ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents annually	Total number of annual responses per respondent	Average annual burden hours per response	Total/annual burden hours
Insurance Match File: Daily, Reporting Electronically	2	251	0.083	41.67
Match File: Daily, Reporting Manually	108	251	0.1	2,710.80

Estimated Total Annual Burden Hours: 2,817.21.

Authority: 42 U.S.C. 652(a)(9), which requires OCSE to operate the FPLS established by 42 U.S.C. 653(a)(1) and 42 U.S.C. 652(m), which authorizes OCSE, through the FPLS, to compare information concerning individuals owing past-due support with information maintained by insurers (or their agents) concerning insurance claims, settlements, awards, and payments, and to furnish information resulting from the data matches to the state child support agencies responsible for collecting child support from the individuals.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–24141 Filed 10–29–20; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3326]

Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is hosting a virtual public meeting on the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2023 through 2027. BsUFA authorizes FDA to collect user fees to support the process for the review of biosimilar biological products. The current legislative authority for BsUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees in future fiscal years. FDA begins the BsUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization. FDA invites public comment as the Agency begins the process to reauthorize the program for FYs 2023 through 2027. These comments will be published and available on FDA's website.

DATES: The public meeting will be held on November 19, 2020, from 9 a.m. to 12:30 p.m., and will be held by webcast only. Registration to attend the meeting and other information can be found at *https://bsufaiii-publicmeeting.eventbrite.com.* Submit either electronic or written comments on this public meeting by December 19, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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 December 19, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 19, 2020. 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 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, 240–402–7500.
- 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–2015–N–3326 for ''Reauthorization of the Biosimilar User Fee Act; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500. Transcripts of the meeting will be available on the FDA website at: *https://www.fda.gov/industry/biosimilar-user-fee-amendments/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-11192020-11192020* approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Emily Ewing, Center for Drug Evaluation and Research, 240–402–0196, *Emily.Ewing@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a virtual public meeting to begin the process for the reauthorization of the Biosimilar User Fee Act (BsUFA). The authority to collect user fees under BsUFA expires in September 2022. Without new legislation, FDA would no longer be able to collect user fees for future fiscal years to fund the biosimilar biological product review process. Before FDA begins negotiations with the regulated industry on BsUFA reauthorization, the Agency is holding the public meeting announced in this notice, at which stakeholders, including all members of the public, may present their views on reauthorization, including any suggestions for changes to the performance goals referred to in the ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022'' (the BsUFA II Commitment Letter). In addition, FDA will provide a period of 30 days after the public meeting for the public to submit written comments. The purpose of this public meeting is to hear stakeholder views on BsUFA as we consider elements to propose, update, or discontinue in the next BsUFA. In addition to any other relevant information the public would like to share, the FDA is interested in responses to the following three general questions:

- What is your assessment of the overall performance of the BsUFA program to date?
- What current elements should be retained, changed, or discontinued to further strengthen and improve the program?
- What new elements should FDA consider adding to the program to enhance the efficiency and effectiveness of the biosimilar biologic review process?

II. What is BsUFA? What does it do?

FDA provides the following information to help potential meeting participants better understand the history and evolution of BsUFA and its status. BsUFA is a law that authorizes FDA to assess and collect fees from drug companies that submit marketing applications for biosimilar biological products. BsUFA was originally enacted in 2012 as the Biosimilar User Fee Act under the Food and Drug Administration Safety and Innovation Act (FDASIA, Pub. L. 112–144) for a period of 5 years. In 2017, BsUFA was renewed for five more years under the FDA Reauthorization Act of 2017 (FDARA, Pub. L. 115–52). BsUFA's intent is to provide additional revenues so that FDA can hire staff, improve systems, and continue a well-managed biosimilar biological product review process to make biosimilar biological product therapies available to patients sooner. As part of FDA's agreements with industry during prior BsUFA authorizations, the Agency agreed to certain performance and procedural goals and other commitments, which are documented on FDA's website. The goals apply to the process for the review of biosimilar biological product applications, including biosimilar biological product development meetings, review of applications and supplements, and other review activities. FDA's website provides more information about BsUFA, including the statutory text of the FDA Reauthorization Act of 2017 (FDARA, Pub. L. 115–52), the BsUFA II Commitment Letter, ''Biosimilar Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the BsUFA Commitment Letter), key **Federal Register** documents, BsUFA-related guidances, BsUFA user fee rates, performance reports, and financial reports: *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

With the current authorization of BsUFA II under FDARA, FDA implemented a review program (''the Program'') to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval. The Program allowed for additional communication between the FDA review team and applicants of biosimilar biological products, including pre-submission meetings, mid-cycle communications and late-cycle meetings, while adding 60 days to the review clock to provide for this increased interaction and to address review issues to accommodate this additional interaction. BsUFA II also includes commitments to advance development of biosimilar biological products through further clarification of the 351(k) regulatory pathway, and to enhance capacity for biosimilar regulations and guidance development, reviewer training, and timely communication. More information on these commitments can be found in the BsUFA II commitment letter at *https://www.fda.gov/media/100573/download.*

BsUFA II established an independent fee structure and fee amounts to ensure stable and predictable user fee funding, improve the predictability of FDA funding and sponsor invoices, improve efficiency by simplifying the administration of user fees, and enhance flexibility of financial mechanisms to improve management of BsUFA program funding. The structure also established a BsUFA target revenue based on BsUFA program costs and updated the overall fee structure. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and third-party evaluation of program resource management, management of the carryover balance, along with the publication and annual update of a five-year financial plan.

The current authorization also includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. A list of the deliverables developed to meet BsUFA II commitments is available on the FDA web page at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-ii-deliverables.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

The meeting format will include presentations by FDA and a series of panels representing different stakeholder groups. We will also provide an opportunity for other stakeholders to provide public comment at the meeting. FDA policy issues outside of the BsUFA program are beyond the scope of these reauthorization discussions. Accordingly, the comments should focus on process enhancements and funding issues, and not on policy issues.

B. Participating in the Public Meeting

Registration: Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on November 5, 2020, at *https://bsufaiii-publicmeeting.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone.

Opportunity for Public Comment: Those who register online by November 5, 2020, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify 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 comments and request time jointly. All requests to make a public comment during the meeting must be received by November 5, 2020, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by November 12, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is available at *https://collaboration.fda.gov/bsufanov2020/.*

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 meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-11192020-11192020.*

Dated: October 26, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–24028 Filed 10–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2088]

Sanofi-Aventis U.S. LLC, et.al.; Withdrawal of Approval of 11 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 11 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 30, 2020.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 061884	Rifamate (isoniazid and rifampin) Capsules, 150 milligrams (mg); 300 mg.	Sanofi-Aventis U.S. LLC 55 Corporate Dr., Bridgewater, NJ 08807.
ANDA 065196	Ceftazidime for Injection, 1 gram(g)/vial	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 065197	Cefotaxime for Injection, Equivalent to (EQ) 1 g base/vial; EQ 2 g base/vial; EQ 500 mg base/vial.	Do.
ANDA 078229	Terbinafine Hydrochloride (HCl) Tablets, EQ 250 mg base.	Do.
ANDA 081134	Niacin Tablets, 500 mg	Do.
ANDA 091659	Heparin Sodium Injection, 5,000 units/milliliter (mL)	CASI Pharmaceuticals, Inc., 9620 Medical Center Dr., Suite 300, Rockville, MD 20850.
ANDA 202647	Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL).	Yung Shin Pharmaceutical Industrial Co., Ltd./Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008.
ANDA 202648	Granisetron HCl Injection, EQ 1 mg base/mL (EQ 1 mg base/mL); EQ 4 mg base/4 mL (EQ 1 mg base/mL).	Do.
ANDA 205173	Bosentan Tablets, 62.5 mg and 125 mg	Mylan Pharmaceuticals Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 207843	Telmisartan Tablets, 20 mg, 40 mg, and 80 mg	Hisun Pharmaceutical (Hangzhou) Co., Ltd./Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.