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 The draft guidance, when finalized, will supplement the April 2008 Guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on recommendations for MVGTs.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The draft guidance refers to previously approved collections of information found in FDA regulations.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*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.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: State and Territorial Health Disparities Survey Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS) is requesting approval from the Office of Management and Budget (OMB) for a new data collection activity for the State and Territorial Health Disparities Survey (STHD Survey).

OMH has a long history of collaborating with states to improve minority health outcomes and reduce health and health care disparities. A strong partnership with state and territorial offices is a key to continue progress toward eliminating health disparities. To best facilitate continued partnerships, OMH needs information about the current activities, challenges, and resources within state and territorial offices of minority health. The State and Territorial Health Disparities Survey is intended to support OMH informational needs by collecting, organizing, and presenting a variety of information about states and U.S. territories, including the current status of minority health and health disparities, the organization and operation of state and territorial offices of minority health, and state/territorial implementation of federal standards and evidence-based practices designed to address disparities and improve minority health. The STHD Survey, which will focus on the activities, staffing, and funding of State Minority Health Entities, is part of a larger project to catalog the extent of health disparities and the activities underway to reduce them in each state and U.S. territory. The STHD Survey supports OMH's goals of working with states and territories to improve the health of racial and ethnic minority populations and eliminate health disparities. While existing, state/territorial-specific information sources (*e.g.,* quantitative data points available from the Agency for Healthcare Research and Quality's *National Healthcare Disparities Report State Snapshots*) offer important facts about the status of health disparities, they do not provide context around the efforts underway to reduce them. Likely Respondents—Data will be collected using semi-structured telephone interviews with state/territorial minority health entity directors (or their designees) in approximately 54 states and territories (50 states plus the District of Columbia and the U.S. territories of Guam, Puerto Rico, and the U.S. Virgin Islands). The purpose of this interview is to collect qualitative information about state/territory program goals and activities, partnerships, and organizational structure, as well as quantitative data elements on staffing and funding.

Form Name	Number of respondents	Number of responses per respondents	Average hours per response	Total burden hours
State and Territorial Survey	54	1	1.5	81
Total	54			81

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–26058 Filed 10–13–15; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0937–0166]

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 renewal of the approved information collection assigned OMB control number 0937–0166, scheduled to expire on October 31, 2015. 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.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0937–0166 for reference.

Information Collection Request Title: HHS 42 CFR part 50, subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects—OMB No. 0937–0166–Extension–OASH, Office of Population Affairs—Office of Family Planning.

Abstract: This is a request for extension of a currently approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B (''Sterilization of Persons in Federally Assisted Family Planning Projects''). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the Public Health Service (PHS). Consent forms are signed by individuals undergoing a federally funded sterilization procedure and certified by necessary medical authorities. Forms are incorporated into the patient's medical records and the agency's records. Through periodic site audits and visits, PHS staff review completed consent forms to determine compliance with the regulation. Thus, the purpose of the consent form is twofold. First, it serves as a mechanism to ensure that a person receives information about sterilization and voluntarily consents to the procedure. Second, it facilitates compliance monitoring. The Sterilization Consent