DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6530]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' This draft guidance outlines the recommendations to industry on formal meetings between the FDA and sponsors or applicants relating to the development and review of new drug or biological drug products. This draft guidance replaces the guidance ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' issued on December 29, 2017.

DATES: Submit either electronic or written comments on the draft guidance by December 21, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6530 for ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Mercier, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5390, Silver Spring, MD 20993–0002, 301–796–0957; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' This draft guidance outlines the recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of drug or biological drug products as agreed upon during the Prescription Drug User Fee Act (PDUFA) VII negotiations. The draft guidance describes the different meeting types, formats, and timelines associated with those requests. It also provides industry with the information necessary to have a complete meeting request and background package to help facilitate the meeting to gain useful feedback for product development. The draft

guidance provides examples to help guide stakeholders on selecting and requesting the proper meeting type for a given scenario.

This draft guidance replaces the draft guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' issued on December 29, 2017 (82 FR 61763). FDA considered comments received on the draft guidance as the guidance was revised. Changes made include the addition of Type D and Initial Targeted Engagement for Regulatory Advice on CDER and CBER ProducTs (INTERACT) meetings, request for clarification/followup opportunity correspondence, and virtual meetings as a face-to-face meeting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to meetings, including ''End-of-phase 2'' and ''pre-NDA'', have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to formal meetings between sponsors or applicants and FDA have been approved under OMB control number 0910–0001. The collections of information pertaining to formal meetings between the FDA and sponsors or applicants for biological products have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20592 Filed 9–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3031]

Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications.'' This draft guidance provides information to applicants on how FDA intends to use alternative tools to assess manufacturing facilities identified in a marketing application (*i.e.,* a new drug application (NDA), an abbreviated new drug application (ANDA), a biologics license application (BLA), or a supplement to any of these types of applications). As part of the negotiations relating to the reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA), as described in ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' (PDUFA VII commitment letter) and ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures for Fiscal Years 2023 Through 2027'' (BsUFA III commitment letter), FDA agreed to issue guidance on the use of alternative tools to assess manufacturing facilities named in pending applications and to incorporate best practices from the use of such tools during the Coronavirus Disease 2019 (COVID–19) pandemic. This draft guidance, within the context of approval and licensure decisions by FDA, describes the use of alternative tools to assess manufacturing facilities identified in an NDA, an ANDA, or a BLA to establish that these facilities meet the applicable requirements, including under the Federal Food, Drug, and Cosmetic (FD&C Act) or the Public Health Service Act (PHS Act).

DATES: Submit either electronic or written comments on the draft guidance by November 21, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
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Instructions: All submissions received must include the Docket No. FDA–2023–D–3031 for ''Alternative Tools: Assessing Drug Manufacturing Facilities Identified in Pending Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.