

402-7930, elizabeth.giaquinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.” This guidance finalizes the October 2017 draft guidance for industry “ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.” This guidance is intended to assist applicants preparing to submit amendments to ANDAs or to PASs to FDA under section 505(j) of the FD&C Act (21 U.S.C. 355(j)) by explaining how the review goals established as part of GDUFA II apply to these submissions. In accordance with the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Commitment Letter: <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrug/UserFees/ucm525234.pdf>), FDA agreed to certain review goals and procedures for the review of amendments pending as of or received on or after the GDUFA II effective date.

The GDUFA II Commitment Letter reflects significant changes in the classification of and review goals for amendments to ANDAs and PASs under the Generic Drug User Fee Amendments of 2012 (GDUFA I). Under GDUFA I, amendments were classified into a complex Tier system based on the following factors: (1) Whether the amendment was solicited (submitted in response to a complete response letter) or unsolicited (submitted on the applicant’s own initiative); (2) whether the amendment was major or minor; the number of amendments submitted to the ANDA or PAS; and (3) whether an inspection was necessary to support the information contained in the amendment.

GDUFA II simplified the amendment review goals and no longer subjects them to a Tier system; however, review goals are still dependent on several factors. In general, under GDUFA II, amendments will be designated as either standard or priority; will be classified as major or minor, and will receive a goal date based on the factors discussed in the draft guidance, including whether a preapproval inspection is needed. This guidance supersedes the December 2001 guidance for industry “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” and the July 2014 draft guidance for industry

“ANDA Submissions—Amendments and Easily Correctable Deficiencies Under GDUFA,” both of which will be withdrawn. This guidance finalizes the October 2017 draft guidance for industry “ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.” The final guidance contains clarifications to the draft guidance of the same title that published in October 2017.

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 “ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA.” 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in 21 CFR 314.96 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: June 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14429 Filed 7–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer’s Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer’s Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer’s Research, Care, and Services provides advice on how to prevent or reduce the

burden of Alzheimer’s disease and related dementias on people with the disease and their caregivers. The Advisory Council will spend the majority of the July meeting considering recommendations made by each of the three subcommittees to present to the Secretary of HHS and Congress. Additional presentations in the afternoon will include a presentation on a recent study by RAND on the health care infrastructure, the CDC/Alzheimer’s Association’s joint Healthy Brain Initiative Roadmap, federal workgroup updates, and updates on work by the non-federal members.

DATES: The meeting will be held on July 30, 2018 from 9:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to napa@hhs.gov. Those submitting written comments should identify themselves and any relevant organizational affiliations. Those intending to make public comments at the meeting must submit their comments either by mail or email ahead of time for the record. Comments are due no later than Monday, July 23, 2018.

FOR FURTHER INFORMATION CONTACT:

Rohini Khillan (202) 690–5932, rohini.khillan@hhs.gov. Note: Seating may be limited. Those wishing to attend the meeting must send an email to napa@hhs.gov and put “July 30 Meeting Attendance” in the Subject line by Friday, July 20, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the

Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will spend the majority of the July meeting considering recommendations made by each of the three subcommittees to present to the Secretary of HHS and Congress. Additional presentations in the afternoon will include a presentation on a recent study by RAND on the health care infrastructure, the CDC/Alzheimer's Association's joint Healthy Brain Initiative Roadmap, federal workgroup updates, and updates on work by the non-federal members.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at www.hhs.gov/live.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 28, 2018.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2018-14376 Filed 7-3-18; 8:45 am]

BILLING CODE 4150-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; Tribal Management Grant Program

Announcement Type: New and Competing Continuation.

Funding Announcement Number: HHS-2018-IHS-TMD-0001.

Catalog of Federal Domestic Assistance Number (CFDA): 93.228.

Key Dates

Application Deadline Date: August 17, 2018.

Review Date: August 20–24, 2018.

Earliest Anticipated Start Date: September 1, 2018.

Signed Tribal Resolutions Due Date: August 17, 2018.

Proof of Non-Profit Status Due Date: August 17, 2018.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive grant applications for the Tribal Management Grant (TMG) Program. This program is authorized under 25 U.S.C. § 5322(b)(2) and 25

U.S.C. § 5322(e) of the Indian Self-Determination and Education Assistance Act (ISDEAA), Public Law (P.L.) 93-638, as amended. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.228.

Background

The TMG Program is a competitive grant program that is capacity building and developmental in nature and has been available for federally recognized Indian Tribes and Tribal Organizations (T/TOs) since shortly after enactment of the ISDEAA in 1975. The TMG Program was established to assist T/TOs to prepare for assuming all or part of existing IHS programs, functions, services, and activities (PFSAs) and further develop and improve Tribal health management capabilities. The TMG Program provides competitive grants to T/TOs to establish goals and performance measures for current health programs; assess current management capacity to determine if new components are appropriate; analyze programs to determine if a Tribe or Tribal Organization's management is practicable; and develop infrastructure systems to manage or organize PFSAs.

Purpose

The purpose of this IHS grant announcement is to announce the availability of the TMG Program to enhance and develop health management infrastructure and assist T/TOs in assuming all or part of existing IHS PFSAs through a Title I contract and assist established Title I contractors and Title V compactors to further develop and improve management capability. In addition, Tribal Management Grants are available to T/TOs under the authority of 25 U.S.C. 5322(e) for the following: (1) Obtaining technical assistance from providers designated by the Tribe/Tribal Organization (including T/TOs that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management, and the development of cost allocation plans for indirect cost rates; and (2) planning, designing, monitoring, and evaluating Federal programs serving T/TOs, including Federal administrative functions.

II. Award Information

Type of Award

Grant.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2018 is approximately \$2,412,000. Individual award amounts are anticipated to be between \$50,000 and \$100,000. The amount of funding available for new and competing continuation awards issued under this grant 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 grant announcement.

Anticipated Number of Awards

Approximately 16–18 awards will be issued under this grant announcement.

Period of Performance

The Tribal Management Grant (TMG Project) period of performance vary based on the project type selected. Period of performance could run from 1 to 3 years and will run consecutively from the earliest anticipated start date of September 1, 2018 through August 31, 2019, for 1-year projects; September 1, 2018, through August 31, 2020, for 2-year projects; and September 1, 2018, through August 31, 2021, for 3-year projects. Please refer to "Eligible TMG Project Types, Maximum Funding Levels, and Periods of Performance," for additional details. State the number of years for the period of performance and include the exact dates.

III. Eligibility Information

I.

1. Eligibility

Eligible Applicants: "Indian Tribes" and "Tribal Organizations" (T/TOs) as defined by the ISDEAA are eligible to apply for the TMG Program. The definitions for each entity type are outlined below. Only one application per Tribe/Tribal organization is allowed.

Definitions: "Indian Tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. 25 U.S.C. 5304(e).

"Tribal organization" means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult