search-fda-guidance-documents, or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16638 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4698]

Determination That LASIX (Furosemide) Tablets, 20 Milligrams, 40 Milligrams, and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that LASIX (furosemide) tablets, 20 milligrams (mg), 40 mg, and 80 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035, *jennifer.forde@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, are the subject of NDA 016273, held by Validus Pharmaceuticals LLC, and initially approved on July 1, 1966. LASIX is indicated for adults and pediatric patients for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including nephrotic syndrome. Oral LASIX may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents.

LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 29, 2026 (Docket No. FDA–2026–P–4698), under 21 CFR 10.30, requesting that the Agency determine whether LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16648 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8163]

Reauthorization of the Prescription Drug 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 public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2028 through 2032. PDUFA authorizes FDA to collect user fees to support the process for the review of human drug applications. The current legislative authority for PDUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting prescription drug 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 hybrid public meeting will be held on September 16, 2026, from 9 a.m. to 2 p.m. (ET), and will take place in person and virtually. Submit either electronic or written comments on this public meeting by October 16, 2026.

ADDRESSES: The public workshop will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the 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. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

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 October 16, 2026. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. (ET) at the end of October 16, 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–2026–N–8163 for ''Reauthorization of the Prescription Drug 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. (ET), 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.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.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a hybrid public meeting to discuss proposed recommendations for the reauthorization of PDUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of human drug applications. The current authorization of the program (PDUFA VII) expires in September 2027. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the process for the review of human drug applications. Section 736B(f)(5) of the FD&C Act (21 U.S.C. 379h–2(f)(5)) requires that after FDA holds negotiations with regulated industry and periodic consultations with stakeholders, 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 30-day comment period, and the public meeting help satisfy these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the Congressional committees. The

purpose of the meeting is to hear the public's views on the proposed recommendations for the reauthorized program (PDUFA VIII). The following information is provided to help potential meeting participants better understand the history and evolution of the PDUFA program and the status of the proposed PDUFA VIII recommendations.

II. What is PDUFA and What Does it Do?

The following information is provided to help potential meeting participants better understand the history and evolution of PDUFA and its status. The Prescription Drug User Fee Act (PDUFA) is a law that authorizes FDA to collect fees from drug companies that submit marketing applications for certain human drug and biological products. PDUFA was originally enacted in 1992 as the Prescription Drug User Fee Act (Pub. L. 102–571) for a period of 5 years. In 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (FDAMA, Pub. L. 105–115), which renewed the program (PDUFA II) for an additional 5 years. Congress then extended PDUFA again for another 5 years (PDUFA III), through FY 2007, in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188). In 2007, Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA, Pub. L. 110–85) reauthorized PDUFA through FY 2012 (PDUFA IV, Pub. L. 112–144), and in 2012 the Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized the law through FY 2017 (PDUFA V). PDUFA was again reauthorized through FY 2022 (PDUFA VI) under Title I of the FDA Reauthorization Act of 2017 (FDARA). PDUFA was most recently reauthorized in 2022 under the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) which lasts through FY 2027 (PDUFA VII).

PDUFA's intent is to provide additional revenues so that FDA can hire staff, improve systems, and establish a better managed human drug review process to make important therapies available to patients sooner without compromising review quality or FDA's high standards for safety, efficacy, and quality. As part of FDA's negotiated agreement with industry during each reauthorization, the Agency agrees to certain performance and procedural goals and other commitments that apply to aspects of the human drug review program. These goals apply, for example, to the process for the review of original new human drug and biological product applications, postmarket safety activities, and new data standards and technology enhancements.

During the first few years of PDUFA I, the additional funding enabled FDA to eliminate backlogs of original applications and supplements. Phased in over the 5 years of PDUFA I, the goals were to review and act on 90 percent of priority new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements within 6 months of submission of a complete application; to review and act on 90 percent of standard original NDAs, BLAs, and efficacy supplements within 12 months, and to review and act on resubmissions and manufacturing supplements within 6 months. Over the course of PDUFA I, FDA exceeded all these performance goals and significantly reduced median review times of both priority and standard NDAs and BLAs.

Under PDUFA II, the review performance goals were shortened, and new procedural goals were added to improve FDA's interactions with industry sponsors and to help facilitate the drug development process. The procedural goals, for example, articulated time frames for scheduling sponsor-requested meetings intended to address issues or questions regarding specific drug development programs, as well as time frames for the timely response to industry-submitted questions on special study protocols. FDA met or exceeded all the review and procedural goals under PDUFA II. However, concerns grew that overworked review teams often had to return applications as ''approvable'' because they did not have the resources and sufficient staff time to work with the sponsors to resolve issues so that applications could be approved in the first review cycle.

A sound financial footing and support for limited postmarket risk management were key themes of PDUFA III. Base user fee resources were significantly increased and a mechanism to account for changes in human drug review workload was adopted. PDUFA III also expanded the scope of user fee activities to include postmarket surveillance of new therapies for up to 3 years after marketing approval. FDA committed to the development of guidance for industry on risk assessment, risk management, and pharmacovigilance, as well as guidance to review staff and industry on review management principles. The draft guidance for industry entitled ''Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications'' (GRMPs) was originally published in April 2005 and was subsequently revised and republished in September 2018 (available at *https://www.fda.gov/media/72259/download* (83 FR 48435, September 25, 2018)).[1] Initiatives to improve application submission and Agency-sponsor interactions during the drug development and application review processes were also adopted.

With PDUFA's reauthorization under FDAAA Title I (PDUFA IV), FDA obtained a significant increase in base fee funding and committed to full implementation of GRMPs, which included providing a planned review timeline for premarket review, development of new guidance for industry on innovative clinical trials, modernization of postmarket safety, and elimination of the 3-year limitation on fee support for postmarket surveillance. Additional provisions in FDAAA (Titles IV, V, and IX) gave FDA additional statutory authority that increased the pre- and postmarket review process requirements, added new deadlines, and effectively increased review workload. Specifically, the new provisions expanded FDA's drug safety authorities, such as the authority to require risk evaluation mitigation strategies (REMS), order safety labeling changes, and require postmarket studies.

Under Title I of FDASIA, the fourth renewal of PDUFA, FDA implemented a new review program (''the Program'') to promote greater transparency and increase communication between the FDA review team and the applicant on the most innovative products reviewed by the Agency. The Program applied to all new molecular entity (NME) NDAs and original BLAs received by the Agency from October 1, 2012, through September 30, 2017. The Program added new opportunities for communication between the FDA review team and the applicant during review of a marketing application, including 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 for these complex applications. PDUFA V also required an assessment of the impact of the Program. The independent assessment of the Program entitled ''Assessment of the Program for Enhanced Review Transparency and Communication for

[1] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

NME NDAs and Original BLAs in PDUFA V,'' is available at *https://www.fda.gov/media/101907/download.*

In August 2017, FDARA was enacted, which renewed the prescription drug user fee program for a fifth time. This iteration of the program continued and built upon the successes of PDUFA V. In PDUFA VI, FDA and industry members agreed to continue the Program model developed in PDUFA V to continue to promote the efficiency and effectiveness of the first cycle review process. PDUFA VI includes commitments to enhance regulatory science and expedite drug development by focusing on enhancing communication between FDA and sponsors during drug development, early consultation on the use of new surrogate endpoints, and exploring the use of real-world evidence for use in regulatory decision-making, among other enhancements. This iteration included commitments to enhance the use of regulatory tools to support drug development and review through incorporation of the patient's voice in drug development, expanded use of a benefit-risk framework in drug reviews, and advancing the use of complex innovative trial designs and model informed drug development.

Under PDUFA VI, FDA also modernized the user fee structure to improve program funding predictability, stability, and administrative efficiency. The new structure eliminated the supplement fees, replaced the establishment and product fees with a program fee, and shifted a greater proportion of the target revenue to the new more predictable and stable annual program fee. The agreement also included commitments to enhance management of user fee resources through the development of a resource capacity planning capability and financial transparency activities. PDUFA VI included several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system.

The current authorization of PDUFA (PDUFA VII) introduced new enhancements to address changes in the drug development landscape, built on successful enhancements, and refined elements from previous authorizations. The PDUFA VII agreement strengthened staff capacity and capability in the Center for Biologics Evaluation and Research (CBER) to support the development, review, and approval of cell and gene therapy products. It incorporated new allergenic extract products into the PDUFA program and provided resources for review of those products. The agreement introduced timelines and performance goals for pre-approval review of postmarketing requirements and use-related risk analysis and human factor protocol submissions. It also included two new meeting types (Type D and INTERACT) to allow for focused discussion around specific and novel issues. PDUFA VII introduced four new pilot programs focused on advancing different aspects of drug development and review, including rare diseases (Rare Diseases Endpoint Advancement Pilot), real-world evidence (Advancing Real-World Evidence Program), manufacturing (Chemistry, Manufacturing, and Controls Development and Readiness Pilot), and drugs for unmet therapeutic areas (Split Real-Time Application Review). The agreement continued paired meeting programs (Model-Informed Drug Development Paired Meeting Program and Complex Innovative Trial Design Paired Meeting Program) that target complex applications. It introduced a series of new enhancements related to product quality reviews, chemistry, manufacturing, controls approaches, and advancing utilization of innovative manufacturing technologies. PDUFA VII built on the financial enhancements included in PDUFA VI to ensure optimal use of user fee resources and transparency around the use of financial resources. The agreement committed FDA to initiatives in leveraging cloud technology, modernizing the Agency's information technology systems, enhancing bioinformatics support, and use of digital health technologies to support drug development and review.

More information on these commitments can be found in the PDUFA VII commitment letter at: *https://www.fda.gov/media/151712/download?Attachment.* A list of the deliverables developed to meet PDUFA VII commitments is available on the FDA web page at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vii-deliverables.*

III. Proposed PDUFA VIII Recommendations

In preparing the proposed recommendations to Congress for PDUFA reauthorization, FDA conducted discussions with the regulated industry and consulted with stakeholders, as required by the law. We began the PDUFA reauthorization process by publishing a notice in the **Federal Register** requesting public input on the reauthorization and announcing a public meeting that was held on July 14, 2025.[2] 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-prescription-drug-user-fee-act-pdufa-07142025.*

Following the July 2025 public meeting, FDA conducted negotiations with the regulated industry and held monthly consultations with stakeholders from November 2025 through May 2026. As directed by Congress, FDA posted minutes of these meetings on its web page ''PDUFA VIII: Fiscal Years 2028–2032,'' available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032.*

The proposed enhancements for PDUFA VIII address many of the priorities identified by public stakeholders, the regulated industry, and FDA. While some of the proposed enhancements are new, many streamline or refine elements from the existing program. The enhancements are proposed in the following areas: premarket review (including regulatory decision tools); postmarketing evaluation; chemistry, manufacturing, and controls (CMC); financial management; and information technology. Across the commitment letter, FDA proposes to remove one-time commitments completed under PDUFA VII and streamline the text where possible. In some cases, FDA proposes to discontinue pilots initiated in PDUFA VII that were found to be underutilized or overtaken by new enhancements, including the Split Real-Time Application Review (STAR) pilot and the CMC Development and Readiness Pilot (CDRP). The full text of the proposed PDUFA VIII commitment letter can be found on the Agency's web page ''PDUFA VIII: Fiscal Years 2028–2032,'' available at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032.* Each significant new or modified enhancement is described briefly below:

[2] See ''Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments,'' 90 FR 21315, May 19, 2025.

A. Assessment of the Program, Efficacy Supplements, and Communications

To understand and enhance first cycle review processes, 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 (1) help FDA and sponsors limit first cycle complete responses (for applications that are ultimately approvable), missed goal dates, and review clock extensions, and (2) increase the effectiveness of FDA-sponsor communications during review. This enhancement is described in section I.C of the proposed PDUFA VIII commitment letter.

B. Pivotal Protocol Prioritization

To help ensure applicants receive feedback on critical questions prior to study initiation, FDA proposes to implement a process for prioritizing review of submitted pivotal protocols for studies intended to form the primary basis of an efficacy claim for a marketing application. Sponsors will identify relevant submissions as ''Pivotal Protocols'' in the cover letter, and FDA will prioritize review of such protocols. FDA proposes to update relevant Manuals of Policies and Procedures (MAPPs) and Standard Operating Policies and Procedures (SOPPs) describing processes and timelines for protocol review to account for this enhancement. This enhancement is described in section I.J of the proposed PDUFA VIII commitment letter.

C. Meeting Management Goals

To improve overall meeting management, FDA proposes two enhancements: highlighting the availability of multi-divisional meetings and introducing new processes for requesting and justifying meeting format. FDA proposes to highlight that sponsors may submit a request for a multi-divisional meeting within the existing formal PDUFA meeting types if they are developing an investigational product under multiple investigational new drugs (INDs) across multiple therapeutic areas. The goals of multi-divisional meetings are to increase efficiency and alignment across participating review divisions. FDA also proposes to add a new process for sponsors to request that pre-IND, Type C, Type D, and INTERACT (Initial Targeted Engagement for Regulatory Advice on CBER/CDER (Center for Drug Evaluation and Research) ProducTs) meetings be held face-to-face and, if not granted in that format, for FDA to convey a specific rationale for why a written response is sufficient. These enhancements are described in section I.K of the proposed PDUFA VIII commitment letter.

D. Expediting Drug Development and Enhancing the Use of Regulatory Science Tools

To extend and continue FDA's efforts to enhance regulatory science and expedite drug development, FDA proposes to expand the availability of regulatory science pilots and programs and incorporate those programs into review practice. FDA proposes transitioning the Model-Informed Drug Development (MIDD) Paired Meeting Program to Type C–MIDD meetings and working towards eliminating the quarterly cadence and cap on the number of meeting requests. FDA similarly proposes incorporating the Rare Disease Endpoint Advancement (RDEA) Pilot, Complex Innovative Trial Design (CID) Paired Meeting Program, and Advancing Real-World Evidence (RWE) Program into existing formal meeting requests. These enhancements are described in section I.L of the proposed PDUFA VIII commitment letter. Highlights from that section are included below. FDA proposes to introduce up to 10 Rare Disease Innovation, Science, and Exploration (RISE) workshops that build on the success of the rare disease programs in CDER and CBER and address key scientific and drug development barriers. FDA also proposes to publish case studies demonstrating how patient experience data was considered in specific regulatory decisions across different therapeutic areas. FDA will host a public meeting to discuss case studies and facilitate broader dialogue about the collection, submission, and use of patient experience data in drug development and regulatory review. To increase transparency and shared learnings, FDA proposes to hold a public meeting to discuss best practices for communicating the use of regulatory science tools in drug development and regulatory decision-making. Following the public meeting, FDA proposes to issue a summary report.

E. Enhancement and Modernization of the FDA Drug Safety System

FDA will continue to utilize user fees to enhance the drug safety system, including adopting new scientific approaches, improving the utility of existing tools for the detection, evaluation, prevention, and mitigation of adverse events, conducting Risk Evaluation and Mitigation Strategies (REMS) assessments, and coordinating regulatory activity in the premarket and postmarket settings. Enhancements to the drug safety system will improve public health by increasing patient protection while continuing to enable access to needed medical products.

FDA proposes to maintain the high-quality and large quantity of data available to support the Agency's pharmacoepidemiology needs, advance implementation of the Sentinel 3.0 operating model through support for data infrastructure, and sustain the processes and tools required to ensure appropriate use of these data, including comprehensive training of review staff. Additional proposed enhancements include streamlined reporting and enhanced transparency via biannual meetings with regulated industry. These enhancements are described in I.M of the proposed PDUFA VIII commitment letter.

F. Advancing Chemistry, Manufacturing, and Controls (CMC) Facility Assessment: A Risk-Based Lifecycle Approach

To support the timely development and availability of new and innovative products, FDA proposes to introduce a risk-based lifecycle approach to identifying and addressing manufacturing facility deficiencies. This proposed PDUFA VIII 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-Approval Inspection (PAI) or Pre-License Inspection (PLI) meeting, when needed, to discuss inspection findings that impact application approval and corrective actions that may address identified approvability issues. FDA proposes to publish guidance describing the implementation of the facility lifecycle program and to conduct a third-party assessment and associated public workshop to assess the effectiveness of the facility lifecycle program and the impact of the program on facility-issue driven complete responses. These enhancements are described in section I.N of the proposed PDUFA VIII commitment letter.

G. Supporting Review of Allergenic Extract Products

New allergenic extract products were incorporated and included in the PDUFA program under PDUFA VII. FDA proposes that epicutaneous-test diagnostic products (sometimes referred to as patch tests) be exempt from the PDUFA program and fees beginning in PDUFA VIII, to encourage continued development of these uniquely situated products. These enhancements are described in section I.P of the proposed PDUFA VIII commitment letter.

H. 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 PDUFA 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 transparency and understanding of the PDUFA program finances, and to publish minutes from these meetings on its public website. To identify whether efficiencies have been realized and determine whether those efficiencies should be reflected in the PDUFA revenue amounts, FDA proposes to partner with a third party to evaluate the operations of the PDUFA program. The proposed assessment would include a summary report and documentation of FDA's decision and rationale for any adjustment to be implemented as a result of the assessment. These enhancements are described in section II of the proposed PDUFA VIII commitment letter.

I. 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 PDUFA VIII. The updates include a process to assess whether any efficiencies identified in a planned assessment can be reflected in the revenue amounts (starting in fiscal year 2030), discontinuation of the Strategic Hiring and Retention Adjustment, limits on the use of the Capacity Planning Adjustment, discontinuation of the Additional Dollar Amounts, a reduction in the maximum operating reserve, and updates to the dollar amounts for the Additional Direct Costs.

The Enterprise Performance Adjustment (EPA) is part of the process proposed to identify whether efficiencies have been realized and, if so, whether those efficiencies should be reflected in the PDUFA program revenue amounts in fiscal years 2030–2032. This process would be informed by an independent third-party study of the full scope of the PDUFA program, including review of human drug applications and shared services that support the process for the review of human drug applications. This study would be made public on the FDA website.

PDUFA VIII 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 PDUFA 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 process for the review of human drugs. Until the FDA's PDUFA-fee funded personnel compensation and benefits (PC&B) spend exceeds the amount established as the PC&B target amount, the Capacity Planning Adjustment would be unavailable. Once the Capacity Planning Adjustment is available, it would be limited to no more than 3% of the inflation-adjusted revenue amount for the fiscal year.

The PDUFA VIII agreement proposes fee structure changes. PDUFA VIII would update the fee structure such that sponsors would receive a 50% reduction in the application fee if the application includes clinical data from at least one phase 1 trial anchored in the United States initiated after October 1, 2027. PDUFA VIII would also modify the fee structure to charge sponsors a fee, equal to 50% of the full application fee, for the first supplement seeking approval for a non-orphan indication for an application that was subject to the orphan application fee exception. The orphan program fee exemption would also be limited to products approved only for orphan indications. PDUFA VIII 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).

J. Impact of PDUFA VIII Enhancements on User Fee Revenue

The PDUFA VIII agreement proposes reductions in target revenue resulting from the sunsetting of limited-time operating costs under PDUFA VII and savings from administrative efficiencies realized by FDA. FDA proposes to redirect existing resources to fund enhancements for PDUFA VIII and restaff the PDUFA program in targeted areas.

The proposed base revenue amount also reflects a reduction of about $56.0 million in recognition of savings from administrative efficiencies and an increase of about $7.8 million for net additional positions reflecting the PDUFA VIII agreement. The net effect is a $48.3 million proposed reduction to the base revenue for PDUFA VIII.

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The meeting will include presentations by FDA and a series of panels with FDA and regulated industry representatives to present and discuss the agreed-upon proposed enhancements. The meeting will also include verbal comments on the proposed enhancements from other interested parties, which may include scientific and academic experts, healthcare professionals, representatives of patient and consumer advocacy groups, and the general public. A draft agenda and other background information for the public meeting will be posted at: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-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/prescription-drug-user-fee-amendments/pdufa-viii-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. If you need special accommodation due to a disability, please contact *PDUFAReauthorization@fda.hhs.gov* (mail to: *PDUFAReauthorization@fda.hhs.gov*) no later than September 2, 2026.

Opportunity for Public Comment: If you wish to speak during the public comment session, complete the request

form at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032* and identify which topic(s) you wish to address. All requests to make a public comment during the meeting must be received by September 2, 2026, 11:59 p.m. Eastern Time. 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. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and plan to select and notify participants by September 9, 2026. No commercial or promotional material will be permitted to be presented 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/prescription-drug-user-fee-amendments/pdufa-viii-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 the internet at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-viii-fiscal-years-2028-2032.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16650 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–3166]

Determination That ANSAID (Flurbiprofen) Tablets, 50 Milligrams and 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that ANSAID (flurbiprofen) tablets, 50 milligrams (mg) and 100 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for flurbiprofen tablets, 50 mg and 100 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Molly Arndt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6281, Silver Spring, MD 20993–0002, *Molly.Arndt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, are the subject of NDA 018766, held by Pharmacia and Upjohn Company, and initially approved on October 31, 1988. ANSAID is indicated for relief of the signs and symptoms of rheumatoid arthritis, and relief of the signs and symptoms of osteoarthritis.

ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of October 4, 2016 (81 FR 68427), FDA announced that it was withdrawing approval of NDA 018766, effective November 3, 2016.

Premier Research International, LLC submitted a citizen petition dated March 25, 2026 (Docket No. FDA–2026–P–3166), under 21 CFR 10.30, requesting that the Agency determine whether ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ANSAID (flurbiprofen) tablets, 50 mg and 100 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16666 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P