meeting, 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,
oraly 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 5 days in advance of the
meeting.

FIDA 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; 8:43 am]
BILLING CODE 4160–01–P
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 bimonthly 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 guidelines and opportunities 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/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentstotheFDCAct/ FDASA/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 is 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]