enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 5, 2016, during session I, the topic to be addressed will be reclassification of quantitative Cytomegalovirus (CMV) viral load devices from class III (Premarket approval) to class II (510(k)). A nucleic acid-based in vitro diagnostic device for the quantitation of CMV viral load, within the context of transplant patient management, is a post-amendment device classified into class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)). To date, the following product code has been established for CMV viral load devices: PAB (Cytomegalovirus (CMV) DNA Quantitative Assay). During session II, the topics to be addressed include appropriate initial classification for qualitative or quantitative viral load devices for Epstein-Barr virus (EBV), BK virus (BK), JC virus (JCV), Human Herpesvirus 6 (HHV6), and Adenovirus infections. FDA is seeking expert recommendations to assess the potential risks and benefits of these devices when used in patients following solid-organ or stem cell transplantation.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 29, 2016. Oral presentations from the public will be scheduled on October 5, 2016, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 21, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 22, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this document. The docket number is FDA–2016–N–1660. The docket will close on November 9, 2016. Comments received on or before September 21, 2016, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21045 Filed 8–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Endocrinologic and Metabolic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Endocrinologic and Metabolic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until August 27, 2018.

DATES: Authority for the Endocrinologic and Metabolic Drugs Advisory Committee will expire on August 27, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, *EMDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Endocrinologic and Metabolic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Endocrinologic and Metabolic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of endocrinology, metabolism, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm100261.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21040 Filed 8–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Public Health Support; Division of Planning, Evaluation & Research; National Native Health Research Training Initiative

Announcement Type: New.

Funding Announcement Number: HHS–2017–IHS–DPER–001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates:

Application Deadline Date: October 30, 2016.

Approximate Review Date: November 2–4, 2016.

Earliest Anticipated Start Date: November 15, 2016.

Proof of Non-Profit Status Due Date: October 30, 2016.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support (OPHS), Division of Planning, Evaluation and Research (DPER), is accepting applications for one new cooperative agreement for the National Native Health Research Training Initiative. This initiative will help build capacity and disseminate new and best practices for American Indian and Alaska Native (AI/AN) health research and promote Tribally-driven research activity through a variety of educational and training opportunities. Focus will be on the promotion of health research and related opportunities for AI/AN students, highlighting promising practices and practice-based approaches to improving the health of AI/AN people, and culture-based approaches to reducing health disparities between AI/AN people and the U.S. population. Other areas will focus on resilience and protective factors and their role in AI/AN health outcomes, innovative and culturally-based approaches to improving the health of AI/AN youth, and dissemination of study findings in AI/AN health science research to investigators and providers working in or with Tribal communities as well as Tribal leaders and health officials. Activities will include the planning, coordination, and hosting of research meetings and conferences, webinars, hosting of a Web site/Web page for dissemination of AI/AN health science research information, and other activities to be determined. This IHS activity is authorized under the Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Consolidated Appropriations Act, 2012, Public Law 112–74 and the Continuing Appropriations Resolution, 2013, Public Law 112–175. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The AI/AN populations have long experienced poorer health status compared to other Americans. Although major gains in reducing health disparities were made during the last half of the twentieth century, most gains stopped by the mid-1980s (Trends in Indian Health 1998–99) and a few diseases, *e.g.,* diabetes, worsened. ''All Indian'' rates contain marked variation among the ''IHS Areas'' or regions (Regional Differences in Indian Health 2002–2003); variation by Tribe exists within Areas as well. The Trends and Regional Differences reference can be found on the IHS Web site at *http://www.ihs.gov/dps/publications/.* The daunting task confronting Tribes, research scientists, and health programs is to reduce the disparities among and within areas and Tribes. Factors known to contribute to health status and disparities are complex, and include underlying biology, physiology, and epigenetics, as well as ethnicity, culture, socioeconomic status, gender/sex, age, geographical access to care, and levels of insurance.

Additional factors known to contribute to health status and disparities include:

1. Family, home, and work environments;
2. general or culturally specific health practices;
3. social support systems;
4. lack of access to culturally-appropriate health care; and
5. attitudes and beliefs about health.

Health disparities of AI/ANs may also reflect a lack of in depth research relevant to improving their health status. Many AI/ANs also distrust research for historical reasons. One approach that combats this distrust is to ensure that Tribes are managing partners in training and research that involves them, as for example in community-based participatory research (CBPR) (*i.e.,* a collaborative research process between researchers and community representatives). This approach is especially helpful to design both training relevant to researchers from Tribal communities and research relevant to health needs of the communities. Another approach is increasing the number of AI/AN scientists and growing the intellectual community of researchers working with AIAN health research issues.

DPER has the responsibility of promoting health research to help improve the health status of AI/ANs. The development of AI/AN scientists and scientist-practitioners and enhancing the ability of Tribes to participate in and initiate their own research projects is a key part of improving quality and delivery of health services. Scientific meetings, conferences, and other training opportunities will support AI/AN faculty and student development and promote participatory collaboration between Tribes and the academic community. Such meetings and other