for conduct relating to the regulation of any drug product under the FD&C Act. On November 17, 2025, Dr. Aslam was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Eastern District of Michigan, when the court entered judgment against him after his plea of guilty to one count of the illegal sale or trade of prescription drugs, in violation of 21 U.S.C. 333(a)(2) (section 303(a)(2) of the FD&C Act), which constitutes a felony under Federal law.

The underlying facts supporting the conviction are as follows: As described in the Indictment and Plea Agreement in Dr. Aslam's case, Dr. Aslam was a licensed oncologist practicing medicine at Somerset Hematology Oncology, P.C. (Somerset). Dr. Aslam and Somerset were healthcare entities under 21 CFR 203.3(q) because Dr. Aslam, through Somerset, provided medical treatment to patients. Through Somerset, Dr. Aslam had access to several prescription cancer medications that he could buy from drug distributors, including Distributor-1, a publicly traded company that distributed prescription drugs including Enhertu®, Padcev®, Poteligo®, Tivdak®, and Trodelvy®.

Samer Youssef owned and operated SMA Patient Care LLC (SMA), which was both a retail pharmacy and engaged in the wholesale distribution of prescription drugs. SMA and its customers were not healthcare entities under 21 CFR 203.3(q). Youssef operated SMA with the assistance of Houda Bazzi. As part of Youssef and Bazzi's business, they learned about customers who wanted to purchase certain prescription drugs, and they worked to acquire the prescription drugs and re-sell them at a profit. Youssef and Bazzi, however, did not have access to several prescription cancer drugs.

Dr. Aslam came to an agreement with Youssef and Bazzi to purchase and acquire prescription cancer drugs for purposes of selling these drugs to and through SMA and its customers. But as a healthcare entity, it was unlawful for Dr. Aslam to buy and resell prescription cancer drugs because he was only allowed to buy drugs to administer to his patients. Thus, to obtain these prescription drugs from Distributor-1 for purposes of the illegal resale to SMA and its customers, Dr. Aslam made or caused to be made numerous false and misleading statements including that these drugs were to be purchased to treat patients pursuant to a valid prescription and that they would be resold in compliance with the law. Immediately after receiving the prescription drugs, Dr. Aslam contacted Bazzi and Youssef, and they arranged to pick up the drugs from Somerset for resale to their customers.

From 2019 to 2023, Dr. Aslam used his medical license and arrangement with Distributor-1 to purchase more than 20 different prescription cancer drugs that he resold to and through SMA, including for example, Enhertu®, Poteligeo®, Tivdak®, and Trodelvy®. He did so without ensuring the drugs—many of which required special handling or were infusion drugs—were shipped properly. None of the prescription drugs were administered or intended to be administered to treat patients as required by law and the applicable contract terms with Distributor-1. Dr. Aslam profited from his purchase and resale of illegally purchased prescription cancer drugs by charging SMA more than he paid Distributor-1, sharing the profit when SMA resold the drugs for more than he charged SMA for the drugs, and receiving rebates and discounts from Distributor-1 based on the amount of qualifying drugs he purchased. During this time period, Dr. Aslam bought from Distributor-1 more than $16 million in prescription drugs that he resold to SMA. Based on a comparison of records showing how much Dr. Aslam paid Distributor-1 and how much SMA paid Dr. Aslam and Somerset, Dr. Aslam received $2,601,568.47 in proceeds from the sales.

As a result of this conviction, FDA sent Dr. Aslam, by certified mail, on June 1, 2026, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Aslam was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Dr. Aslam of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Aslam received the proposal and notice of opportunity for a hearing on June 9, 2026. Dr. Aslam failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Dr. Naveed Aslam has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Aslam is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act.

Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Dr. Aslam during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Aslam provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act. In addition, FDA will not accept or review any abbreviated new drug application from Dr. Aslam during his period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this [FD&C] Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19654 Filed 9–24–26; 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 product applications. 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. Following discussions with the regulated industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations, as necessary.

DATES: The public meeting will be held on October 26, 2026, from 9 a.m. to 12 p.m. Eastern Time, and will take place in person and virtually. Either electronic or written comments on the proposed recommendations must be submitted by November 25, 2026.

ADDRESSES: The hybrid 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.*

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 November 25, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2026. 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.
- 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. 4171, Silver Spring, MD 20993–0002, 301–796–6645, *BSUFAReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a hybrid public meeting to begin the reauthorization process for BsUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of biosimilar biological product applications. The current authorization of the program (BsUFA III) expires in

September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to help fund the process for the review of biosimilar biological product applications. Section 744I(f)(5) of the FD&C Act (21 U.S.C. 379j–53(f)(5)) requires that after FDA holds negotiations with regulated industry and periodic consultations with patient and consumer advocacy groups, we do the following: (1) present the recommendations to the relevant Congressional committees, (2) publish the recommendations in the **Federal Register**, (3) provide a period of 30 days for the public to provide written comments on the recommendations, (4) hold a meeting at which the public may present its views, and (5) after consideration of public views and comments, revise the recommendations as necessary.

This notice, the comment period, and the public meeting described in this notice help satisfy these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the relevant Congressional committees. The purpose of the meeting is to hear the public's views on the proposed recommendations for the reauthorized program (BsUFA IV). The following information is provided to help potential meeting participants better understand the history and evolution of the BsUFA program and the status of the proposed BsUFA IV recommendations.

II. What is BsUFA and what does it do?

The following information is provided to help potential meeting participants better understand the history and evolution of the BsUFA program and its status. BsUFA is a law that authorizes FDA to assess and collect fees from drug companies that submit marketing applications for certain biosimilar biological products. BsUFA was originally enacted in 2012 under the Food and Drug Administration Safety and Innovation Act (FDASIA) (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 (FDARA) (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 without compromising review quality or FDA's high standards for safety, efficacy, and quality. 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 available at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

The current authorization of BsUFA (BsUFA III) introduced new supplement categories, timelines, and performance goals to expedite the review of supplemental biosimilar biological product applications. It established 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 modified two meeting types (Biosimilar Initial Advisory and Type 4), created a new meeting type (Type 2a), and provided a new follow-up opportunity after meetings or written-response-only communication. The agreement introduced 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 included additional commitments to advance interchangeable biosimilar biological product development through publishing foundational guidances and stakeholder engagement. BsUFA III included 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 built upon 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 committed 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 FDA's website at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/completed-bsufa-iii-deliverables.*

III. Proposed BsUFA IV Recommendations

In preparing the proposed recommendations to Congress for BsUFA reauthorization, FDA conducted discussions with the regulated industry and consulted with patient and consumer advocacy groups, as required by law. We began the BsUFA reauthorization process by publishing a notice in the **Federal Register** (90 FR 52967, November 24, 2025) requesting public input on the reauthorization and announcing a public meeting that was held on December 3, 2025. The meeting included a presentation by FDA, remarks from representatives of regulated industry, and public comments from representatives of a number of different stakeholder groups, including patient advocates, consumer advocacy groups, health care professionals, and academic researchers. The materials from the meeting, including a transcript and webcast recording, can be found at *https://www.fda.gov/industry/public-meeting-reauthorization-biosimilar-user-fee-act-bsufa-12032025.*

Following the December 2025 public meeting, FDA conducted negotiations with the regulated industry and held monthly consultations with patient and consumer advocacy groups from April 2026 through June 2026. As directed by Congress, FDA posted minutes of these meetings on its web page, BsUFA IV: Fiscal Years 2028–2032, available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032.*

The proposed enhancements for BsUFA IV address many of the priorities identified by public stakeholders, the regulated industry, and FDA. The proposed enhancements modify aspects of the program to match advances in science and changes in the industry, establish new processes to increase efficiency and enhance communication, advance a lifecycle approach to addressing manufacturing issues, and enhance regulatory and financial

transparency. Across the commitment letter, FDA proposes to remove one-time commitments completed under BsUFA III and streamline the text where possible. The full text of the proposed BsUFA IV Commitment Letter can be found on the Agency's web page, BsUFA IV: Fiscal Years 2028–2032, available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032.* Each significant new or modified enhancement is described briefly below.

A. Original and Resubmitted Supplemental Biosimilar Biological Product Applications

To streamline and simplify review, FDA proposes to modify the supplement categories and timelines. FDA proposes to replace the BsUFA III supplement categories with two categories that correspond with either 4- or 6-month review timelines. FDA also proposes to issue guidance and/or a manual of policies and procedures on (1) post-approval submissions to 351(k) applications that seek to make labeling changes to conform to changes in reference product labeling and (2) submissions for unbranded 351(k) application labeling. These enhancements are described in section I.A.2 of the proposed BsUFA IV Commitment Letter.

B. Provisional Determinations

To facilitate Agency action on biosimilar biological applications upon the expiration of applicable exclusivity periods, FDA proposes to establish a structured process and review timeline for approval requests submitted for applications in a provisional determination status, which refers to applications that otherwise meet applicable licensure standards but cannot be approved due to an unexpired period of exclusivity. FDA also proposes to issue guidance or a manual of policies and procedures on the provisional determination process. These enhancements are described in section I.A.6. of the proposed BsUFA IV Commitment Letter.

C. Imminent Action

To promote efficient review, FDA proposes to enable the Agency to work 60 days past an application goal date to address discrete, late-arising, resolvable issues to help avoid otherwise unnecessary provisional determinations and complete response actions. This enhancement is described in section I.A.7. of the proposed BsUFA IV Commitment Letter.

D. New Target Action Date

To enhance communication with applicants, FDA proposes to establish a process under which the Agency would notify the applicant of an anticipated missed biologics license application (BLA) or supplement goal date, establish a new internal target action date, and identify the issue(s) responsible for the delay. If the new target action date is not met, the Agency would contact the applicant and provide an update on the issue causing delay and the estimated timeline for action, when possible. These enhancements are described in section I.A.8. of the proposed BsUFA IV Commitment Letter.

E. Initial Pediatric Study Plan

To enhance the efficiency of initial pediatric study plan (iPSP) submissions, FDA proposes to publish a biosimilar-specific iPSP template and make it available for public comment. FDA proposes to finalize the template following consideration of public comments. FDA also proposes to issue guidance addressing pediatric study plans for biosimilar products and how biosimilar applicants can meet applicable Pediatric Research Equity Act (PREA) requirements. These enhancements are described in section I.C. of the proposed BsUFA IV Commitment Letter.

F. Multi-Dose Pharmacokinetic and/or Pharmacodynamic Study and Comparative Efficacy Study Protocol Review

To help ensure applicants receive feedback on critical questions prior to study initiation, FDA proposes to implement a process for prioritizing review of multi-dose pharmacokinetic and/or pharmacodynamic study or comparative efficacy study (CES) protocols. FDA proposes to update relevant manuals of policies and procedures and standard operating policies and procedures describing processes and timelines for protocol review to account for this enhancement. This enhancement is described in section I.H. of the proposed BsUFA IV Commitment Letter.

G. Meeting Management

To improve overall meeting management, FDA proposes three enhancements: (1) eliminating the biosimilar initial advisory (BIA) meeting; (2) providing sponsors with the option to request a written response only (WRO) for all BsUFA meeting types; and (3) allowing applicants to use the follow-up opportunity to seek clarification of FDA's advice following a meeting, a WRO, or a correspondence that responds to a sponsor's meeting question. Additionally, FDA proposes revising the biosimilar biological product development (BPD) Type 2b meeting description. This update replaces the BIA meeting with the Type 2b meeting as a sponsor's initial interaction with FDA to discuss a proposed development program. These enhancements are described in section I.I. of the proposed BsUFA IV Commitment Letter.

H. Combination Products

To support the development of biosimilar biological-device combination products, FDA proposes to establish human factors (HF) protocol review goals and issue guidance on alternative approaches to comparative use HF studies. FDA also proposes expanding the BPD Type 2b meeting description to allow sponsors to request a review of use-related risk analysis, comparative analysis, or HF study protocols. These enhancements are described in section I.J. of the proposed BsUFA IV Commitment Letter.

I. Advancing Chemistry, Manufacturing, and Controls Facility Assessment: A Risk-Based Lifecycle Approach

To support the timely development and availability of biosimilar products, FDA proposes to introduce a risk-based lifecycle approach to identifying and addressing manufacturing facility deficiencies. This proposed BsUFA IV chemistry, manufacturing, and controls (CMC) facility lifecycle program is designed to facilitate a proactive approach to addressing manufacturing facility deficiencies through new and enhanced engagement mechanisms between FDA and the regulated industry that may happen before, during, and after an application review cycle. The program introduces a new option for a single CMC facility pre-submission meeting to discuss manufacturing facilities for a proposed application to facilitate readiness before a facility evaluation and inspection. The program also introduces a new post-pre-license inspection (PLI) meeting, when needed, to discuss inspection findings that may impact application approval and corrective actions that may address identified approvability issues. In addition, the program introduces a CMC facility post-action meeting for applications that receive a complete response due in part to manufacturing facility deficiencies. This meeting provides an opportunity to discuss and understand the deficiencies that should be corrected before the application can be approved. FDA proposes to issue guidance describing the implementation

of the facility lifecycle program, as well as conduct a third-party assessment and associated public workshop to assess the program's effectiveness and its impact on facility-issue driven complete responses. These enhancements are described in section I.K. of the proposed BsUFA IV Commitment Letter.

J. BsUFA Regulatory Science Pilot Program

Given the goals for the BsUFA regulatory science pilot program were met, FDA proposes sunsetting the program at the end of BsUFA III. If the Agency conducts regulatory science research using BsUFA operating funds during BsUFA IV, FDA proposes the Agency would notify industry and make the research results publicly available, as appropriate. These enhancements are described in section I.L. of the proposed BsUFA IV Commitment Letter.

K. BLA Revocation and Reissuance

To facilitate the transfer of 351(k) BLA(s) between applicants, FDA proposes establishing a 180-day timeline for revoking and reissuing licenses following the receipt of a complete transfer request. The proposed 180-day timeline does not apply in instances when (1) transfers include BLAs regulated by both the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research or (2) the BLA has outstanding facility issues. This enhancement is described in section I.M. of the proposed BsUFA IV Commitment Letter.

L. Assessment of BsUFA Review Program for Pre-Investigational New Drug Applications, Investigational New Drug Applications, and BLAs

To understand and enhance the efficiency of the biosimilar development and regulatory review program, FDA proposes a third-party assessment of review processes, outcomes, and communications between FDA and sponsors during first cycle review. This assessment will help FDA and regulated industry understand challenges and best practices and provide recommendations to help FDA and sponsors (1) limit first cycle complete responses (for applications that are ultimately approvable) and missed goal dates; (2) increase the effectiveness and efficiency of key review processes, communications, and materials; and (3) assess the use of imminent action, new target action dates, and review clock extensions. This enhancement is described in section I.N. of the proposed BsUFA IV Commitment Letter.

M. Continued Enhancement of User Fee Resource Management

FDA will build on the financial enhancements included in prior authorization cycles to ensure optimal use of user fee resources and the alignment of staff to workload through the continued operation of the Agency's resource capacity planning capability. FDA will also continue activities to promote transparency of the use of financial resources in support of the BsUFA program through publication of a 5-year financial plan (along with annual updates). FDA proposes to update the topics included in the financial plan, as well as in the annual Financial Report submitted to Congress. FDA proposes to offer annual technical staff meetings with regulated industry to support the transparency and understanding of BsUFA program finances, and to publish minutes from these meetings on its public website. These enhancements are described in section II of the proposed BsUFA IV Commitment Letter.

N. Enhancements to Fee Mechanisms

While the proposed statutory framework for setting the annual revenue amount is generally consistent with the current authorization, some updates are proposed for BsUFA IV. The updates include the discontinuation of the Strategic Hiring and Retention Adjustment, limits on the use of the Capacity Planning Adjustment, and a reduction in the maximum operating reserve.

BsUFA IV proposes a personnel compensation and benefits (PC&B) set-aside. This PC&B set-aside would ensure that FDA will reserve the funding needed to restaff the BsUFA program at a level consistent with fiscal year 2025, with appropriate adjustments for terminated staff and those intended to be transferred to Shared Services. The PC&B set-aside would ensure that the funds that are set aside will only be used for purposes relating to the hiring and retaining of staff for the review of biosimilar biological product applications. Until FDA's BsUFA-fee-funded PC&B spend exceeds the amount established as the PC&B target amount, the Capacity Planning Adjustment would be unavailable. FDA proposes to redirect existing resources to fund enhancements for BsUFA and restaff the BsUFA program in targeted areas.

The BsUFA IV agreement proposes fee structure changes. BsUFA IV would eliminate the initial, annual, and reactivation BPD fees. For sponsors that intend to submit more than one BLA that contains substantially the same information about the drug substance, BsUFA IV would also introduce a tiered application fee to incentivize such sponsors to submit the BLAs at the same time. This simultaneous filing structure allows the Agency to realize efficiencies in review workload. The proposed tiered application fee structure establishes: (1) a full application fee without the current statutory fee differentiation based on clinical data; (2) no fee for BLAs containing substantially the same information about the drug substance (or drug substances in the case of either a fixed-combination product or a combination product) as another BLA submitted by the same sponsor on the same day; and (3) a half application fee for BLAs containing substantially the same information about the drug substance (or drug substances in the case of either a fixed-combination product or a combination product) as another BLA submitted by the same sponsor on a prior day. BsUFA IV also proposes to update the eligibility for the small business waiver to only companies based in the United States (*i.e.,* applicants created or organized under the laws of any State).

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The meeting will include presentations by FDA and panels with FDA and regulated industry representatives to present and discuss the agreed-upon proposed enhancements. The meeting will also provide an opportunity for other interested parties, including scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, and the general public, to verbally comment on the proposed enhancements. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032.*

B. Participating in the Public Meeting

Registration: Information about how to register for the public meeting is available on FDA's web page for this public meeting: *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032.* 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 October 16, 2026, 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 public comments 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 October 19, 2026. All requests to make a public comment during the meeting must be received via registration by October 16, 2026, 11:59 p.m. Eastern Time. Onsite registration for public comments on the day of the public meeting will not be provided. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: When available, the virtual link to the hybrid public meeting will be posted on FDA's public web page at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032*. FDA will also distribute the link via email to registered attendees.

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 FDA's public web page at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iv-fiscal-years-2028-2032*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19660 Filed 9–24–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–9505]

Robotically-Assisted Surgical Devices—Premarket Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance titled ''Robotically-Assisted Surgical Devices—Premarket Submissions.'' This draft guidance provides draft recommendations for premarket submissions for robotically-assisted surgical devices (RASDs). This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 24, 2026 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–2026–N–9505 for ''Robotically-Assisted Surgical Devices—Premarket Submissions.'' 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