Regarding the guidance: Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0002, 301–796–1036; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes; International Council for Harmonisation; Draft Guidance for Industry.'' The draft guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are the FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In September 2021, the ICH Assembly endorsed the draft guideline entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance adds monographs for seven new compounds to the M7 Guideline which outlines considerations for assessment and control of DNA reactive (mutagenic) impurities to limit potential carcinogenic risk. The compounds are: Acetaldehyde, dibromoethane, epichlorohydrin, ethyl bromide, formaldehyde, styrene, and vinyl acetate. The addendum is intended to update the M7 Guideline in line with the ICH process for its maintenance and includes other revisions.

This draft guidance has been left in the original ICH format. It contains only a list of revisions to the M7(R1) Guideline as well as the monographs for seven new compounds submitted for public consultation. The final guidance will include a complete, integrated M7(R2) Guideline and Addendum and will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication.

The draft guidance, when finalized, will represent the current thinking of FDA on ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk'' and its Addendum. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, and the collection of information under 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: April 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07395 Filed 4–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0907]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a virtual public meeting entitled ''Medical Device User Fee Amendments.'' The purpose of the meeting is to discuss proposed recommendations for the

reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2023 through 2027. MDUFA authorizes FDA to collect fees and use them for the process for the review of device applications. The current legislative authority for MDUFA expires September 30, 2022. At that time, new legislation will be required for FDA to continue collecting device user fees in future fiscal years. Following discussions with the device 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**, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views 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 virtually on April 19, 2022, from 12 p.m. to 4:30 p.m. Eastern Time. Submit electronic or written comments to the public docket by April 21, 2022.

ADDRESSES: Registration to attend this virtual public meeting and other information can be found at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

You may submit written comments on the recommendations as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 21, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 21, 2022. 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–2020–N–0907 for ''Medical Device User Fee Amendments; Public Meeting.'' FDA published the commitment letter on March 22, 2022. The commitment letter can be found in the docket and on this website at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* The docket will close on April 21, 2022. 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 available 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: Mimi Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5547, Silver Spring, MD 20993, 301–796–4125, *MDUFAVReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of proposed recommendations for the reauthorization of MDUFA, which authorizes FDA to collect user fees and use them for the process for the review of device applications. We are also announcing a virtual public meeting to discuss such recommendations. The current authorization of the MDUFA program continues until September 30, 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to provide funds for the process for the review of device applications.

Section 738A(b)(4) of the FD&C Act (21 U.S.C. 379j–1(b)(4)) requires that, after holding negotiations with regulated industry, we take the following actions: (1) Present the recommendations to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and

Pensions of the U.S. Senate; (2) publish the recommendations in the **Federal Register**; (3) provide a period of 30 days for the public to submit written comments on the recommendations; (4) hold a meeting at which the public may present its views on the recommendations; 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 parts of these requirements. After the public meeting, we will revise the recommendations as necessary. In addition, the Agency will present the recommendations to the Congressional committees.

The purpose of the meeting is for the public to present its views on the proposed recommendations for the reauthorized program (MDUFA V). The meeting format will include presentations by FDA and different stakeholder interest groups (such as industry, patient and consumer advocates, healthcare professionals, and scientific and academic experts). The Agency will also provide an opportunity for other interested individuals to make presentations at the meeting.

The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and the current status of the proposed MDUFA V recommendations.

II. What is MDUFA and what does it do?

MDUFA is the law that authorizes FDA to collect fees from device companies that register their establishments, submit applications to market devices, and make other types of device submissions. In the years preceding enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance. MDUFMA was enacted ''in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier point in time, and to ensure that reprocessed medical devices are as safe and effective as original devices.'' H.R. Rep. 107–728 at p. 21 (October 7, 2002). MDUFMA was authorized for 5 years and contained two important features that relate to reauthorization:

- User fees for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. User fees and other appropriations for the medical device program helped FDA expand available expertise, modernize its information management systems, provide new review options, and provide more guidance to prospective submitters. The ultimate goal was for FDA to clear or approve safe and effective medical devices more rapidly and predictably, benefiting applicants, the healthcare community, and most importantly, patients.
- Negotiated performance goals for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and included FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA also agreed to several other commitments that did not have specific timeframes or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals had not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations were viewed by FDA, Congress, and industry stakeholders as essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for—and reauthorizations have maintained—fee discounts and waivers for qualifying small businesses. Small businesses make up a large proportion of the medical device industry, and these discounts and waivers helped reduce the financial impact of user fees on this sector of the device industry, which plays an important role in fostering innovation.

Since MDUFMA was first enacted in 2002, it has been reauthorized three times through the Medical Device User Fee Amendments of 2007 (MDUFA II), the Medical Device User Fee Amendments of 2012 (MDUFA III), and the Medical Device User Fee Amendments of 2017 (MDUFA IV). MDUFA IV has been in effect since 2017 and will expire on September 30, 2022 (*https://www.fda.gov/media/100848/download).* The MDUFA IV agreement enabled FDA to continue making progress on reducing review times and bringing devices to patients more quickly, while also enabling FDA to move forward in critical areas, including:

- Building a sustainable infrastructure for efficient, consistent, transparent, and high-quality regulation of devices throughout the total product lifecycle;
- Accessing and using real-world evidence in the regulatory decision-making process;
- Advancing patient engagement and the regulatory science of patient input;
- Advancing the smart oversight of digital health technologies in ways that support innovation, balance innovation and safety, and show promise as a potential blueprint for future regulatory approaches to emerging technologies.

In terms of review goals, FDA's performance was strong during the initial years of MDUFA IV (FY 2018 and FY2019), continuing to meet and exceed performance goals and working to reduce the time for patients to have access to safe, new, innovative devices. During this time, FDA achieved all of our submission review goals, met 21 of 24 performance enhancement goals, and FDA and industry met three of four shared outcome goals. Starting in FY 2020, the strain from the pandemic, as well as a workload that exceeded assumptions underlying the MDUFA IV agreement, resulted in failure to meet certain MDUFA IV goals.

Preliminary performance data through September 30, 2021, including completed and pending reviews, indicate that FDA has met (or has the potential to meet) 13 of the 16 FY 2020 review goals and 9 of the 13 FY 2021 review goals for which FDA had a sufficient MDUFA cohort to calculate performance. FDA also completed, on time, all eight performance enhancement goals due in FY 2021. However, FDA's response to the unprecedented COVID–19 public health emergency has impacted FDA's MDUFA performance, resulting in three missed FY 2020 review goals and four missed FY 2021 review goals. Information about FDA's performance is available in the yearly and quarterly MDUFA performance reports, which are online at: *https://www.fda.gov/about-fda/user-fee-performance-reports/mdufa-performance-reports and https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports.*

III. Proposed MDUFA V Recommendations

In preparing the proposed recommendations to Congress for MDUFA reauthorization, FDA conducted discussions with the device

industry and consulted with stakeholders, as required by the FD&C Act. The Agency began the MDUFA 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 October 27, 2020. The meeting included presentations by FDA (which complemented videos released ahead of the public meeting highlighting FDA's efforts and accomplishments under the MDUFA IV agreement) and a series of panels with representatives of different stakeholder groups, including patient and consumer advocacy groups, regulated industry, and healthcare professionals. The materials from the meeting, including a transcript and webcast recording, can be found at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-10272020.*

From February 2021 through March 2022, FDA conducted negotiations with representatives of the device industry: The Advanced Medical Technology Association; the Medical Device Manufacturers Association; the Medical Imaging and Technology Alliance; and the American Clinical Laboratory Association. During its negotiations with industry, FDA also held monthly consultations with representatives of patient and consumer advocacy groups and other public stakeholders. Meeting minutes are posted on FDA's website at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.*

The proposed recommendations for MDUFA V address many priorities identified by industry and other stakeholders. While some of the proposed recommendations are new, many either build on successful enhancements or refine elements from the existing program. FDA posted the full text of the proposed MDUFA V commitment letter at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* Each significant new or modified recommendation is briefly described below with reference to the applicable section of the proposed commitment letter.

A. Shared Outcome Goals

FDA and representatives of the device industry believe that the process improvements outlined in the proposed commitment letter, when implemented by all parties as intended, should reduce the average Total Time to Decision for premarket approval applications (PMAs), and premarket notification (510(k)) submissions, provided that the total funding of the device review program adheres to the assumptions underlying the MDUFA V agreement. Reducing average Total Time to Decision, as defined in the commitment letter, is an important aspect of the user fee program, so that safe and effective devices reach patients and healthcare professionals more quickly. FDA proposes, for PMA and 510(k) submissions, with the performance improvement adjustments described below, that the Total Time to Decision will reach 270 calendar days for original PMA and panel-track supplement submissions and 108 calendar days for 510(k)s by FY 2027.

Additional details regarding the shared outcome goals can be found in Sections I and III of the proposed commitment letter.

B. Pre-Submissions

MDUFA V provides additional resources for FDA to address the increasing volume of Pre-Submissions requests and to improve the Pre-submission performance goal. FDA proposes to ramp up to a performance goal of providing written feedback on at least 90 percent of Pre-Submissions within 70 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner, by FY 2025. With the performance improvement adjustments described below, FDA may continue to improve this performance goal in FY 2026–2027. FDA will also update guidance to include additional information to assist applicants and review staff in identifying the circumstances in which an applicant's question is most appropriate for informal communication instead of a Pre-Submission. Additional details regarding Pre-Submissions can be found in Sections II.A and III.C of the proposed commitment letter.

C. De Novo Requests

FDA will have an opportunity, with the performance improvement adjustments described below, to ramp up to a De Novo decision goal of 90 percent of De Novo request submissions within 150 days in FY 2027. Additional details regarding De Novo requests can be found in Sections II.E and III.B of the proposed commitment letter.

D. Opportunity for Performance Improvements

FDA proposes adding a new performance improvement adjustment for MDUFA V that would allow FDA to collect fees in addition to annual total revenue in FY 2025, FY 2026, and/or FY 2027, if certain review performance and/or shared outcome goals are met for FY 2023, 2024, and/or 2025. If applicable, these fee increases will apply solely to establishment registration fees and support improvements to the 510(k) and PMA Shared Outcome Total Time to Decision goals, the Pre-Submission Written Feedback goal, and the De Novo decision goal. The following examples describe adjustments if goals are met for FY 2023:

- If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met for FY 2023, and fee revenue above the annual total revenue amount is provided in FYs 2026 and 2027, then the 510(k) Shared Outcome Total Time to Decision goal and the PMA Shared Outcome Total Time to Decision goal will be adjusted. Specifically, the 510(k) Shared Outcome Total Time to Decision goal will be improved to 108 days for FYs 2026 and 2027, and the PMA Shared Outcome Total Time to Decision goal will be improved to 275 days for FYs 2026 and 2027.
- If the Pre-Submission Written Feedback goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided to support performance improvements in FYs 2025, 2026, and 2027, the maximum number of Pre-Submissions subject to the goal will improve to 4,700 Pre-Submissions in FYs 2025, 2026, and 2027.
- If the De Novo decision goal is met for FY 2023, and fee revenue above the annual total revenue amount is provided in FYs 2026 and 2027 to support performance improvements, the goal will improve to 80 percent of De Novo requests receiving a MDUFA decision within 150 FDA days for FYs 2026 and 2027.

Additional details regarding the opportunity for performance improvements can be found in Section III of the proposed commitment letter. Under the new performance improvement adjustment, FDA may receive additional funding up to the following maximum amounts (which would be adjusted for inflation):

- $15,396,600 for FY 2025
- $44,135,700 for FY 2026
- $56,244,000 for FY 2027

E. Deficiency Letters

To support improved communication in FDA letters requesting additional

information, FDA will clarify what constitutes a statement of the basis for the deficiency in updated guidance, train staff and managers on the updated guidance, and establish a performance goal for providing a statement of the basis for the deficiency that ramps up to 95 percent by FY 2027.

F. Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot

FDA will launch a voluntary pilot program to provide more frequent and timely interactions for industry and other stakeholders earlier in the device development process with a focus on Breakthrough (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program*) and Safer Technologies Program devices (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices*). Through the TAP Pilot, FDA will provide strategic engagement for innovative devices of public health importance by facilitating improved strategic decision making during product development, including earlier identification, assessment, and mitigation of product-development risk. The TAP Pilot will also support engagement to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process. Additional details regarding the TAP Pilot can be found in Section V.J of the proposed commitment letter.

G. Patient Science and Engagement

FDA proposes to continue building the Patient Science and Engagement program, which engages patients and supports incorporating their perspectives in the regulatory process. In particular, FDA proposes to expand the program through the following activities: Facilitate patient engagement through patient-friendly educational content; explore ways to advance health equity; continue to expand patient science review expertise and capacity; improve the regulatory predictability and impact of patient science, including shared examples; hold a public meeting on patient-generated health data for collecting clinical outcome assessment (COA) data and for remote clinical trials; and issue draft guidance on incorporating COA into premarket studies and update patient preference information guidance. Additional details regarding patient science and engagement can be found in Section V.E of the proposed commitment letter.

H. Enhanced Use of Consensus Standards

During MDUFA IV, FDA initiated the voluntary Accreditation Scheme for Conformity Assessment (ASCA) pilot to enhance product reviewers' and device manufacturers' confidence in medical device testing when manufacturers rely on testing completed by ASCA-accredited testing laboratories. FDA proposes to use lessons learned from implementation of the ASCA pilot in MDUFA IV to transition to a sustainable and expanded program in MDUFA V. Additional details regarding the enhanced use of consensus standards can be found in Section V.C of the proposed commitment letter.

I. International Harmonization

FDA will enhance international harmonization activities by expanding engagement in international harmonization and convergence efforts to promote alignment with international best practices and internationally developed policies. Additional details regarding international harmonization can be found in Section V.I of the proposed commitment letter.

J. Third Party Premarket Review Program

FDA proposes to maintain the Accredited Persons (Third Party Review) program in MDUFA V. Additional details regarding the Third Party Review program can be found in Section V.D of the proposed commitment letter.

K. Real World Evidence (RWE)

FDA proposes to continue to advance the development of Real-World Data (RWD) and RWE methods and policies to advance regulatory acceptance for premarket submissions. Additional details regarding RWE can be found in Section V.F of the proposed commitment letter.

L. Digital Health

FDA proposes to continue building its digital health expertise, working to streamline and align FDA review processes with software lifecycles for digital health products, engaging in international harmonization efforts related to software review, and conducting other activities related to digital health. Additional details regarding digital health can be found in Section V.G of the proposed commitment letter.

M. Information Technology (IT)

FDA proposes to continue to enhance IT infrastructure to support the process for the review of device applications, including improving a submission progress tracking system and developing electronic submission templates for more submission types. Additional details regarding IT can be found in Section IV.C of the proposed commitment letter.

N. Financial Transparency and Hiring

FDA proposes to take several new steps to provide additional transparency and accountability measures with respect to MDUFA V finances and hiring. The Agency proposes to publish a MDUFA 5-year financial plan that will be updated annually. In addition, new statutory language for an operating reserve adjustment is proposed to reflect FDA and industry-agreed measures for managing the amount of operating reserves in the MDUFA carryover balance. Under this new provision, FDA would decrease registration fees if the amount of operating reserves exceeds the designated amount. The designated amount for a fiscal year is equal to 13 weeks of operating reserves plus the 1 month of operating reserves required by statute. Further, the amount of carryover user fees intended to support the Third Party Review program and TAP Pilot during MDUFA V would be excluded for the period of FY 2023 through FY 2026 when calculating the amount of operating reserves to determine if registration fees will be decreased. User fee funds in the carryover balance that are considered unappropriated or unearned are not included in the operating reserves.

To help ensure that FDA accomplishes hiring in accordance with the assumptions underlying the MDUFA V agreement, FDA proposes to set annual hiring goals for MDUFA V positions. Proposed statutory language would provide for the reduction of establishment registration fees for FYs 2025, 2026, and 2027, if the Agency does not meet those goals for FYs 2023, 2024, and 2025, respectively, by a certain threshold. The amount of the hiring adjustment fee decrease would be the product of the number of hires by which the hiring goal was missed and one-quarter of the inflation-adjusted cost per full time equivalent. Additional details regarding financial transparency and hiring can be found in Section IV.B of the proposed commitment letter.

O. Independent Assessments

FDA and industry propose to participate in a targeted assessment of the management of the process for the review of device applications. FDA also proposes to retain an independent contractor with expertise in assessing public sector workforce data analysis

and reporting to conduct an assessment of current methodologies and data/metrics available to represent the MDUFA workforce. Additional details regarding the independent assessments can be found in Section VI of the proposed commitment letter.

P. Performance Reports

FDA proposes to continue to report quarterly and annually on performance against commitments. Additionally, FDA proposes to report quarterly on progress toward hiring goals and funding intended for RWE activities. FDA will report annually on the primary cost drivers for changes to personnel compensation and benefits costs. Additional details regarding performance reporting can be found in Section VII of the proposed commitment letter.

Q. User Fee Revenue and Fee Allocations

As part of MDUFA V, FDA and industry propose updating the base fee amounts for PMAs and annual establishment registrations, as well as the annual total revenue amounts, to reflect negotiated fee levels. The statutory total revenue amounts, base fee amounts, and amounts for potential performance improvement adjustments are proposed in FY 2021 dollars, such that annual inflation adjustments will be used to inflate FY 2021 dollars to the appropriate amounts for each fiscal year in MDUFA V. FDA and industry also propose to change the fee for a PMA Panel-Track supplement from 75 percent to 80 percent of the fee for an original PMA and to change the fee for a 510(k) submission from 3.4 percent to 4.5 percent of the fee for a PMA. Finally, a minor change is proposed to the statutory provisions regarding fee waivers and reductions for small businesses to clarify that an applicant seeking a waiver or reduction is not required to submit a certification from the national taxing authority of the foreign country in which the applicant, or its affiliate, is located, if the country has no national taxing authority.

FDA will post the agenda approximately 5 days before the meeting at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

IV. Participating in the Public Meeting

Registration: To register for the public meeting, please visit *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.* Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Registrants will receive confirmation after they have been accepted.

Registration is free. Persons interested in attending by webcast the MDUFA virtual public meeting must register online by 4 p.m. Eastern Time, April 18, 2022. Early registration is recommended.

If you need special accommodations because of a disability, please contact Susan Monahan at 240–205–2260 or *Susan.Monahan@fda.hhs.gov* no later than April 11, 2022.

Requests for Oral Presentations: This meeting includes a public comment session and topic-focused sessions. During online registration you may indicate if you wish to present during the public comment session or a specific session, and which topic(s) you wish to address. All requests to make oral presentations virtually by webcast must be received by April 11, 2022, at 4 p.m. Eastern Time. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify speakers by April 12, 2022. If selected for presentation, any presentation materials must be emailed to Mimi Nguyen (see **FOR FURTHER INFORMATION CONTACT**) no later than April 13, 2022, at 4 p.m.. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

FDA is holding this meeting to provide information on the proposed recommendations for the reauthorization of MDUFA for FYs 2023 through 2027. To permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The docket was opened on March 22, 2022. The proposed commitment letter was posted in the docket and on this website at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v.* The docket will close on April 21, 2022, 30 days after the proposed commitment letter was posted.

Streaming Webcast of the Public Meeting: The webcast link will be available on the registration web page after April 11, 2022. Organizations are requested to register all participants.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *in the docket 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 approximately 45 days after the public workshop on the internet at: *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-04192022.*

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07451 Filed 4–6–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; COVID–19 Provider Relief Fund (PRF) and American Rescue Plan (ARP) Rural Payment Reporting Activities, OMB No. 0906–0068—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than June 6, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft