



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

The previous guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,” issued on November 18, 2015, has been withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2018-D-1922 for “Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability.” 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.

- 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.gpo.gov/fdsys/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.

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 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. 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: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6468, Silver Spring, MD 20993-0002, 301-796-0970; or Stephen Ripley, 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 BsUFA Products.” This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by CDER or CBER. This draft guidance does not apply to meetings associated with the development of products intended for submission in, or review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), biologics license applications under section 351(a) of the Public Health Service Act, or submissions for devices under the FD&C Act. For the purposes of this draft guidance, formal meeting includes any meeting that is requested by a sponsor or applicant following the procedures provided in this draft guidance and includes meetings conducted in any format (i.e., face to face, teleconference/videoconference, written response only).

The Biosimilar User Fee Act of 2012 (BsUFA I) added sections 744G and 744H to the FD&C Act, authorizing FDA to collect user fees for a 5-year period for biosimilar biological products. BsUFA was reauthorized for a 5-year period in 2017 under Title IV of the FDA Reauthorization Act of 2017 (BsUFA II), enacted on August 18, 2017. In conjunction with that reauthorization, FDA agreed to specific performance goals and procedures described in the

document, “Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022” (BsUFA II goals letter available at <https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf>). The BsUFA II goals letter includes meeting management goals for formal meetings that occur between the FDA and sponsors or applicants.

In the BsUFA II goals letter, FDA committed to issuing this draft guidance. This draft guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting formal meetings between FDA and sponsors or applicants of BsUFA products.

The previous guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,” issued on November 18, 2015, has been withdrawn.

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 BsUFA 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information referred to in the guidance for industry entitled “Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants” have been approved under OMB control number 0910-0802. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014 and collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,
,
<https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: May 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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