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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Peter Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Rm. 2112, Silver Spring, MD 20993, 240–402–8605, *Peter.Chen@fda.hhs.gov;* 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017.'' This guidance concerns the implementation of the PDUFA VI and certain changes in policies and procedures surrounding its application. Because PDUFA VI created significant changes to the user fee program, this guidance serves to provide an explanation about the new fee structure and types of fees for which applicants are responsible.

PDUFA VI provides two different fee types that applicants pay: Application and program fees. This guidance describes when these fees are incurred and the process by which applicants can submit payments. The guidance also provides information on consequences of failing to pay PDUFA VI fees as well as the process for submitting a reconsideration and appeals request.

In the **Federal Register** of October 13, 2017 (82 FR 47748), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. We have reviewed the comments submitted to the docket and determined that they did not raise any relevant issues. This guidance does not include any substantive changes from the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on assessing user fees under PDUFA VI. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: April 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09366 Filed 5–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force). The meeting will be open to the public; public comment sessions will be held during the meeting.

DATES: The inaugural meeting will be held on Wednesday, May 30, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time and Thursday, May 31, 2018, from 9:00 a.m. to 3:30 p.m. Eastern Time The agenda will be posted on the Task Force website at *https://www.hhs.gov/ash/advisory-committees/pain/index.html*.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Email: *paintaskforce@hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) authorizes the Secretary of Health and Human Services, in cooperation with

the Secretaries of Defense and Veterans Affairs, to convene the Task Force no later than two years after the date of the enactment of CARA (by July 22, 2018) and develop a report to Congress with updates on best practices and recommendations on addressing gaps or inconsistencies for pain management, including chronic and acute pain. The Task Force is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The Task Force will identify, review, and determine whether there are gaps or inconsistencies between best practices for pain management, including chronic and acute pain, developed or adopted by federal agencies; propose updates to best practices and recommendations on addressing identified gaps or inconsistencies; provide the public with an opportunity to comment on any proposed updates and recommendations; and develop a strategy for disseminating such proposed updates and recommendations to relevant federal agencies and the general public.

This inaugural meeting of the Task Force will consist of an overview of various topics surrounding pain management, and the establishment of the Task Force subcommittee structure. Federal, state, local, and professional medical and health organization representatives will provide their current perspectives on pain management. The Task Force will discuss clinical best practices, gaps and inconsistencies focused on prevention and treatment; mental health and addiction; special populations; education; providers; payors; service and delivery; and research and innovation. Personal testimonials of people living in pain will be given. The Task Force will deliberate and vote on establishing subcommittees for developing the report to Congress. Information about the final meeting agenda will be posted prior to the meeting on the Task Force website: *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

Members of the public are invited to participate in person or by webcast. To join the meeting, individuals must pre-register at the Task Force website at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.* Seating will be provided first to those who have pre-registered. Anyone who has not pre-registered will be accommodated on a first come, first served basis if additional seats are available 10 minutes before the meeting starts. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying the Office of the Assistant Secretary for Health via email at *paintaskforce@hhs.gov* by May 22, 2018. The subject line of the email should read, ''Task Force Meeting Accommodations.'' Non-U.S. citizens who plan to attend in person are required to provide additional information and must notify the Task Force staff via email at *paintaskforce@hhs.gov* 10 business days before the meeting, May 16, 2018. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

Members of the public can provide comments at the Task Force meeting during the following designated dates and times: May 30, 2018 from 11:40 a.m. to 12:10 p.m. Eastern Time and May 31, 2018 from 1:50 p.m. to 2:20 p.m. Eastern Time. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should submit their comments through the Federal eRulemaking Portal at *http://www.regulations.gov* by May 25, 2018.

Dated: April 26, 2018.

Vanila M. Singh,

Chief Medical Officer, Office of the Assistant Secretary for Health.

[FR Doc. 2018–09379 Filed 5–2–18; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Stakeholder Listening Session in Preparation for the 71st World Health Assembly; Meeting

Subject: Office of Global Affairs: Stakeholder Listening Session in preparation for the 71st World Health Assembly

Time and date: Friday, May 11th, 2018, 3:00 p.m.–4:30 p.m. EST

Place: Hubert H. Humphrey Building, Auditorium, 200 Independence Ave, SW, Washington, District of Columbia 20201.

Status: Open, but requiring RSVP to *OGA.RSVP@hhs.gov* by Monday, May 7, 2018.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 71st World Health Assembly—will hold an informal Stakeholder Listening Session on Friday, May 11 from 3:00 p.m. to 4:30 p.m., in the Hubert H. Humphrey Building Auditorium, 200 Independence Ave. SW, Washington, DC 20201.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all individuals interested in and affected by agenda items to be discussed at the 71st World Health Assembly. Participants will be limited to 3 minute statements per agenda item. Your input will contribute to informing U.S. positions as we negotiate with our international colleagues at the World Health Assembly on these important health topics.

The listening session will be organized by agenda item, and participation is welcome from all individuals, including individuals familiar with the following topics and groups:

- Public health and advocacy activities;
- State, local, and Tribal issues;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 71st World Health Assembly can be found at this website: *http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_1-en.pdf*

RSVP: Due to security restrictions for entry into the HHS Hubert H. Humphrey Building, RSVPs are required for this event. Please send your full name and organization to *OGA.RSVP@hhs.gov* . Please RSVP no later than Monday, May 7, 2018.

If you are *not* a U.S. citizen *and* do not have a U.S. government issued form of identification, please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information required for your clearance. Photo identification for all attendees is required for building access without exception.

Written comments are welcome and encouraged, even if you are planning on attending in person. Please send your written comments to *OGA.RSVP@hhs.gov.*

We look forward to hearing your comments related to the 71st World Health Assembly agenda items.