approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act. The guidance also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

This guidance finalizes the draft guidance of the same name issued October 2008 and includes the following substantive changes based on public comment.

- The procedure for FDA to add diseases to the list is described
- Clarification is provided for when a voucher can be used
- A statement was added to say that FDA may provide a preliminary nonbinding opinion, before approval, that an application appears to meet the criteria for voucher eligibility
- Clarification is provided regarding the eligibility of combination products to receive a voucher
- Clarification is provided regarding the timing of payment of the priority review user fee
- Clarification is provided regarding whether FDA can remove tropical diseases from the list

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 obtaining tropical disease priority review vouchers. 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 in this guidance was approved under OMB control number 0910–0822.

III. Electronic Access

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

Dated: September 30, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–24232 Filed 10–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the Council on Graduate Medical Education (COGME). This meeting will be open to the public. Information about COGME and the agenda for this meeting can be obtained by accessing the COGME Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/COGME.*

DATES: October 20, 2016, 10:00 a.m.–4:30 p.m. ET

ADDRESSES: This meeting will be held by webinar only. Information on connecting to the webinar can be found on the COGME Web site.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding COGME should contact Dr. Kennita Carter, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Dr. Kennita Carter, Designated Federal Official, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, 15N–116, Rockville, Maryland 20857; (2) call 301–945–3505; or (3) send an email to *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: COGME provides advice and recommendations to the Secretary of HHS and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, 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.

During the meeting, COGME members will discuss topics and issues related to the preparation of its 23rd report. COGME's reports are submitted to the Secretary of HHS; the Committee on Health, Education, Labor, and Pensions of the Senate; and the Committee on Energy and Commerce of the House of Representatives.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to COGME should be made using the contact address or phone number above by October 13, 2016.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–24167 Filed 10–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Tuesday, October 25, 2016, from 8:30 a.m. until 5:00 p.m. and Wednesday, October 26, 2016, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP or Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP); U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as