ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hour per response	Total burden hours
Program Monitoring Forms	1500	3	10	45,000

John M. Sweet Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–19811 Filed 9–4–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0907]

Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027; 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 or the Agency) is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2023 through 2027 (MDUFA V). MDUFA authorizes FDA to collect user fees to support the process for the review of medical device applications. The current legislative authority for MDUFA expires after September 30, 2022, and new legislation will be required for FDA to continue collecting user fees for the medical device program in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA begin MDUFA reauthorization by publishing a notice in the **Federal Register** requesting public input and holding a public meeting where the public may present its views on the reauthorization, providing a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA, and publishing the comments on FDA's website.

DATES: The public meeting will be held on October 27, 2020, from 9 a.m. Eastern Time to 2 p.m. Eastern Time. Submit either electronic or written comments on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program by November 27, 2020. Registration to view the meeting must be received by October 23, 2020.

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/2020-medical-device-meetings-and-workshops.* (Select this meeting from the posted events list.) 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 November 27, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on November 27, 2020. 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 for Fiscal Years 2023 Through 2027.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting

of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1664, Silver Spring, MD 20993, 301–796–4322, *ellen.olson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a virtual public meeting to begin the reauthorization process of MDUFA, the legislation that authorizes FDA to collect user fees to support the process for the review of device applications. Without new legislation, FDA will no longer be able to collect user fees after FY 2022 to fund the medical device review process.

Section 738A(b)(2) of the FD&C Act (21 U.S.C. 379j–1(b)(2)) requires that before FDA begins negotiations with the regulated industry on MDUFA reauthorization, the Agency perform the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting where the public may present its views on the reauthorization, including specific suggestions for changes to the goals set under MDUFA IV; (3) provide a period of 30 days after the public meeting to obtain written comments from the public; and (4) publish the comments on FDA's website at *https://www.fda.gov.* This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on FDA's website will satisfy these requirements.

The purpose of the meeting is to hear stakeholder views on MDUFA as we consider the features to propose, update, and discontinue in the next MDUFA and FDA's recommendation to Congress. Information about the MDUFA program can be found at *https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.* Information about MDUFA IV can be found at *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2017-mdufa-iv* and the MDUFA IV Performance Goals and Procedures can be found at *https://www.fda.gov/media/102699/download.* FDA is interested in responses to the following general questions and welcomes any other pertinent information stakeholders would like to share:

(1) What is your assessment of the overall performance of MDUFA IV thus far?

(2) What programs/commitments under MDUFA IV are working well?

(3) What programs/commitments can be added or improved to enhance the efficiency and effectiveness of the medical device review process for MDUFA V?

(4) What should the medical device ecosystem, and our medical device program in particular, look like at the end of MDUFA V (*i.e.,* September 2027), and how can MDUFA V support achieving that future state?

II. Topics for Discussion at the Public Meeting

In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder groups (such as patient advocates, consumer protection groups, industry, healthcare professionals, and academic researchers). FDA will also provide an opportunity for public comment at the meeting, and for organizations and individuals to submit written comments to the docket. The presentations should focus on program improvements and funding issues, including specific suggestions for changes to performance goals, and not focus on policy issues. We will make the agenda for the public meeting available by October 13, 2020, on the internet at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/2020-medical-device-meetings-and-workshops.* (Select this meeting from the posted events list.)

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in viewing this public meeting must register by October 23, 2020, by 4 p.m. Eastern Time. Registrants will receive confirmation when their registration has been accepted. You will be notified if you are on a waiting list. We will update the website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5661, *susan.monahan@fda.hhs.gov* no later than October 13, 2020.

Requests for Oral Presentations: During online registration, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. All requests to make oral presentations must be received by September 28, 2020, at 4 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 presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify selected speakers by October 5, 2020. If selected for presentation, any presentation materials must be emailed to Ellen Olson (see **FOR FURTHER INFORMATION CONTACT**) no later than October 20, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: The webcast link will be available on the registration web page after October 13, 2020.

Transcripts: As soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this meeting from the posted events list.)

Dated: September 2, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–19771 Filed 9–4–20; 8:45 am]

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