane to the issues to be discussed at  
320 the meeting. These materials are often necessary to a committee's consideration of the  
321 safety and effectiveness of a product being discussed and committees and sponsors  
322 routinely discuss such matters at open advisory committee meetings. It is widely  
323 understood that, when advisory committees consider such products, the information  
324 contained in these materials will be the subject of open discussion.

325

326           **C. Information in Briefing Materials That Will Typically Be Exempt from**  
327           **Disclosure**

328

329 We generally will consider the following types of information to be exempt from  
330 disclosure under FOIA:

- 331           • Information about product functions, mechanics, engineering, and schematic  
332 drawings not in the proposed labeling and not within the scope of the agenda for  
333 the meeting;
- 334           • Proprietary physical characteristics and performance parameters not in the  
335 proposed labeling and not within the scope of the agenda for the meeting;
- 336           • Manufacturing process information;
- 337           • Manufacturing quality control information;
- 338           • Clinical raw data;<sup>9</sup>
- 339           • Non-clinical raw data;
- 340           • Supplier names, customer lists, production costs, inventory information, failure  
341 rates of products, production quality control information;

---

<sup>9</sup> For the purposes of this guidance, FDA considers "raw data" to be a complete data set of case report forms, case report tabulations, or line listings. Data that summarize individual or multiple subject outcomes or results are considered summaries. Summaries may include examples of specific findings.

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- 342       • Information for which the release would constitute an unwarranted invasion of  
343       personal privacy; and
- 344       • Product formulation information not in the labeling.  
345

346 The above list is neither exhaustive nor absolute.  
347

348 The advisory committee members will receive complete copies of the briefing materials,  
349 including information that is exempt from disclosure under FOIA. However, we will not  
350 include information that is exempt from disclosure under FOIA in the publicly available  
351 version of the briefing materials, and we will notify the committee members that such  
352 exempt information may not be discussed during any open portion of the advisory  
353 committee meeting.  
354

355               **D. Fully Releasable Sponsor Briefing Materials**  
356

357 To shorten the process for complying with FACA's disclosure requirements, we strongly  
358 encourage sponsors to submit briefing materials that may be released to the public in their  
359 entirety without redaction (i.e., that do not contain any information that the sponsor  
360 asserts is exempt from disclosure under FOIA). Sponsors also benefit from preparing  
361 fully releasable briefing materials because such briefing materials eliminate the need for  
362 us to redact trade secret and/or confidential commercial information and, as a result, can  
363 be submitted to us closer in time to the advisory committee meeting than briefing  
364 materials containing information that the sponsor asserts is exempt from disclosure under  
365 FOIA. As a result, sponsors may be able to devote more time to preparing their  
366 submissions before the advisory committee meeting occurs (see timelines in the  
367 Appendices).  
368

369 If a sponsor chooses to submit fully releasable briefing materials, it should mark the  
370 materials as: “*Advisory Committee Briefing Materials: Available for Public Release.*”  
371

372 When we receive briefing materials marked as fully releasable, we will review the  
373 materials for completeness. We will assume that sponsors who mark their materials  
374 “Available for Public Release” have carefully reviewed the included materials to make  
375 sure that they all may be made available to the public without redaction. Sponsors should  
376 not expect us to identify trade secret or confidential commercial information in briefing  
377 materials marked as “Available for Public Release.” We will, however, review sponsor  
378 briefing materials for information that, if publicly released, would constitute a clearly  
379 unwarranted invasion of personal privacy, and we will redact such information.  
380

381               **E. Sponsor Briefing Materials that Contain Information Claimed to be**  
382               **Exempt from Disclosure**  
383

384 A sponsor may elect to prepare advisory committee briefing materials that contain  
385 information that it believes is exempt from disclosure under FOIA (see section IV.C. for  
386 a discussion of what types of information we generally will consider to be exempt from

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387 disclosure). If the sponsor chooses to prepare such briefing materials, it should prepare  
388 two versions of its briefing materials at the same time. One version should be complete,  
389 and should include the information that the sponsor believes should not be available for  
390 public release. The second version should be a publicly releasable version.

391

392 We recommend that, when preparing briefing materials that contain information the  
393 sponsor believes is exempt from disclosure, the sponsor should segregate the information  
394 it believes is exempt from disclosure from the releasable information (e.g., by placing it  
395 in a separate portion of the briefing materials) or clearly identify the specific information  
396 that it believes is exempt from disclosure.

397

398 The complete version of the briefing materials (that is, the one that would not be  
399 available for public release because it includes the information the sponsor believes is  
400 exempt from disclosure under FOIA) should be clearly marked as: “*Draft: Advisory  
401 Committee Briefing Materials: Not for Public Release: Contains Trade Secret and/or  
402 Confidential Commercial Information.*”

403

404 For the version of the briefing materials that would be publicly releasable, the sponsor  
405 should prepare and submit a copy of the *same* materials as are included in the version that  
406 is not for public release, but this version should indicate what information the sponsor  
407 believes is exempt from disclosure under FOIA. Sponsors should indicate the  
408 information they believe is exempt by providing a redacted copy. We suggest that, when  
409 redacting information, sponsors should identify any proposed deletions and indicate  
410 exactly how much material should be redacted. Sponsors can indicate the amount of  
411 information that has been removed in several ways. For example, a sponsor could  
412 include a statement such as “two paragraphs have been deleted,” or “five pages have been  
413 removed.” For each document or portion of a document that the sponsor believes is  
414 exempt from disclosure under FOIA, the sponsor should explain, in detail, why it  
415 believes that the information is exempt from disclosure under FOIA. We caution that, to  
416 the extent that the sponsor intends to discuss specific information during the open portion  
417 of the meeting, it will be difficult for the sponsor to claim that the information is exempt  
418 from disclosure under FOIA.

419

420 Sponsors should label the redacted copy prominently as: “*Draft: Advisory Committee  
421 Briefing Materials: Available for Public Release.*”

422

423 After we receive the two versions of the briefing materials (the non-public and publicly  
424 releasable versions), we will review the briefing materials for completeness and  
425 determine if the sponsor appropriately identified exempt information. If we disagree that  
426 any of the information the sponsor has redacted is exempt from disclosure under FOIA,  
427 we will discuss the matter with the sponsor. When the discussions are concluded, we will  
428 notify the sponsor of our final decision. Once we have notified the sponsor of our final  
429 decision, no new documents or information may be added to the briefing materials. See  
430 the Appendices for details on the timing of this process.

431

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432 When the sponsor receives our final decision regarding what information, if any, we have  
433 determined to be exempt from disclosure under FOIA, the sponsor has four options:

434

435 • Option 1: The sponsor may remove from the briefing materials information  
436 that we have determined is not exempt from disclosure under FOIA and thus  
437 would not be redacted from the materials. The sponsor may reformat the  
438 materials accordingly.

439

440 • Option 2: If the sponsor accepts our determination as to the releasability of  
441 the information in the briefing materials, and there is still information in the  
442 materials that we and the sponsor agree is exempt from disclosure, the sponsor  
443 may submit a final copy of both versions of the briefing materials. The final  
444 documents should be prominently labeled: “*Final: Advisory Committee*  
445 *Briefing Materials: Not for Public Release: Contains Trade Secret and/or*  
446 *Confidential Commercial Information*” and “*Final: Advisory Committee*  
447 *Briefing Materials: Available for Public Release.*”

448

449 • Option 3: If we and the sponsor agree that no information in the materials is  
450 exempt from disclosure under FOIA, then the sponsor should submit a copy  
451 marked “*Final: Advisory Committee Briefing Materials: Available for Public*  
452 *Release.*”

453

454 • Option 4: If the sponsor disagrees with our determination regarding the  
455 releasability of information in the briefing materials, the sponsor may seek  
456 judicial review in federal court to prevent us from releasing the information.  
457 If the sponsor chooses this option, we will not release the information that is  
458 in dispute and may postpone the advisory committee meeting where the  
459 information would be discussed until the matter is resolved.

460

461 When this process is complete, we will send the final unredacted version of the sponsor-  
462 prepared briefing materials to the advisory committee members in preparation for the  
463 scheduled meeting. We will identify any information in the materials that is exempt from  
464 disclosure under FOIA for the advisory committee members, and we will advise them  
465 that such exempt information may not be discussed during any open portion of the  
466 advisory committee meeting. Additionally, the sponsor should not discuss any  
467 information which we and the sponsor agree is exempt from disclosure under FOIA at  
468 any open portion of the advisory committee meeting.

469

470 **F. FDA-Prepared Advisory Committee Briefing Materials**

471

472

473 For most advisory committee meetings, we prepare our own briefing materials and send  
474 them to the advisory committee members. When we have prepared our briefing  
475 materials, we will review them to determine if they contain information that, under  
476 certain circumstances, could be considered to be exempt from disclosure under FOIA

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477 (specifically, confidential commercial or trade secret information belonging to a sponsor).  
478 If the materials do not contain information that, under certain circumstances, could be  
479 considered to be confidential commercial or trade secret information belonging to a  
480 sponsor, the portions of the timelines (see Appendices) that pertain to sharing our briefing  
481 materials with sponsors will not apply. As discussed in section III.B., we may post such  
482 briefing materials on our Web site earlier than two full business days before an advisory  
483 committee meeting is scheduled to occur.

484

485 If we determine that the briefing materials contain information that, under certain  
486 circumstances, could be considered to be confidential commercial or trade secret  
487 information belonging to a sponsor, the timelines in the Appendices will apply, and we  
488 will send our briefing materials to the sponsor as described in the timelines. If the  
489 briefing materials include information pertaining to more than one sponsor, we will send  
490 only the relevant portion to each sponsor. We will discuss with each sponsor any  
491 disagreements it may have about the disclosability of information in the materials. When  
492 these discussions are concluded, we will notify each sponsor of our final decision  
493 regarding the public availability of the information in our briefing materials. If the  
494 sponsor disagrees with our determination regarding the releasability of information in our  
495 briefing materials, the sponsor may seek judicial review in federal court to prevent us  
496 from releasing the information. If the sponsor chooses this option, we will not release the  
497 information that is in dispute and may postpone the advisory committee meeting where  
498 the information would be discussed until the matter is resolved.

499

500 **G. Posting Briefing Materials on FDA’s Web Site**

501

502 We will post the briefing materials for an open advisory committee meeting subject to  
503 this guidance on our Web site at <http://www.fda.gov/ohrms/dockets/ac/acwhatsnew.htm>.  
504 The materials also will be available in hard copy at our Division of Dockets  
505 Management’s Public Reading Room.<sup>10</sup> We will post only the publicly available  
506 sponsor-prepared briefing materials and the publicly available FDA-prepared briefing  
507 materials on our Web site.

508

509 To avoid any misunderstanding that we have endorsed the contents of a sponsor’s  
510 briefing materials by posting them on our Web site, we will display the following  
511 statement with the sponsor’s briefing materials placed on our Web site:

512

513 *“The statements contained in this document are those of*  
514 *the product’s sponsor. FDA does not necessarily agree*  
515 *with the sponsor’s statements. FDA has not made a final*  
516 *determination about the issues described in this*  
517 *document”.*

518

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<sup>10</sup> The Public Reading Room is open Monday through Friday, 9:00 a.m. to 4:00 p.m. The Public Reading Room is located at 5630 Fishers Lane, Room 1061, Rockville, Maryland 20857.

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519 We also may take appropriate action to address any information that may be promotional  
520 or misleading, including posting a correction on our Web site.

521

522 Please note that if unforeseen difficulties prevent us from posting the briefing materials  
523 on our Web site before an advisory committee meeting, we will make hard copies  
524 available to the public at the time of the advisory committee meeting.

525

526 If you have questions, please refer to the contact information listed below.

527

528 • **For briefing materials pertaining to the Center for Biologics Evaluation and**  
529 **Research:**

530

531 Office of Communication, Training, and Manufacturers Assistance, HFM-40

532 Center for Biologics Evaluation and Research

533 1401 Rockville Pike, Suite 200N

534 Rockville, MD 20852

535 Phone: 301-827-1800

536

537 • **For briefing materials pertaining to the Center for Devices and Radiological**  
538 **Health:**

539

540 Freedom of Information Officer, Joy Lazaroff

541 Office of Management Operations

542 Division of Ethics and Management Operations, HFZ-23

543 Center for Devices and Radiological Health

544 7520 Standish Place

545 Rockville, MD 20855

546 Phone: 301-827-7258

547

548 • **For briefing materials pertaining to the Center for Drug Evaluation and**  
549 **Research:**

550

551 Advisors and Consultants Staff, HFD-21

552 Center for Drug Evaluation and Research

553 5630 Fishers Lane, Room 1093

554 Rockville, MD 20850

555 Phone: (301) 827-7001

556

557 • **For briefing materials pertaining to the Center for Food Safety and Applied**  
558 **Nutrition:**

559

560 Freedom of Information Officer, Patricia Gee

561 Executive Operations Staff, HFS-22

562 Center for Food Safety and Applied Nutrition

563 5100 Paint Branch Parkway

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564 College Park, MD 20740-3835  
565 Phone: 301-436-2121

566

567 • **For briefing materials pertaining to the Center for Veterinary Medicine:**

568

569 Freedom of Information Officer, Marilyn Broderick  
570 Communications Staff, HFV-12  
571 Center for Veterinary Medicine  
572 7519 Standish Place  
573 Rockville, MD 20855  
574 Phone: 240-276-9107

575

576 • **For briefing materials pertaining to the National Center for Toxicological**  
577 **Research:**

578

579 Rose Huber  
580 Office of the Director, HFT-1  
581 National Center for Toxicological Research  
582 3900 NCTR Road  
583 Jefferson, AR 72079  
584 Phone: 870-543-7130

585

586 • **For briefing materials pertaining to the Office of the Commissioner:**

587

588 Carlos Peña, PhD, MS  
589 Office of Science and Health Coordination  
590 Office of the Commissioner  
591 5600 Fishers Lane, HF-33  
592 Rockville, MD 20857  
593 Phone : 301-827-3340

594

595

596

597

## Appendices

598

599

### APPENDIX A: TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS THAT ARE FULLY RELEASABLE

600

601

602

FDA Action	Business Days Before Meeting	Sponsor Action
	22	The sponsor should submit its briefing materials to the appropriate agency staff.
<p>We will conduct the following activities:</p> <ul style="list-style-type: none"> <li>• We will review the sponsor-prepared briefing materials for completeness.</li> <li>• We will review both the sponsor and final agency briefing materials for disclosure. <ul style="list-style-type: none"> <li>○ We will send the complete (unredacted) agency briefing materials to the advisory committee members.</li> <li>○ We will send a copy of our briefing materials (or relevant portions thereof), as prepared for public release, to the sponsor to review.</li> </ul> </li> </ul>	21 through 14	
<p>We will discuss with the sponsor any concerns it has regarding the disclosability of any information in our briefing materials.</p>	13 through 9	<p>The sponsor will review our briefing materials (or relevant portions thereof), as prepared for public release.</p> <p>The sponsor will discuss with appropriate center staff any concerns it has regarding the disclosability of any information in our briefing materials.</p> <p>The sponsor will inform us whether it disagrees with us regarding the disclosability of any information in our briefing materials.</p>
<p>We will inform the sponsor of our final decision regarding the redaction, if any, of our briefing materials.</p> <p>We will submit both the sponsor’s and the agency’s briefing materials to our Division of Dockets Management for posting on our Web site.</p>	7	
<p>We will post on our Web site the sponsor’s publicly available briefing materials and our</p>	At least 2 full business days	

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<b>FDA Action</b>	<b>Business Days Before Meeting</b>	<b>Sponsor Action</b>
publicly available briefing materials.	<b>before the day on which the sponsor's topic will be discussed</b>	

603

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604 **APPENDIX B: TIMELINE FOR OPEN FDA ADVISORY COMMITTEE MEETINGS**  
605 **INVOLVING FDA BRIEFING MATERIALS AND SPONSOR BRIEFING MATERIALS**  
606 **THAT ARE NOT FULLY RELEASABLE**

607

<b>FDA Action</b>	<b>Business Days Before Meeting</b>	<b>Sponsor Action</b>
We intend to notify the sponsor that we are taking an issue directly relevant to the sponsor to an advisory committee.	<b>55</b>	
	<b>42</b>	The sponsor will submit two versions of its briefing materials: a complete (unredacted) version and a redacted version.
We will send copies of both the complete (unredacted) and the redacted sponsor's submissions to the appropriate disclosure staff and a copy of the complete sponsor submission to the appropriate review staff.	<b>41</b>	
We will inform the sponsor whether we agree with the sponsor's proposed redactions to the sponsor's briefing materials.	<b>34</b>	
We will discuss redaction of sponsor's briefing materials with the sponsor.	<b>30</b>	The sponsor will discuss redaction of the sponsor's briefing materials with us.
We will inform the sponsor of our final decision regarding the redaction of information from the sponsor's briefing materials.	<b>28</b>	The sponsor will decide whether to remove any materials that we have decided will not be redacted and to reformat the materials accordingly. No new documents or information may be added to the briefing materials at this time.
See Appendix A for Days 22 through 2.	<b>22 through 2</b>	

608

609