

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by May 4, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: louise.ryan@acl.gov. Submit written comments on the collection of information to Louise Ryan, U.S. Administration for Community Living, 1 Massachusetts Avenue, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Louise Ryan, telephone: (202) 357-3503; email: louise.ryan@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, AoA has submitted the following proposed collection of information to OMB for review and clearance.

States provide the following data and narrative information in the report:

1. Numbers and descriptions of cases filed and complaints made on behalf of long-term care facility residents to the statewide ombudsman program;
2. Major issues identified impacting on the quality of care and life of long-term care facility residents;
3. Statewide program operations; and
4. Ombudsman activities in addition to complaint investigation.

The report form and instructions have been in continuous use, with minor modifications, since they were first approved by OMB for the FY 1995 reporting period. This request is for approval to extend use of the current form and instructions, with no modifications, for three years, covering the FY 2015-2017 reporting periods.

The data collected on complaints filed with Ombudsman programs and narrative on long-term care issues provide information to Centers for Medicare and Medicaid Services and others on patterns of concerns and major long-term care issues affecting residents of long-term care facilities. Both the complaint and program data collected assist the states and local Ombudsman programs in planning strategies and activities, providing training and technical assistance and developing performance measures.

A reporting form and instructions may be viewed in the ombudsman section of the AoA Web site, http://www.aoa.acl.gov/AoA_Programs/Elder_Rights/Ombudsman/NORS.aspx. AoA

estimates the burden of this collection and entering the report information as follows: Approximately 7,702.3 hours, with 52 State Long-Term Care Ombudsman programs responding annually.

Dated: February 26, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-04470 Filed 3-3-15; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Intent To Award a Single Source Non-Competing Continuation Cooperative Agreement to Amputee Coalition

AGENCY: Administration for Community Living, HHS.

SUMMARY: The Administration for Community Living (ACL) is proud to announce the Center for Improved Health of Persons with Limb Loss (Limb Loss Program) is moving to ACL as a result of the 2015 budget recently signed by President Obama.

The Limb Loss Program supports a national resource center and related activities that provides comprehensive information and resources to assist individuals and families dealing with Limb Loss. The Limb Loss Program currently operates through a cooperative agreement between the Amputee Coalition and the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC). ACL will be working with the CDC on transitioning the program to ACL.

Program Name: Limb Loss Program
Award Amount: \$2,730,000
Project Period: 4/1/2015 to 3/31/2016
Award Type: Cooperative Agreement

Statutory Authority: This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b-4)); Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113-235 (Dec. 16, 2014).

Catalog of Federal Domestic Assistance (CFDA) Number: 93.325 Discretionary Projects

DATES: Estimated Project Period—April 1, 2015 through March 31, 2016.

I. Program Description

The purpose of this cooperative agreement is to continue existing activities to promote health, wellness and the adoption of healthy behaviors with the objective of preventing and/or reducing chronic conditions associated with limb loss. The grantee will

continue to use both traditional and innovative approaches that will educate and inform people with disabilities, their family members, health care providers, policy makers, community members, and the general public.

Justification: The Limb Loss Program currently operates through a cooperative agreement between the Amputee Coalition and the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC). ACL will be working with the CDC on transitioning the program to ACL. To ensure uninterrupted continuation of the grant goals and objectives, ACL plans to issue a one year non-competing award to the incumbent Limb Loss Program grantee, Amputee Coalition.

II. Agency Contact

For further information or comments regarding this action, contact Ophelia M. McLain, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Innovation, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 690-7025; fax (202) 357-3560; email Ophelia.McLain@acl.hhs.gov.

Dated: February 26, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015-04460 Filed 3-3-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 April 14, 2015, from 7:30 a.m. to 5:15 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 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>.

Contact Person: Philip Bautista, 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, 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 <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: During the morning session, the committee will discuss the results of the cardiovascular outcomes trial (CVOT), Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus, for new drug application (NDA) 22350, Onglyza (saxagliptin) and NDA 200678, Kombiglyze XR (saxagliptin and metformin HCl extended-release) tablets manufactured/ marketed by AstraZeneca AB.

During the afternoon session, the committee will discuss the results of the CVOT, Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care, for NDA 22271, Nesina (ALOGLIPTIN); NDA 022426, Oseni (ALOGLIPTIN and PIOGLITAZONE); and NDA 203414, Kazano (ALOGLIPTIN and METFORMIN) tablets marketed by Takeda Pharmaceutical U.S.A., Inc.

Saxagliptin and ALOGLIPTIN are dipeptidyl peptidase-4 inhibitors, both indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Both CVOTs were submitted in accordance with the 2008 FDA Draft Guidance, "Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes," to demonstrate that a new antidiabetic therapy to treat type 2

diabetes is not associated with an unacceptable increase in 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 <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 March 31, 2015. Oral presentations from the public will be scheduled between approximately 10:10 a.m. to 10:40 a.m., and 3:30 p.m. to 4 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 March 23, 2015. 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 March 24, 2015.

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 Philip Bautista 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: February 26, 2015.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-04395 Filed 3-3-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric 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: Pediatric 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 March 24, 2015, from 8 a.m. to 5:30 p.m.

Location: Double Tree by Hilton, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200. 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>.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301-796-0885, email: walter.ellenberg@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