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This guidance finalizes the draft guidance of the same name issued October 2008 and includes the following substantive changes based on public comment.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

amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Tuesday, October 25, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Subpart A Subcommittee (SAS) will then present their report, including recommendations regarding single IRB review and the draft joint OHRP–FDA draft guidance, ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' This will be followed by the Subcommittee on Harmonization's (SOH) report, including recommendations involving clustered randomized trials, benchmarking, and the ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,'' Appendix M.

SAS was established by SACHRP in October 2006. The subcommittee is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. On Wednesday, October 26, 2016, SACHRP will discuss recommendations from the SOH on the FDA Draft Guidance ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,'' issued July 27, 2016.

The meeting will adjourn at 4:30 p.m. October 26, 2016. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting. Note that public comment must be relevant to agenda topics.

Dated: October 3, 2016.

Julia Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2016–24251 Filed 10–5–16; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Modifications of Healthy People 2020 Objectives

AGENCY: Office of the Secretary, Office of the Assistant Secretary of Health, Office of Disease Prevention and Health Promotion, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services solicits written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period. Public participation helps shape Healthy People 2020, its framework, objectives, organization, and targets. Healthy People provides opportunities for public input periodically throughout the decade to ensure that Healthy People 2020 reflects current public health priorities and public input. The updated set of Healthy People 2020 objectives will be incorporated on *www.HealthyPeople.gov*. This set will reflect further review and deliberation by the topic area workgroups, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

DATES: Written comments will be accepted until 5:00 p.m. ET on October 27, 2016.

ADDRESSES: Written comments will be accepted via an online public comment database at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment;* by mail at the Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Attn: Public Comment, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852; fax—(240) 453–8281; or email—*HP2020@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Caitie Blood, MPH, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Room LL–100, Rockville, MD 20852, *Caitlin.Blood@HHS.gov* (email), (240) 453–8265 (telephone), (240) 453–8281 (fax).

SUPPLEMENTARY INFORMATION: For three decades, Healthy People has provided a comprehensive set of national 10-year health promotion and disease prevention objectives aimed at improving the health of all Americans. Healthy People 2020 objectives provide a framework by presenting a comprehensive picture of the nation's health at the beginning of the decade, establishing national goals and targets to be achieved by the year 2020, and monitoring progress over time. The U.S. Department of Health and Human Services is soliciting the submission of written comments regarding a new objective proposed to be added to Healthy People 2020 since the fall 2015 public comment period.

Healthy People 2020 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2020's development. During the first phase of planning for Healthy People 2020, HHS asked for the public's comments on the vision, mission, and implementation of Healthy People 2020. Those comments helped set the framework for Healthy People 2020. The public was also invited to submit comments on proposed Healthy People 2020 objectives, which helped shape the final set of Healthy People 2020 objectives.

The public is now invited to comment on a new objective proposed to be added to Healthy People 2020, which can be found at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment.* This new objective was developed by the HIV topic area workgroup led by the Centers for Disease Control and Prevention and Health Resources and Services Administration. It has been reviewed by the Federal Interagency Workgroup on Healthy People 2020 and is presented now for the public's review and comment. Comments are restricted to this specific HIV objective. Having reached the midpoint in the decade, Healthy People will not be soliciting proposals for additional new objectives.

Written comments will be accepted at *http://www.healthypeople.gov/2020/about/history-development/Public-Comment.* The public will also be able