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 Both CVOTs were submitted in accordance with the 2008 FDA Draft Guidance, ''Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes,'' to demonstrate that a new antidiabetic therapy to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]

BILLING CODE 4164–01–P

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

to learn about possible modifications before coming to the meeting.

Agenda: On March 24, 2015, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). The PAC will meet to discuss the following products: CYMBALTA (duloxetine hydrochloride), QUILLIVANT XR (methylphenidate hydrochloride), LUNESTA (eszopiclone), RISPERDAL (risperidone), OXTELLAR XR (oxcarbazepine), REVATIO (sildenafil), ADVAIR HFA (fluticasone propionate/salmeterol), DYMISTA (azelastine hydrochloride/fluticasone proprionate), QNASL (beclomethasone dipropionate), VENOFER (iron sucrose), INVIRASE (saquinavir), ALTABAX Ointment (retapamulin), FluMist QUADRIVALENT (influenza vaccine live, intranasal), FLUARIX QUADRIVALENT (influenza virus vaccine), Medtronic ACTIVA DYSTONIA THERAPY, and LIPOSORBER LA–15 System. In addition, there will be a short presentation of the ethical issues discussed by the Pediatric Ethics Subcommittee of the PAC on March 23, 2015.

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 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 16, 2015. Oral presentations from the public will be scheduled on March 24, 2015, between approximately 9 a.m. and 10 a.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 6, 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 9, 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 Walter Ellenberg 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. 2015–04394 Filed 3–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 05, 2015, 11:00 a.m. to March 05, 2015, 05:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on February 24, 2015, 80 FR 9738.

The meeting will be held on March 12, 2015. The meeting location and time remain the same. The meeting is closed to the public.

Dated: February 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–04408 Filed 3–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.

Date: May 28–29, 2015.

Open: May 28, 2015, 8:00 a.m. to 3:00 p.m.

Agenda: Report by the Director, NINDS; Report by the Associate Director for Extramural Research; Administrative and Program Developments; and an Overview of the NINDS Intramural Program.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: May 28, 2015, 3:00 p.m. to 4:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: May 28, 2015, 4:45 p.m. to 5:15 p.m.

Agenda: To review and evaluate the Division of Intramural Research Board of Scientific Counselors' Reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: May 29, 2015, 8:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robert Finkelstein, Ph.D., Associate Director for Extramural Research,