

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 August 19, 2014. Oral presentations from the public will be scheduled between approximately 3:25 p.m. and 5 p.m. on September 4, 2014. 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 August 11, 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 August 12, 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 Cindy Hong 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: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Nonprescription Drugs 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: Nonprescription Drugs 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 September 3, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. 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: Jennifer Shepherd, 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, FAX: 301-847-8533, email: NDAC@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 standards used to demonstrate that over-the-counter (OTC) topical

antiseptics used in healthcare settings are generally recognized as safe and effective. The discussion will focus on antiseptic active ingredients marketed under the OTC Drug Review (also known as the OTC Drug Monograph) for the following healthcare antiseptic uses: Healthcare personnel hand washes and rubs, surgical hand scrubs and rubs, and patient preoperative and preinjection skin preparations.

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 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 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 August 19, 2014. Oral presentations from the public will be scheduled 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 August 11, 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 August 12, 2014.

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Dated: July 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance Program; Planning Cooperative Agreement

Announcement Type: New—Limited Competition.

Funding Announcement Number: HHS-2014-IHS-TSGP-0001.

Catalog of Federal Domestic Assistance Number: 93.444.

Key Dates

Application Deadline Date: August 29, 2014.

Review Date: September 8, 2014.

Earliest Anticipated Start Date: September 15, 2014.

Signed Tribal Resolutions Due Date: August 29, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition Planning Cooperative Agreement applications for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 458aaa-2(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA), available at <https://www.cfda.gov/>, under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the government-to-government relationship between the United States and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions and Activities (PSFAs), or portions thereof,

which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual PSFAs that the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), or (3) compact with the IHS to assume control over healthcare PSFAs that the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs to the needs of their communities.

The TSGP is a Tribally-driven initiative and strong Tribal/Federal partnerships are essential for program success. The IHS established the OTSG to implement Tribal Self-Governance authorities. The OTSG: (1) serves as the primary liaison and advocate for Tribes participating in the TSGP, (2) develops, directs, and implements Tribal Self-Governance policies and procedures, (3) provides information and technical assistance to Self-Governance Tribes, and (4) advises the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director, who has the authority to negotiate Self-Governance Compacts and Funding Agreements. A Tribe should contact the respective ALN to begin the Self-Governance planning process or, if currently an existing Self-Governance Tribe, discuss methods to expand current PSFAs. The ALN shall provide an overview of the TSGP and provide technical assistance on the planning process or expanding current PSFAs.

Purpose

The purpose of this Planning Cooperative Agreement is to provide resources to Tribes interested in entering the TSGP and to existing Self-Governance Tribes interested in assuming new or expanded PSFAs. Title V of the ISDEAA requires a Tribe or Tribal organization to complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organization preparation relating to

the administration of health care programs. See 25 U.S.C. 458aaa-2(d).

The planning phase helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to successfully support those PSFAs. A thorough planning phase improves timeliness and efficiency of negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

A Planning Cooperative Agreement is not a prerequisite to enter the TSGP and a Tribe may use other resources to meet the planning requirements. Tribes that receive a Planning Cooperative Agreement are not obligated to participate in the TSGP and may choose to delay or decline participation based on the outcome of their planning activities. This also applies to existing Self-Governance Tribes exploring the option to expand their current PSFAs or assume additional PSFAs.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria. See 25 U.S.C. 458aaa-2(e); 42 CFR 137.24-26; see also 42 CFR 137.10.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for fiscal year (FY) 2014 is approximately \$360,000. Individual award amounts are anticipated to be \$120,000. The amount of funding available for competing 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

Approximately three awards will be issued under this program announcement.

Project Period

The project period is for 12 months and runs from September 1, 2014 to August 31, 2015.

Cooperative Agreement

Cooperative Agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. The funding agency (IHS) is required to have