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.

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