If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than August 13, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations or request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by August 10, 2018. All requests to make oral presentations must be received by the close of registration on August 6, 2018. If selected for presentation, any presentation materials must be emailed to *NonTraditionalTherapiesWorkshop 2018@fda.hhs.gov* no later than August 14, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at the following site: *https://collaboration.fda.gov/dcontpfbi/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm606052.htm.*

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14048 Filed 6–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6209]

Assessing User Fees Under the Biosimilar User Fee Amendments of 2017; 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 final guidance for industry entitled ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.'' This guidance concerns FDA's implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II) and certain changes in policies and procedures surrounding its application.

DATES: The announcement of the guidance is published in the **Federal Register** on June 29, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–6209 for ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.'' 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Beena Alex, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2185, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov*; 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 guidance for industry entitled ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.'' This guidance concerns the implementation of BsUFA II, including an explanation about the new fee structure and types of fees for which entities are responsible. BsUFA II extends FDA's authority to collect user fees from fiscal year (FY) 2018 to 2022 and introduces a number of technical revisions that affect what fees are collected and how fees are collected. Fees authorized by this legislation help fund the process for the review of biosimilar biological product applications and have played an important role in expediting the review and approval process.

BsUFA II authorizes biosimilar biological product development program fees (BPD fees), biosimilar biological product application fees, and biosimilar biological product program fees. This guidance describes when these fees are incurred and the process by which applicants can submit payments. The guidance also provides information on consequences of failing to pay BsUFA II fees and the processes for submitting reconsideration and appeal requests.

In the **Federal Register** of November 16, 2017 (82 FR 53505), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. We have reviewed the comment submitted to the docket. This guidance does not include any substantive changes from the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the current thinking of FDA on assessing user fees under the biosimilar user fee amendments of 2017. 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 guidance contains information collection provisions 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 title, description, and respondent description of the information collection are given under this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

With respect to the collection of information associated with this document, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Assessing User Fees Under the Biosimilar User Fee Amendments of 2017: Guidance for Industry.

Description: This guidance provides information on the assessment of biosimilar biological product user fees, describes the types of user fees authorized, the process for submitting payments to FDA, and consequences for failing to pay BsUFA fees. The guidance also describes how FDA determines which products are subject to a fee and the changes to certain FDA policies regarding BsUFA fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Act of 2012 and recently renewed in 2017 (BsUFA) under the FDA Reauthorization Act of 2017, authorizes FDA to assess and collect user fees from companies that produce biosimilar biological products in conjunction with the review of biosimilar biological product applications. The guidance includes processing and policies for the initial and the annual biosimilar biological product development (BPD) fees; the BPD discontinuation process requirements and BPD reactivation fees; process and policies for biosimilar biological product application fees including exceptions to the application fees and refund of fees; process and policies for the small business waiver of the biosimilar application fee; and implementation of the biosimilar biological product program fee.

The burdens associated with requesting a small business waiver of BsUFA fees and the associated burdens for new activities as noted in the guidance are listed in table 1.

FDA estimates the annual burden of these new collections of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Request for discontinuation from BPD program.	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list.	5	1	5	0.5 (30 minutes)	2.5
Small business waiver of the BsUFA application fee.	1	1	1	16	16
Small business waiver reconsiderations	1	1	1	24	24
Small business waiver appeals	1	1	1	12	12
Annual Fee Determination Survey	35	1	35	1	35
Annual BsUFA fees correspondence	35	1	35	2	70
Total					161.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This guidance also refers to previously approved collections of information found in FDA forms developed to support its user fee program. Specifically, the guidance refers to Form FDA 3792; Forms FDA 3913 and 3914; and Form FDA 3971, which have been approved under OMB control numbers 0910–0718, 0910–0719, 0910–0805, and 0910–0693, respectively. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 are currently approved under OMB control number 0910–0014; the collections of information regarding new drug applications under the FD&C Act are approved under OMB control number 0910–0001; and biologics license applications under sections 351(a) or 351(k) of the Public Health Service Act are approved under OMB control numbers 0910–0338 and 0910–0719, respectively.

This final guidance contains information collection provisions subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Except for the provisions listed in table 1, the information collections already have been approved. The applicable provisions are shaded in the guidance to identify those for which OMB approval has not yet been obtained. When approval of these provisions has been received, FDA will provide notice. BsUFA II provides the statutory authority to collect user fees from FY 2018 through FY 2022. Consistent with the statutory requirements of BsUFA II, FDA is issuing this guidance to facilitate understanding and enhancing implementation of the policies and processes in the assessment of biosimilar user fees in upcoming fiscal years.

III. Electronic Access

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

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14049 Filed 6–28–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection supporting the Agency's Biosimilars User Fee Program.

DATES: Submit either electronic or written comments on the collection of information by August 28, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 28, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 28, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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