reasons of safety or effectiveness. Although the citizen petition did not address the 10 mg, 20 mg, 30 mg, and 40 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to SULAR (nisoldipine) extended-release tablets. Additional ANDAs that refer to SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20043 Filed 8–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cellular, Tissue and Gene Therapies Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 6, 2014, from 9 a.m. to approximately 4:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Gail Dapolito or Rosanna Harvey, Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993, 240–402–8046 or 240–402–8072, email: *Gail.Dapolito@fda.hhs.gov* or *Roasanna.Harvey@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly 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.

Agenda: The committee will discuss the draft guidance for industry entitled ''Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products'' and the Dear Gene Therapy IND or Master File Sponsor Letter.

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 October 23, 2014. Oral presentations from the public will be scheduled between approximately 11:05 a.m. and 12:05 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 October 15, 2014. 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 October 16, 2014.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito 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 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20016 Filed 8–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education

Announcement Type: Limited New and Competing Continuation.

Funding Announcement Number: HHS–2014–IHS–NIHOE–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: September 25, 2014.

Review Date: September 26, 2014.

Earliest Anticipated Start Date: September 30, 2014.

Proof of Non-Profit Status Due Date: September 25, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the National Indian Health Outreach and Education (NIHOE) I limited competition cooperative agreement program. This award includes the following four components, as described in this announcement: ''Line Item 128 Health Education and Outreach funds,'' ''Health Care Policy Analysis and Review,'' ''Budget Formulation,'' and ''Tribal Leaders Diabetes Committee'' (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE program carries out health program objectives in the American Indian and Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. This program requires that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. This program also requires that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS based on Tribal input through a broad based consumer network.

Purpose

The purpose of this IHS cooperative agreement is to further IHS's mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. This award includes the following four health services components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and Tribal Leaders Diabetes Committee (TLDC).

Limited Competition Justification

Competition for the award included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between the Department of Health and Human Services (HHS) and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2014 is approximately $766,000. Three hundred thousand dollars ($300,000) is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal Shares with the IHS (this amount could vary based on Tribal Shares assumptions; Line Item 128 Health Education and Outreach funding will be awarded in partial increments based on availability and amount of funding); $200,000 for the Health Care Policy Analysis and Review; $16,000 for the Budget Formulation; and $250,000 associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI). The amount of funding available for both competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

One award will be issued under this program announcement comprised of the following four components: Line Item 128 Health Education and Outreach; Health Care Policy Analysis and Review; Budget Formulation; and TLDC.

Project Period

The project period will run for one year from September 30, 2014 through September 29, 2015.