FD&C Act, we have developed the following topical guidance documents:

• ''*Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*'' (January 3, 2017), available on our website at *https://www.fda.gov/media/90173/download.* The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under section 503B of the FD&C Act. Once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance describes who must report, the format of the report, the content to include in each report, when to report, how outsourcing facilities may submit reports to FDA, and the consequences of outsourcing facilities' failure to submit reports.

• ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (October 8, 2015), available at *https://www.fda.gov/media/90997/download.*

The guidance documents were issued consistent with FDA's good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 503B of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
503B AERs	55	1	55	1.10	61
503B Recordkeeping AERs	55	1	55	16	880
503A Reporting	45	~197	8,879	0.87	7,968
503A Recordkeeping	45	2	90	1	90
503A Disclosure (MOU)	1	1	1	1	1
Outsourcing facility registration & reporting under 503B(b)			8,111		214
Total			17,191		9,214

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

Based upon our evaluation of the information collection, we have retained our currently approved burden estimate.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20773 Filed 11–21–25; 8:45 am]

BILLING CODE 4164–01–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, the Agency, or we) is hosting a hybrid public meeting to discuss proposed recommendations for the reauthorization of the Biosimilar User Fee Act (BsUFA) for fiscal years (FYs) 2028 through 2032. The 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 2027. 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 2028 through 2032. These comments will be published and available on FDA's website.

DATES: The public meeting will be held on December 3, 2025, from 9 a.m. to 12 p.m. Eastern Time, and will take place in person and virtually. Either electronic or written comments on this public meeting must be submitted by January 2, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held in-person at the FDA White Oak Campus, 10903 New Hampshire Ave., Building Conference Center, the White Oak Great Room, Silver Spring, MD 20993–0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. Participants must be REAL ID compliant to access Federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.* For security and parking information, please refer to *https://www.fda.gov/about-fda/visitor-information* and *https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.* Any changes to the public meeting location and remote information, as appropriate, will be posted to *https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 2, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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.

• 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, 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.

FOR FURTHER INFORMATION CONTACT: Thamar Bailey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32 Rm. 4103, Silver Spring, MD 20993–0002, 301–796–6645, *BSUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a hybrid public meeting to begin the reauthorization process for BsUFA. The authority to collect user fees under BsUFA expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future FYs 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 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 2023 through 2027'' (the BsUFA III Commitment Letter) (available at *https://www.fda.gov/media/152279/download?attachment*). 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 the public's 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 four general questions:

• What is your assessment of the overall performance of the current reauthorization of BsUFA FYs 2023 through 2027 to date?

• What current elements of BsUFA should be retained, changed, or discontinued to further strengthen and improve the program?

• What new elements, if any, should FDA consider adding to the program to enhance the efficiency and effectiveness of the biosimilar biological product review process?

• What changes, if any, could be made to the current fee structures and amounts to better advance the goals of the agreement, including facilitating product development and timely access for consumers?

II. What is BsUFA and 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 under the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) for a 5-year period. Congress reauthorized BsUFA (BsUFA II) for an additional 5 years, through FY 2022, under the FDA Reauthorization Act of 2017 (Pub. L. 115–52). BsUFA was most recently reauthorized in 2022 under Title IV of the FDA User Fee Reauthorization Act of 2022 (FDAUFRA)(Pub. L. 117–180), extending the program through FY 2027 (BsUFA III).

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 FDAUFRA, the BsUFA III 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.*

The current authorization of BsUFA (BsUFA III) introduces new supplement categories, timelines, and performance goals to expedite the review of supplemental biosimilar biological product applications. It establishes new procedures and performance goals for the review of use-related risk analysis and human factors protocol submissions, aimed at advancing the development of biosimilar biological product-device combination products. To improve overall meeting management, BsUFA III modifies two meeting types (Biosimilar Initial Advisory and Type 4), creates a new meeting type (Type 2a), and provides a new follow up opportunity after meetings or written-response-only communication. The agreement introduces a regulatory science pilot program focused on advancing the development of interchangeable biosimilar biological products and improving the efficiency of biosimilar biological product development. It includes additional commitments to advance interchangeable biosimilar biological product development through publishing foundational guidances and stakeholder engagement. BsUFA III includes commitments to promote best practices in communication between FDA and sponsors during application reviews, enhance inspection communication, and provide guidance on alternative tools to assess manufacturing facilities.

BsUFA III builds on the financial enhancements included in BsUFA II to ensure optimal use of user fee resources, transparency around the use of financial resources, and management of the carryover balance. The agreement commits FDA to leveraging cloud technology to modernize the Electronic Submissions Gateway and to establish and progress a data and technology modernization strategy. A comprehensive list of the deliverables developed to meet BsUFA III commitments is available on the FDA website at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-iii-deliverables.*

III. Public Meeting Information

A. Purpose and Scope of the Meeting

The public meeting's format will include presentations by FDA and other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, the biosimilar biological product industry, and the general public. FDA policy issues outside of the BsUFA program are beyond the scope of these reauthorization discussions. Accordingly, comments should focus on process enhancements and funding issues, and not on policy issues outside of the BsUFA program scope. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

B. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following web page: *https://bsufareauthorization.eventbrite.com/.* Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email.

Registration is free for both in-person and virtual attendance. In-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If you need special accommodations due to a disability, please email *BsUFAReauthorization@fda.hhs.gov* no later than November 21, 2025, 11:59 p.m. Eastern Time.

Opportunity for Public Comment: During online registration, you may indicate if you wish to make a public comment. 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 and request time jointly. Following the close of registration, we will determine the amount of time allotted to each commenter and the approximate time each comment is to begin, and will notify participants by November 26, 2025. All requests to make a public comment during the meeting must be received via registration by November 21, 2025, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. The webcast link for this public meeting can be found here: *https://teams.microsoft.com/l/meetup-join/19%3ameeting_MTVlZjIxZWEtZWU4YS00M2U1LWJjZjYtMjMwMjYzOTNhMTFh%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%228bdc93ee-b39c-48de-bb43-4e71da4f3d52%22%7d.*

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/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

Notice of this meeting is given pursuant to 21 U.S.C 379j–53.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20654 Filed 11–21–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0835]

Tobacco Products Scientific Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC or the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues related to tobacco products. The meeting will be open to the public. FDA is establishing a docket for public comments related to the TPSAC meeting.

DATES: The meeting will be held on January 22, 2026, from 9:00 a.m. to 4:30 p.m. Eastern Time (ET).

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be