4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0891]

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 virtual public meeting entitled "Reauthorization of the Prescription Drug User Fee Act." The purpose of the public meeting is to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2023 through 2027. 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 2022. 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 (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 September 28, 2021, from 9 a.m. to 2 p.m. Eastern Time, and will be held by webcast only. Submit either electronic or written comments on this public meeting by October 28, 2021.

ADDRESSES: Registration to attend the virtual meeting and other information can be found at https://pdufavii-reauthorization.eventbrite.com. See the SUPPLEMENTARY INFORMATION section for registration date and 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 28, 2021. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 28, 2021. 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-2021-N-0891 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., 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. Transcripts of the meeting will be available on FDA's website at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027 approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Patrick Zhou, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1148, Silver Spring, MD 20993-0002, 301-348-1817, Patrick.Zhou@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing a virtual 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 VI) expires in September 2022. 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)(4) of the FD&C Act (21 U.S.C. 379h-2(f)(4)) requires that after FDA holds negotiations with regulated industry and periodic consultations with stakeholders, we do the following: (1) present recommendations to the relevant Congressional committees, (2) publish 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 will satisfy some of 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 VII). 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 VII 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. 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 most recently renewed in 2017 under Title I of the FDA Reauthorization Act of 2017 (FDARA) which lasts through FY 2022 (PDUFA VI).

PDUFA's intent is to provide additional revenues so that FDA can hire more 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.

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[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.

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 FDA's 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 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 reauthorization also 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. More information on these commitments can be found in the PDUFA VI commitment letter at https://www.fda.gov/media/99140/download.

As part of the current authorization, 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 third-party evaluation of program resource management, along with the publication and annual update of a 5-year financial plan.

Recognizing the challenges with hiring in PDUFA V, the current authorization also includes several commitments to improve the hiring and retention of critical review staff through modernization of FDA's hiring system, augmentation of hiring staff capacity and capabilities, creation of a dedicated function focused on staffing the program, reporting on hiring metrics, and a comprehensive and continuous assessment of hiring and retention. Annual performance reports for the PDUFA program can be found through FDA's web page "PDUFA Performance Reports," available at https://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports. Additionally, a list of some public-facing deliverables developed to meet PDUFA VI commitments is available on FDA's web page "Completed PDUFA VI Deliverables," available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/completed-pdufa-vi-deliverables.

III. Proposed PDUFA VII 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 23, 2020.[2] The meeting included presentations by FDA and a series of panels with representatives of different stakeholder groups, including patient advocates, consumer groups, regulated industry, health professionals, and academic researchers. The materials from the meeting, including a transcript and webcast recording, can be found at https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-reauthorization-prescription-drug-user-fee-act-pdufa-07232020-07232020.

Following the July 2020 public meeting, FDA conducted negotiations with the regulated industry and held monthly consultations with stakeholders from September 2020 through February 2021. As directed by Congress, FDA posted minutes of these meetings on its web page "PDUFA VII: Fiscal Years 2023-2027," available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027.

The proposed enhancements for PDUFA VII address many of the top priorities identified by public stakeholders, the regulated industry, and FDA. While some of the proposed enhancements are new, many either build on successful enhancements or refine elements from the existing program. The enhancements are proposed in the following areas: Center for Biologics Evaluation and Research (CBER) product review support, premarket review, regulatory decision tools, postmarketing evaluation, digital health and informatics, chemistry, manufacturing, and controls (CMC), and financial management. The full text of the proposed PDUFA VII commitment letter can be found on the Agency's web page "PDUFA VII: Fiscal Years 2023--2027," available at https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027. Each significant new or modified enhancement is described briefly below:

A. NME Milestones and Postmarketing Requirements (PMRs)

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[2] See "Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments," 85 FR 35096, June 8, 2020.

To ensure the timely availability of information on the safety and efficacy of therapies, FDA proposes to establish new timelines, performance goals, and a new process for pre-approval review of PMRs. Sponsors would also have the opportunity to request a review of existing PMRs for release. Any adopted changes and adjustments will be updated in relevant manuals of policies and procedures, standard operating procedures, and guidances. This enhancement is described in section I.C of the proposed PDUFA VII commitment letter.

B. Split Real Time Application Review Pilot Program

To allow earlier patient access to therapies that address an unmet medical need, FDA proposes establishing a pilot program for efficacy supplements that meet specific criteria. Applications that are accepted into the pilot program will be submitted in a "split" fashion, specifically in two parts with each component submitted approximately 2 months apart. The goal is to shorten the time from the date of complete submission of the application to the action date. This enhancement is described in section I.D of the proposed PDUFA VII commitment letter.

C. Meeting Management Goals

To improve overall meeting management, FDA proposes creating two new meeting types to better define the purpose of certain meeting requests: Type D and INTERACT. The Type D meeting allows for quicker discussion on a narrow set of issues (no more than two focused topics) between FDA and a sponsor, such as a followup question that raises a new issue after a formal meeting. The INTERACT meeting facilitates Investigational New Drug Application (IND) enabling efforts where a sponsor is facing a novel, challenging issue that might otherwise delay progress of the product towards entry into the clinic in the absence of this early FDA input. There would also be a new followup opportunity to pose clarifying questions after meetings or a written-response-only communication. These enhancements are described in section I.J of the proposed PDUFA VII commitment letter.

D. Enhancing Regulatory Science and Expediting Drug Development

The extension and continuation of FDA's efforts to enhance regulatory science and expedite drug development will encompass further evaluation and enhancement of FDA-sponsor communications, ensuring the sustained success of the breakthrough therapy program, continuing early consultations between FDA and sponsors on the use of new surrogate endpoints as the primary basis for product approval, advancing rare disease drug development, advancing the development of combination products, and exploring the use of real world evidence for use in regulatory decision making. These enhancements are described in section I.K of the proposed PDUFA VII commitment letter. Highlights from those sections are included below.

1. Advancing Development of Drugs for Rare Diseases

The lack of regulatory precedent, small trial populations, and/or limited understanding of natural history associated with rare diseases creates unique challenges when determining the appropriate efficacy endpoint(s) for clinical trials intended to evaluate the effectiveness of rare disease therapies. Though difficult to establish, well-developed efficacy endpoints, especially those that could apply to other rare diseases with similar manifestations, drive the general advancement of rare disease drug development. In addition to challenges associated with developing endpoints that appropriately capture key signs and symptoms of a rare disease and directly measure how patients feel, function, or survive, surrogate endpoint development is also challenging in diseases with slow progression, small patient populations, or other challenges commonly associated with drug development in rare diseases.

To support the advancement of rare disease treatments, FDA proposes a pilot program for supporting efficacy endpoint development for drugs that treat rare diseases by offering additional engagement opportunities with the Agency to sponsors of development programs that meet specific criteria.

2. Advancing Development of Drug-Device and Biologic Device-Combination Products Regulated by CBER and the Center for Drug Evaluation and Research (CDER)

Sponsors employ Use-Related Risk Analyses (URRA) studies to identify the need for risk mitigation strategies and to design a human factors (HF) validation study. Based on a URRA, a sponsor may propose that an HF validation study submission is not required to support the safe and effective use of a drug-device or biologic-device combination product. FDA proposes establishing new procedures for the review of URRAs along with performance goals.

HF validation studies are conducted to evaluate the user interface of a drug-device or biologic-device combination product to eliminate or mitigate use-related hazards that may affect the safe and effective use of the combination product. Over the past decade, more combination products have been developed to deliver therapeutics via different routes of administration (e.g., parenteral, inhalation) with complex engineering designs. HF validation protocols are reviewed during the IND stage with the goal towards developing a final finished combination product that supports the marketing application. To achieve this objective, FDA proposes updating the procedures for HF validation study protocols along with a new performance goal.

3. Advancing Real-World Evidence for Use in Regulatory Decision Making

In accordance with Section 3022 of the 21st Century Cures Act, and by providing earlier and increased Agency advice, FDA proposes a new pilot program around real-world evidence (RWE) to improve the quality and acceptability of RWE-based approaches in support of new intended labeling claims, including approval of new indications of approved medical products or to satisfy post-approval study requirements.

E. Enhancing Regulatory Decision Tools to Support Drug Development and Review

Building on the success of PDUFA VI, the enhancements under this section focus on enhancing regulatory decision tools to support drug development and review in the areas of patient focused drug development, benefit-risk assessment in regulatory decision making, drug development tools for qualification pathway for biomarkers, model-informed drug development, and complex innovative clinical trial designs. The details of these enhancements can be found in section I.L of the proposed PDUFA VII commitment letter.

F. 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, modernizing 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.

Specifically, PDUFA VII user fees will provide support for modernization and improvement of REMS assessments and optimization of the Sentinel Initiative (https://www.fda.gov/safety/fdas-sentinel-initiative) through: (1) maintenance of Sentinel Initiative capabilities and continued integration into FDA drug safety activities and (2) enhancement of the analytic capabilities of the Sentinel Initiative to address questions of product safety and advance the understanding of how RWE can be used for studying effectiveness. These enhancements are described in section I.M of the proposed PDUFA VII commitment letter.

G. Enhancements Related to Product Quality Reviews, Chemistry, Manufacturing, and Controls Approaches, and Advancing the Utilization of Innovative Manufacturing Technologies

To ensure new and innovative products are developed and available to patients in a timely manner, FDA proposes several enhancements related to communication between FDA and sponsors during product quality reviews, CMC approaches, and advancing use of innovative manufacturing technologies.

For product quality reviews, these enhancements would include promoting the use of structured information requests, a third-party assessment on current practices related to information requests, and a goal to notify sponsors of certain pre-approval inspections. Given the accelerated development of certain human drug products, FDA also proposes a new pilot program to facilitate the expedited CMC development of products under an IND based upon the

anticipated clinical benefit of earlier patient access to products. Additionally, FDA proposes holding a public workshop to help advance utilization and implementation of innovative manufacturing by facilitating and discussing best practices, barriers, and overall strategies. These enhancements are described in section I.N of the proposed PDUFA VII commitment letter.

H. Enhancing CBER's Capacity to Support Development, Review, and Approval of Cell and Gene Therapy Products

To ensure that new and innovative cell and gene therapy products are developed and available to patients in a timely manner, FDA proposes to build on the success of the Cell and Gene Therapy Program (CGTP) in CBER to further support and advance a balanced approach to product development and regulation. To this end, FDA will strengthen staff capacity and capability to meet the increasing challenges and demands in this growing field. Increasing staff capacity will overcome existing resource limitations, allowing staff to spend additional time on meetings and submission reviews including those with breakthrough or regenerative medicine advanced therapy designations, expand stakeholder outreach, invest in new policy and guidance, and facilitate development and use of regulatory tools and scientific technologies. These enhancements are described in section I.O of the proposed PDUFA VII commitment letter.

I. Supporting Review of New Allergenic Extract Products

FDA proposes to incorporate and include new allergenic extract products into the PDUFA program. Allergenic extract products licensed after October 1, 2022, would generally be included in user fees. Allergenic extract products licensed before October 1, 2022, and standardized allergenic extract products submitted pursuant to a notification to the applicant from the Secretary of Health and Human Services regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, would remain excluded from PDUFA. All performance goals, procedures, and commitments in this letter apply to the allergenic products included in the PDUFA program

under PDUFA VII. These enhancements are described in section I.P of the proposed PDUFA VII commitment letter.

J. Continued Enhancement of User Fee Resource Management

FDA is committed to ensuring the sustainability of PDUFA program resources and to enhancing the operational agility of the PDUFA program. FDA will build on the financial enhancements included in PDUFA VI and continue activities in PDUFA VII to ensure optimal use of user fee resources and the alignment of staff to workload through the continued maturation and assessment of the Agency's resource capacity planning capability. This would also include an independent assessment of the 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 annual public meetings, publishing a 5-year financial plan (along with annual updates), and additional reporting in the annual PDUFA Financial Report. These enhancements are described in section II of the proposed PDUFA VII commitment letter.

K. Enhancing Transparency and Leveraging Modern Technology

FDA is committed to enhancing the transparency of its information technology (IT) activities and modernization plans and will continue maintaining catalogs, standards, and plan updates that are published regularly to FDA's website in addition to the publication of a Data and Technology Modernization Strategy document and sharing regular updates on CBER IT modernization progress. FDA will continue regular meetings between FDA and industry IT leadership to discuss challenges, emerging needs, and progress on IT initiatives relevant to PDUFA VII. Additionally, FDA will advance the use of cloud-based technology in the PDUFA program to modernize the Electronic Submission Gateway and promote innovation in drug development and the regulatory review process. These enhancements are described in section IV.A of the proposed PDUFA VII commitment letter.

L. Expanding and Enhancing Bioinformatics Support

Bioinformatics and computational biology are increasingly being used to assess product quality, safety, and efficacy, and facilitate the development, characterization, and manufacture of human drugs and biologics. Recognizing the substantial increase in the volume and diversity of bioinformatics and computational biology information and data in regulatory submissions, such as Next Generation Sequencing, FDA proposes numerous activities to meet this growing need. These activities will include developing additional expertise and staff capacity in both CDER and CBER to efficiently review and provide technical and timely feedback, assessing and strengthening the computational infrastructure to support and advance our informatics platforms, and continuing to develop data standards and to issue/revise guidances on these topics. These enhancements are described in section IV.B of the proposed PDUFA VII commitment letter.

M. Enhancing Use of Digital Health Technologies (DHTs) to Support Drug Development and Review

While the biomedical field has experienced rapid development and implementation of DHTs, FDA has limited experience evaluating novel DHT-based measurements in human drug development. FDA recognizes the potential for DHTs to provide scientific and practical advantages in supporting the assessment of patients by generating information outside of the traditional clinic visit. FDA also recognizes the need to build capacity and expertise to advise the biopharmaceutical industry in their development and implementation and to evaluate DHT outputs including the impact of regulatory initiatives (or regulatory science). To support new drug registration, label expansion, and safety monitoring, DHT-based data need to be fit for the intended purpose. Toward these ends, FDA proposes to undertake numerous activities, including the publication of a framework document to guide the use of DHT-derived data in regulatory decision making, the formation of a committee to provide support to DHT-related efforts, and a series of public meetings, demonstration projects, and new or updated guidances. These enhancements are described in section IV.C of the proposed PDUFA VII commitment letter.

N. Enhancements to Fee Mechanisms for Increased Predictability, Stability, and Efficiency

The PDUFA VII agreement continues to build on the resource capacity planning capability established in PDUFA VI and continues financial transparency initiatives. In addition, PDUFA VII enhances mechanism to manage financial risks by establishing a minimum amount of available operating reserves to be maintained each year. This minimum amount will start at an amount equivalent to 8 weeks of operations and increase to 10 weeks of operations by FY 2025. PDUFA VII also adds a strategic hiring and retention adjustment to ensure FDA has the funding necessary to provide for the costs of retaining and hiring highly qualified scientific and technical staff for the process for the review of human drug applications under PDUFA. This strategic hiring and retention adjustment will add $9 million to the base revenue amount in FY 2023 and $4 million in each subsequent year.

O. Impact of PDUFA VII Enhancements on User Fee Revenue

To implement the proposed enhancements for PDUFA VII, funding for a cumulative total of 352 full-time equivalent staff is proposed to be phased in over the course of PDUFA VII. The new funding will be phased in as follows:

- $65,773,693 for FY 2023
- $25,097,671 for FY 2024
- $14,154,169 for FY 2025
- $4,864,860 for FY 2026
- $1,314,620 for FY 2027

In addition, to support the other additional direct costs associated with PDUFA VII enhancements, the following amounts will be added:

- $44,386,150 for FY 2023
- $60,967,993 for FY 2024
- $35,799,314 for FY 2025
- $35,799,314 for FY 2026
- $35,799,314 for FY 2027

IV. Public Meeting Information

A. Purpose and Scope of the Meeting

The meeting will include a presentation by FDA and a series of panels with FDA and Industry representatives to present and discuss the agreed-upon proposed enhancements. For members of the public who would like to make verbal comments on the proposed enhancements (see instructions below), there will be a public comment period at the end of the meeting. We will also provide an opportunity for individuals to submit written comments to the docket before and after the meeting.

B. Participating in the Public Meeting

Registration: Registration is optional and not required to attend this virtual public meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. If you wish to register, you can do so at https://pdufavii-reauthorization.eventbrite.com.

Opportunity for Verbal Public Comment: Those who register online will receive a confirmation email that includes a link to a request form to make a verbal public comment at the meeting. If you wish to speak during the public comment session, follow the instructions in that email and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by September 14, 2021, 11:59 p.m. Eastern Time. Depending on the number of requests, we will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by September 21, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The Zoom Webinar ID for this public meeting is 161 932 6064. The webcast link for this public meeting can be found here:

https://fda.zoomgov.com/j/1619326064?pwd=WWZhZXhYRDNoYmg0WFRvSVgvdE5BUT09

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The link above should allow you to enter the webinar directly. If Zoom asks for a passcode, please use the case-sensitive passcode below.

Case-Sensitive Passcode for Zoom Webinar: PDUFa7!

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-vii-fiscal-years-2023-2027.

Dated: August 18, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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