(FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective 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 October 18, 2013, 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: Diane Goyette, 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: *AIDAC@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 October 18, 2013, the committee will discuss the safety and effectiveness of new drug application (NDA) 204684, miltefosine capsules, submitted by Paladin Therapeutics, Inc., for the proposed indication of treatment of patients with visceral (involving internal organs), mucosal (involving areas such as inside the mouth and nose), and cutaneous (involving the skin) leishmaniasis, an infection caused by a parasite.

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 October 2, 2013. 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 September 24, 2013. 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 September 25, 2013.

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 Diane Goyette 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: August 2, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–19253 Filed 8–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration Patient Network Annual Meeting; Demystifying Food and Drug Administration: An Exploration of Drug Development Hosted by the Food and Drug Administration Office of Health and Constituent Affairs, Formerly the Office of Special Health Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting for patients, caregivers, patient advocates, as well as patient advocate and health professional groups, to provide a primer on drug product development and explore patient involvement in drug development. The meeting will serve as a forum for FDA's patient stakeholders and the general public, including health professionals, academia, and industry to learn about FDA's role in, and various regulatory issues related to drug development, analyze where in the process patient input may be most practical and most valuable, and explore practicable approaches to incorporating meaningful patient input that will represent broad patient perspectives in drug development and regulatory decision making. Specifically, this meeting will provide information and facilitate a discussion about: FDA's role in drug development and where and how patients can take an active role.

DATES: The meeting will be held on September 10, 2013, from 8:30 a.m. to 4:30 p.m. Register to attend the conference at *http://www.patientnetwork.fda.gov/patient-network-annual-meeting-September-10-2013* on or before August 27, 2013. There is no registration fee for this conference. Early registration is suggested because space is limited. The conference will be available for viewing via Webcast please register at for the Webcast at *http://www.patientnetwork.fda.gov/patient-network-annual-meeting-September-10-2013.* We request that organizations limit the number of representatives to two. For further registration information or problems with registering call Cindy de Sales at 240–316–3200 ext. 207.

If you need special accommodations due to a disability, please specify those accommodations when registering for this 1-day conference.

ADDRESSES: The meeting will be held at the Washington Marriott at Metro Center 775 12th St. NW., Washington DC 20001.

FOR FURTHER INFORMATION CONTACT: Steve Morin, Office of Health and Constituent Affairs, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0161, FAX: 301–847–8623, email: *Steve.Morin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. The FDA Patient Network

This is the second FDA Patient Network Annual Meeting hosted by the FDA Office of Health and Constituent Affairs, formerly the Office of Special Health Issues, the Agency's primary liaison with patient and health professional communities. This annual meeting is being hosted as part of the larger FDA Patient Network program. The FDA Patient Network is a new resource for patients, caregivers, independent patient advocates, and patient advocate groups that seeks to:

- Educate and inform patient stakeholders about FDA, its regulatory authorities and processes, its initiatives and programs, and
- Provide a venue for advocacy for patient stakeholder involvement within FDA, enhancing transparency of Agency actions for patients. In addition to an annual meeting, the FDA Patient Network consists of:
- The FDA Patient Network Web site—A new, patient-centered Web site that contains educational modules, centralized Agency information, and multi-directional communication tools (*www.patientnetwork.fda.gov*);
- The biweekly *FDA Patient Network News* email newsletter containing FDA-related information on a variety of topics, including new product approvals, significant labeling changes, safety warnings, notices of upcoming public meetings, proposed regulatory guidances and opportunity to comment, and other information of interest to patients and patient advocates; and
- Hosting of periodic meetings, briefings, and listening sessions between patient advocates and FDA staff.

II. Patient Involvement in the Drug Development Life Cycle

We believe that enhancing patients' understanding of the drug development process will provide a better foundation for their participation in regulatory decision making, and clarify where patient input can be most meaningful in the drug development life cycle. Patients who live with a disease have a direct stake in the development of new therapies to treat and minimize symptoms they are experiencing. They are in a unique position to contribute to the various product-specific regulatory decisions that occur throughout the drug development process, as well as the policy decisions that impact the drug development and review paradigm. Though several programs exist that facilitate patient representation on Advisory Committees or participation in selected review meetings, there are currently few venues in which the patient perspective is discussed outside of a specific product's marketing application review. FDA believes the medical product review process could benefit from a more scientific, systematic, and expansive approach to obtaining input from patients who are experiencing a particular disease condition.

As part of the Food and Drug Administration Safety and Innovation Act, specifically section 1137 (see: *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm311045.htm*), FDA is tasked with developing and implementing strategies to solicit the views of patients during the medical product development process and consider their perspectives during regulatory discussions. This includes:

- Fostering participation of FDA Patient Representatives as Special Government Employees in appropriate Agency meetings with medical product sponsors and investigators; and
- Exploring means to provide for identification of potential FDA Patient Representatives who do not have any, or have minimal, financial interest in the medical products industry.

FDA is conducting this meeting with patients, caregivers, patient advocates, and patient advocate groups to provide a forum to demystify the drug development process and FDA's role in drug regulation, and facilitate a discussion between these stakeholders and the Agency to foster a collaborative relationship. This meeting, intended to build upon the objectives of the inaugural Patient Network Annual Meeting, held on May 18, 2012, will provide an open forum for patients and patient advocates to engage with FDA on both ongoing and emerging medical product regulatory issues.

Dated: August 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19275 Filed 8–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Rabbit Antibody to Mouse Sphingosine-1-phosphate (S1P) Lyase

Description of Technology: The cleavage of sphingoid base phosphates by sphingosine-1-phosphate (S1P) lyase to produce phosphoethanolamine and a fatty aldehyde is the final degradative step in the sphingolipid metabolic pathway. Researchers at NIH injected rabbits with the C-terminal peptide of the mouse S1P lyase—551–TTDPVTQGNQMNGSPKPR–568—to develop an antibody that can be used in western blotting to study this pathway.

Potential Commercial Applications: The antibody can be used to detect and measure S1P lyase.

Competitive Advantages: The antibody works very well for western blotting.

Development Stage: In vitro data available.

Inventor: Richard L. Proia (NIDDK).

Publication: Bektas M, et al. Sphingosine 1-phosphate lyase deficiency disrupts lipid homeostasis in liver. J Biol Chem. 2010 Apr 2;285(14):10880–9. [PMID 20097939].

Intellectual Property: HHS Reference No. E–465–2013/0—Research Tool. Patent protection is not being pursued for this technology.