In the **Federal Register** of April 10, 2008 (73 FR 19511), FDA announced the availability of the April 2008 Guidance. In that guidance, FDA provided sponsors of a human gene therapy IND, including those with combination products that contain a human gene therapy biological product with a drug or device as part of the final product, with recommendations on CMC information that is to be included in an original IND. That guidance also provided instruction to FDA CMC reviewers about the information to record and assess as part of an IND review. The draft guidance, when finalized, will supplement the April 2008 Guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on recommendations for MVGTs. It does not establish any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations.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 collections of information in 21 CFR parts 211, 610, and 312 have been approved under OMB control numbers 0910–0139 and 0910–0114, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26108 Filed 10–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: October 29, 2015 (10:30 a.m.–4:30 p.m.).

Place: Conference Call/Webinar Format.

Status: The meeting will be open to the public.

Purpose: The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services (the Secretary) on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs. COGME's reports are submitted to the Secretary and ranking members of the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce.

HRSA will conduct an orientation for new members prior to the start of the meeting. COGME will start its official meeting at 10:30 a.m. After the orientation, discussion will focus on one of the recommendations from the March 2015 meeting, namely, to identify actions COGME can take within its current authorities to achieve the development of a National Strategic Plan for Graduate Medical Education.

Agenda: The COGME agenda will be available 2 days prior to the meeting on the HRSA Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html.*

SUPPLEMENTARY INFORMATION: Requests to make oral comments or provide written comments to the COGME should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call and webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Council on Graduate Medical Education.

- The conference call-in number is 1–800–619–2521. The passcode is: 9271697.
- The webinar link is *https://hrsa.connectsolutions.com/cogme-2015/.*

Contact: Anyone requesting information regarding the COGME should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–26053 Filed 10–13–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–New–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before November 13, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.