single hard copy of the draft guidance document entitled ''Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Eli Tomar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5462, Silver Spring, MD 20993–0002, 240–893–1926, 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

For many years, the definition of ''device'' has been codified at section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). As a result of the enactment of the Safeguarding Therapeutics Act (Pub. L. 116–304), the definition of ''device'' was redesignated as paragraph (h)(1) and a new definition of ''counterfeit device'' was codified at paragraph (h)(2) of section 201 of the FD&C Act.

FDA is issuing this draft guidance to clarify how the Agency intends to interpret existing references to section 201(h) of the FD&C Act and how we intend to reference the definitions of ''device'' and ''counterfeit device'' going forward. This guidance, when finalized, is intended to provide clarity on references to the terms ''device'' and ''counterfeit device''—as well as references to section 201(h) of the FD&C Act—in guidance, regulatory documents, and other communications and documents for FDA staff, industry, and other stakeholders.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents.'' 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Referencing the Definition of 'Device' in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 21008 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Dated: December 9, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27266 Filed 12–15–21; 8:45 am]

BILLING CODE 4164–01–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.

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 2022 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: ACTPCMD meetings will be held on:

- February 17, 2022, 10:00 a.m.–5:00 p.m. Eastern Time (ET) and February 18, 2022, 10:00 a.m.–2:00 p.m. ET; and
- August 2, 2022, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings will be held virtually and by teleconference. No in-person meetings will be conducted in 2022. For updates on how the meetings will be held, visit the ACTPCMD website 30 business days before the date of the meeting, where instructions for joining meetings will be posted. 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: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACTPCMD provides advice and recommendations to the Secretary of Health and Human Services (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. The 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. Since priorities dictate

meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2022 meetings, agenda items may include, but are not limited to, inter-professional team-based education, practice, and retention in underserved rural communities, as well as matters pertaining to policy, program development, and other matters of significance concerning medicine and dentistry activities authorized under the relevant sections of the PHS Act. Refer to the ACTPCMD website listed above for all current and updated information concerning the CY 2022 ACTPCMD meetings, including draft agendas and meeting materials that will be posted 30 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 meeting(s). 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 Shane Rogers using the contact information above at least 5 business days before the meeting date(s). Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–27262 Filed 12–15–21; 8:45 am]

BILLING CODE 4165–15–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 2022 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: COGME meetings will be held on:

- March 24, 2022, 10:00 a.m.–5:00 p.m. Eastern Time (ET) and March 25, 2022, 10:00 a.m.–2:00 p.m. ET; and
- September 12, 2022, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings will be held virtually and by teleconference. No in-person meetings will be conducted in 2022. For updates on how the meetings will be held, visit the COGME website 30 business days before the date of the meeting, where instructions for joining meetings will be posted. 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: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The COGME provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning the activities listed in section 762(a) 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.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2022 meetings, agenda items may include, but are not limited to, discussions on advancing health equity, addressing disparities in rural areas, enhancing the delivery of behavioral health and mental health care, and expanding the role of telehealth. Refer to the COGME website listed above for all current and updated information concerning the CY 2022 COGME meetings, including draft agendas and meeting materials that will be posted 30 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 meeting(s). 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 Shane Rogers using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–27263 Filed 12–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Extended Clinical Trial (R01); NIAID Clinical Trial Planning Grants (R34 Clinical Trial Not Allowed).

Date: January 12, 2022.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of