

and epidemiologic studies. Subcommittee proposals on lead poisoning prevention and national lead poisoning prevention efforts will be provided to the Board of Scientific Counselors for deliberation and possible adoption as formal recommendations to NCEH/ATSDR.

*Matters for Discussion:* Agenda items will include the following: Lead Poisoning Prevention Program (status), Flint Registry (status), Revision of Blood Lead Level reference value (status), Discussion of legislative requirements of a new Lead Exposure and Prevention Federal Advisory Committee, Federal partnership efforts.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Amanda Malasky, Coordinator, Lead Poisoning Prevention Subcommittee, BSC, NCEH/ATSDR, 4770 Buford Highway, Mail Stop F-45, Chamblee, Georgia 30345; telephone 770/488-7699, Fax: 770/488-3377; Email: [AMalasky@cdc.gov](mailto:AMalasky@cdc.gov).

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017-10333 Filed 5-19-17; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review**

The meeting announced below concerns the Centers for Disease Control and Prevention (CDC) initial review of applications in response to Funding Opportunity Announcement (FOA) GH16-006, Conducting Public Health Research in Kenya; GH17-004, Conducting Public Health Research Activities in Egypt; GH17-005, Conducting Public Health Research in China.

This publication corrects a notice that was published in the **Federal Register** on May 4, 2017, Volume 82, Number 85, pages 20894-20895. The meeting

announcement and matters for discussion should read as follows:

The meeting announced below concerns the Centers for Disease Control and Prevention (CDC) initial review of applications in response to Funding Opportunity Announcement (FOA) GH17-005, Conducting Public Health Research in China.

*Time and Date:* 9:00 a.m.–2:00 p.m., EDT, May 24, 2017

*Matters for Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Conducting Public Health Research in China”, GH17-005.

**FOR FURTHER INFORMATION CONTACT:**

Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road, NE., Mailstop D-69, Atlanta, Georgia 30033, Telephone: (404) 639-4796, [CGHERPO@CDC.GOV](mailto:CGHERPO@CDC.GOV).

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**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-1988]

**Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on June 20, 2017, from 8 a.m. to 5 p.m. Comments received on or before June 6, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Avenue, Building. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2017-N-1988. All submissions received must include the Docket No. FDA-2017-N-1988 for “Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” For detailed instructions on sending comments, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov/>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov/> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov/>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions” in the **SUPPLEMENTARY INFORMATION** section.

#### FOR FURTHER INFORMATION CONTACT:

LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Building 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [EMDAC@fda.hhs.gov](mailto:EMDAC@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 <https://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:** Public Participation: FDA will close docket FDA 2017-N-1988 on June 19, 2017. Submit either electronic or written comments on this public meeting by that date. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 19, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 19, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-1988 for “Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for

those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Agenda:* The committee will discuss a supplemental new drug application for VICTOZA (liraglutide) injection (sNDA 022341), sponsored by Novo Nordisk, for the proposed additional indication of: As an adjunct to standard treatment of cardiovascular risk factors to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and high cardiovascular risk.

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 <https://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. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before June 6, 2017, will be provided to the committee. 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 May 26, 2017. 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 May 30, 2017.

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 disabilities. If you require accommodations due to a disability, please contact LaToya Bonner 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 <https://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: May 16, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017-10326 Filed 5-19-17; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Indian Health Service**

#### **Office of Tribal Self-Governance; Negotiation Cooperative Agreement**

*Announcement Type:* New—Limited Competition.

*Funding Announcement Number:* HHS-2017-IHS-TSGN-0001.

*Catalog of Federal Domestic Assistance Number:* 93.444.

#### **Key Dates**

*Application Deadline Date:* June 23, 2017.

*Review Date:* July 17–21, 2017.

*Earliest Anticipated Start Date:* August 15, 2017.

*Tribal Resolutions Due Date:* June 23, 2017.

#### **I. Funding Opportunity Description**

##### *Statutory Authority*

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements 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. 5383(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA) 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 (U.S.) 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 affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS

to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting, and (3) compact with the IHS to assume control over health care programs 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.

The TSGP is a Tribally-driven initiative, and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP, (2) develop, direct, and implement TSGP policies and procedures, (3) provide information and technical assistance to Self-Governance Tribes, and (4) advise 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 to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements. Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the self-governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs, should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

##### *Purpose*

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP negotiations are a dynamic, evolving, and Tribally-driven process that requires careful planning and preparation by both Tribal and Federal parties, including the sharing of precise, up-to-date information. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of its current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) Enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs,

(2) observe and respect the government-to-government relationship between the U.S. and each Tribe, and (3) involve the active participation of both Tribal and IHS representatives, including OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and Funding Agreement (FA), the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the government-to-government relationship between the Tribe and the Secretary of Health and Human Services (HHS). The FA: (1) Describes the length of the agreement (whether it will be annual or multi-year); (2) identifies the PSFAs, or portions thereof, the Tribe will assume; (3) specifies the amount of funding associated with the Tribal assumption; and (4) includes terms required by Federal statute and other terms agreed to by the parties. Both the Compact and the Funding Agreement are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and mutually enforceable after both parties sign the documents. Either document can be renegotiated at the request of the Tribe.

The negotiations process has four major stages: (1) Planning, (2) pre-negotiations, (3) negotiations, and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal organization 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 organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d). The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, FA and Tribal shares. They may take the form of a formal meeting or a series of informal meetings or conference calls.

In advance of final negotiations, the Tribe should work with IHS to secure the following: (1) Program titles and