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 (CBER), 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: Keith Verrett, Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 2179, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@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 ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' This guidance provides recommendations to applicants regarding requests for waivers, reductions, or refunds of user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g and 379h). This guidance describes the types of waivers, reductions, and refunds permitted under the user fee provisions of the FD&C Act and the procedures for submitting requests for waivers, reductions, refunds, as well as requests for reconsiderations or appeals. The guidance also provides additional clarification on certain issues such as user fee exemptions for orphan drugs and FDA's current thinking on considerations relevant to eligibility for user fee waivers, reductions, and refunds under the applicable statutory provisions.

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 ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products.'' 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information of this guidance has been approved under OMB control number 0910–0693. The collection of information associated with Form FDA 3397 has been approved under OMB control number 0910–0297. The collections of information associated with new drug applications or biologics license applications have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively. See section X of the guidance document.

III. Electronic Access

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

Dated: October 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22690 Filed 10–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Council on Graduate Medical Education (COGME or Council) will hold public meetings for the 2020 calendar year (CY). Information about COGME, agendas, and materials for these meetings can be found on the COGME website at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/index.html.*

DATES: April 28–29, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; July 17, 2020, 10:00 a.m.–5:00 p.m. ET; December 8–9, 2020, 8:30 a.m.–5:00 p.m. ET and 8:30 a.m.–2:00 p.m.

ADDRESSES: The meetings scheduled on April 28–29, 2020, and December 8–9, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857. The meeting scheduled on July 17, 2020, will be held by teleconference/Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the COGME website 30 business days before the date of the meeting. For meeting information updates, go to the COGME website meeting page at *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Senior Advisor and Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; 301–945–9505; or *BHWCOGME@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on policy, program development, and other matters of significance as specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include the supply and distribution of the physician workforce in the United States, including any projected shortages or excesses; foreign medical school graduates; the nature and financing of undergraduate and graduate

medical education; appropriation levels for certain programs under Title VII of the PHS Act and deficiencies in databases of the supply and distribution of the physician workforce and postgraduate programs for training physicians. COGME submits reports to the Secretary of HHS, the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. Additionally, COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council.

Agenda items are subject to change as priorities dictate. During the CY 2020 COGME meetings, COGME will discuss topics surrounding the rural health workforce. Refer to the COGME website listed above for all current and updated information concerning the CY 2020 COGME meetings, including draft agendas and meeting materials that will be posted before the meeting. An agenda will be posted on the website at least 14 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the COGME should be sent to Kennita Carter using the contact information above at least 5 business days before the meeting dates.

Individuals who need special assistance or another reasonable accommodation should notify Dr. Kennita Carter using the contact information listed above at least 10 business days before the meeting they wish to attend. Since all in person meetings occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–22649 Filed 10–16–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Training and Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training and Primary Care Medicine and Dentistry (ACTPCMD) will hold public meetings for the 2020 calendar year (CY). Information about ACTPCMD, agendas, and materials for these meetings can be found on the ACTPCMD website at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.*

DATES: January 8–9, 2020, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and 8:30 a.m.–2:00 p.m. ET; and August 4, 2020, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: The meeting scheduled on January 8–9, 2020, will be held in-person at 5600 Fishers Lane, Room 5E29, Rockville, Maryland 20857. The meeting scheduled on August 4, 2020, will be held by teleconference/Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the ACTPCMD website 30 business days before the date of the meeting. For meeting information updates, go to the ACTPCMD website meeting page at *https://www.hrsa.gov/advisory-committees/primarycare-dentist/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Kennita Carter, MD, Designated Federal Official (DFO) Division of Medicine and Dentistry, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, 15N116, Rockville, Maryland 20857; 301–945–9505; or *BHWACTPCMD@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the committee, including findings and recommendations made by the committee concerning the activities under Section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary as well as the Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions and the House of Representatives Committee on Energy and Commerce. ACTPCMD develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C of the PHS Act, and recommends appropriation levels for programs under this Part.

During ACTPCMD's CY 2020 meetings, the committee will discuss matters concerning policy, program development, and other matters of significance concerning medicine and dentistry activities. Agenda items are subject to change as priorities dictate. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2020 meetings, including draft agendas and meeting materials that will be posted before the meeting. An agenda will be posted on the website at least 14 calendar days before each meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACTPCMD should be sent to Kennita Carter using the contact information above at least 5 business days before the meeting dates.

Individuals who need special assistance or another reasonable accommodation should notify Kennita Carter using the contact information listed above at least 10 business days before the meeting they wish to attend. Since all in-person meetings occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–22650 Filed 10–16–19; 8:45 am]

BILLING CODE 4165–15–P