participating in this program to contact CDER.

DATES: Pharmaceutical companies may send proposed agendas to the Agency by May 5, 2020.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993–0002, 301–796–0578, *dan.brum@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, which generally lasts a few days, small groups of CDER regulatory project managers, often including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, nonclinical and clinical evaluation, postmarketing activities, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04604 Filed 3–5–20; 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 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) is announcing a public meeting on the reauthorization of the Medical Device User Fee Amendments for fiscal years (FYs) 2023 through 2027 (MDUFA V). The current legislative authority for the medical device user fee program expires on October 1, 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) requires that before FDA begins negotiations with the regulated industry on MDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA, and publish the comments on FDA's website. FDA invites public comment on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program.

DATES: The public meeting will be held on April 7, 2020, from 9 a.m. to 5 p.m. EST. 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 May 6, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus.*

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 May 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on May 6, 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.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting on the reauthorization of the Medical Device User Fee Amendments of 2017 (MDUFA IV), which currently authorizes FDA to collect user fees during FYs 2018–2022 and use them for the process for the review of device applications. Without new legislation, referred to as reauthorization, FDA will not be able to collect user fees after FY 2022 to fund the medical device review process.

Prior to reauthorization, FDA must consult with the regulated industry and make recommendations to Congress regarding the goals for the process for the review of device applications (see 21 U.S.C. 379j–1(b)(1)(F)). Before beginning negotiations with the regulated industry on user fee reauthorization, section 738A(b)(2) of the FD&C Act (21 U.S.C. 379j–1(b)(2)) requires that FDA do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which 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 suggesting changes to MDUFA; and (4) publish the comments on FDA's website. 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 medical device user fee reauthorization as we consider FDA's recommendation to Congress for the next medical device user fee program. 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 programs/commitments under MDUFA IV are currently working well?

2. What programs/commitments can be improved for MDUFA V?

3. What new programs/commitments should be considered as part of MDUFA V?

4. Thinking more broadly than the MDUFA program alone, 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

Through this notice, we are announcing a public meeting to hear stakeholder views on the reauthorization of MDUFA for FYs 2023 through 2027, including specific suggestions for any changes to the user fee program that we should consider. We will conduct the meeting on April 7, 2020. In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection groups, industry, health care professionals, and academic researchers). FDA will also provide an opportunity for individuals to make presentations during the meeting, either during a specific session or the public comment session, and for organizations and individuals to submit written comments to the docket after the meeting. The presentations should focus on program improvements and funding issues, including specific suggestions for changes to performance goals, and not focus on other general policy issues. We will make the agenda for the public meeting available by March 12, 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 attending this public meeting must register by March 26, 2020, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when their registration has been accepted. You will be notified if you are on a waiting list. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will update the website if registration closes before the day of the public meeting.

If you need special accommodations, 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 March 23, 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. 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. Following the close of registration, we 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 April 1, 2020. All requests to make oral presentations must be received by the close of registration on March 26, 2020, at 4 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Ellen Olson (see **FOR FURTHER INFORMATION CONTACT**) no later than March 26, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This meeting will also be webcast. The webcast link will be available on the registration web page after March 26, 2020. Organizations are requested to register all participants, but to view using one connection per location. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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: March 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04638 Filed 3–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5572]

Inclusion of Older Adults in Cancer Clinical Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Inclusion of Older Adults in Cancer Clinical Trials.'' This draft guidance provides recommendations regarding the inclusion of older adult patients in clinical trials of drugs for the treatment of cancer. For the purpose of this draft guidance, older adults are those age 65 years and older. The draft guidance emphasizes the particular importance of including adults over age 75 years in cancer clinical trials. Specifically, this draft guidance includes recommendations for including an adequate representation of older adults in cancer clinical trials to better enable evaluation of the benefit-risk profile of cancer drugs in this population.

DATES: Submit either electronic or written comments on the draft guidance by May 5, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–5572 for ''Inclusion of Older Adults in Cancer Clinical Trials.''