

2016, requesting that Upsher-Smith provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 078706 under section 314.150(d) (21 CFR 314.150(d)).

In a letter dated September 15, 2016, Upsher-Smith informed FDA that it did not intend to submit the requested bioequivalence data and requested that the Agency withdraw approval of ANDA 078706 for ZALEPLON Capsules under section 314.150(d). In that letter, Upsher-Smith also waived any opportunity for a hearing otherwise provided under section 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and 314.150(d), approval of ANDA 078706, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-17301 Filed 8-15-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Appointment to the Tick-Borne Disease Working Group; Amendment

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

ACTION: Notice; amendment.

SUMMARY: A notice was published in the **Federal Register** on Monday, July 17, 2017 (Vol. 82, No. 135, pages 32711–32712), to solicit nominations of individuals who are interested in being considered for appointment to the Tick-Borne Disease Working Group (Working Group). The nomination period is scheduled to end close of business on August 16, 2017. The notice is being amended to extend the solicitation period for one week to allow more time for interested individuals to submit nominations.

DATES: The solicitation period has been extended. All nominations are due to be submitted on or before August 23, 2017.

ADDRESSES: All nominations should be sent to: CAPT Richard Henry; Office of

the Assistant Secretary for Health; Department of Health and Human Services; 330 C Street SW., Suite L100, Washington, DC 20024. Nomination materials, including attachments, also may be submitted electronically to tickbornedisease@hhs.gov.

FOR FURTHER INFORMATION CONTACT: CAPT Richard Henry, Office of the Assistant Secretary for Health; Department of Health and Human Services; Telephone: (202) 795-7615; Email address: richard.henry@hhs.gov.

Dated: August 10, 2017.

Donald Wright,

Acting Assistant Secretary for Health.

[FR Doc. 2017-17323 Filed 8-15-17; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to CARB@hhs.gov. Registration information is available on the Web site <http://www.hhs.gov/ash/carb/> and must be completed by September 5, 2017; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

DATES: The meeting is scheduled to be held on September 13, 2017, from 9:00 a.m. to 5:00 p.m. ET, and September 14, 2017, from 9:00 a.m. to 3:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the Web site for the Advisory

Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than September 5, 2017; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting can also be accessed through a live webcast on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, Acting Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690-5566; email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research

on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The first day of the public meeting, September 13, 2017, will be dedicated to the topic of Stewardship of Antibiotic Prescription and Use. The three working groups on Incentives for Diagnostics, Therapeutics/Anti-Infectives, and Vaccines, will report their final findings to the full Advisory Council for deliberation on the second day of the public meeting, September 14, 2017, and the Advisory Council will deliberate and vote on the final report presented. Additionally, federal agencies will provide updates on their achievements as stipulated in the goals with corresponding objectives and milestones of the National Action Plan on Combating Antibiotic Resistant Bacteria. The meeting agenda will be posted on the Advisory Council Web site at <http://www.hhs.gov/ash/carb/> when it has been finalized. All agenda items are tentative and subject to change.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Advisory Council at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at <http://www.hhs.gov/ash/carb/>.

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing CARB@hhs.gov. Public comments should be sent in by midnight September 5, 2017, and should be limited to no more than one page. All public comments received prior to September 5, 2017, will be provided to Advisory Council members; comments are limited to two minutes per speaker.

Dated: August 2, 2017.

Jomana F. Musmar,

*Acting Designated Federal Officer,
Presidential Advisory Council on Combating
Antibiotic-Resistant Bacteria, Committee
Manager.*

[FR Doc. 2017-17322 Filed 8-15-17; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Epidemiology and Disease Prevention Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: Competing Supplement

Funding Announcement Number: HHS-2017-IHS-EPI-0001

Catalog of Federal Domestic Assistance Number: 93.231

Key Dates

Application Deadline Date: September 19, 2017

Review Date: September 21, 2017

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (IDEP), is accepting applications for a cooperative agreement for competitive supplemental funds to enhance activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities. This program is authorized under: The Public Health Service Act, at 42 U.S.C. 241, 247b(k)(2), 282, 284 and 285t. Funding for this award will be provided by: The Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health (NCEH) and the National Institutes of Health's (NIH) National Institute on Minority Health and Health Disparities (NIMHD). The authorities will be exercised through an Intra-Departmental Delegation of Authority (IDDA) with IHS to create a new funding opportunity for Tribal Epidemiology Centers: This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.231.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1998 as a way to provide public health support to multiple Tribes and Urban Indian communities in each of the IHS Areas. The funding opportunity announcement is open to eligible Tribes, Tribal organizations, Indian organizations, intertribal consortia, and Urban Indian organizations, including currently-funded TECs.

TECs are uniquely positioned within Tribes, Tribal and Urban Indian organizations to conduct disease surveillance, research, prevention and

control of disease, injury, or disability, and to assess the effectiveness of AI/AN public health programs. In addition, they can fill gaps in data needed for Government Performance and Results Act and Healthy People 2020 measures. Some of the existing TECs have already developed innovative strategies to monitor the health status of Tribes and Urban Indian communities, including development of Tribal health registries and use of sophisticated record linkage computer software to correct existing state data sets for racial misclassification. TECs work in partnership with IHS DEDP to provide a more accurate national picture of Indian health status. This program will utilize CDC and NIH funding to further the ongoing work of IHS and the TECs.

The mission of NIMHD is to promote minority health and to lead, coordinate, support, and assess the NIH effort to reduce and ultimately eliminate health disparities.

The NCEH has identified a public health gap in the nation's ability to link environmental hazards and exposure to chronic disease issues, and to provide information to a variety of audiences from a nationwide network of integrated health and environmental data that drives actions to improve health outcomes. The NCEH is seeking, through this announcement, to support the creation of a mechanism by which Tribal data can be submitted to the Environmental Public Health Tracking Network and further explore the application of Tribal data to environmental public health.

Purpose

The purpose of this cooperative agreement is to strengthen public health capacity and to fund Tribes, Tribal and Urban Indian organizations, and intertribal consortia in identifying relevant health status indicators and priorities using sound epidemiologic principles. Work-plans submitted in response to this announcement must clearly state the grantee's desired objectives and address at least one of the Recipient Activities under this announcement. Recipient Activities may address one or all of the below two groups of activities:

A. NIH, NIMHD Activities

(1) Development and implementation of data collection efforts to identify and document health disparities experienced by AI/AN populations;

(2) Compilation of existing data (e.g., healthcare utilization, vital statistics data) to generate health profiles and document health disparities in AI/AN populations;