4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Food and Drug Administration Third Annual Patient Network Meeting; Under the Microscope: Pediatric Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), Office of Health and Constituent Affairs (OHCA) is announcing a 1-day meeting to explore challenges related to pediatric product development. The meeting will serve as a forum for FDA's stakeholders (patients, caregivers, patient advocates, healthcare professional groups, the general public, academia, and industry) to learn about regulations that encourage pediatric product development; to discuss ways to advance pediatric product development, how health disparities impact pediatric product development, the importance of transparency in pediatric clinical trials, and how analysis of information from failed pediatric clinical trials might improve future designs for pediatric trials; and to identify ways patient input can benefit clinical trial design for pediatric trials.

The 1-day meeting will also provide an opportunity to participate in panel discussions on the challenges related to development of products used to treat pediatric patients, including pediatric patients with rare diseases and explore ways that patients/caregivers, FDA, and industry may work together to incorporate patient input in future pediatric product development and regulatory decisionmaking.

DATES: The public meeting will be held on September 10, 2014, from 8 a.m. to 4:30 p.m. If you wish to attend the 1-day meeting, visit the Patient Network at http://patientnetwork.fda.gov/3rd-annual-patient-network. Please register before September 5, 2014. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend the meeting in person or via the webcast. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. There is no registration fee for this meeting and early registration is suggested because space is limited. We request that non-patient organizations limit the number of representatives to three. For further registration information or problems with the Web site call Steve Morin (see FOR FURTHER INFORMATION CONTACT) at 301-796-0161 or email at patientnetwork@fda.hhs.gov.

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

ADDRESSES: The meeting will be held at the Washington Marriott at Metro Center, 775 12th St NW, Washington DC, 20005.

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, patientnetwork@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. The FDA Patient Network

This is the third FDA Patient Network Annual Meeting hosted by OHCA, 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 resource that seeks to:

- Educate and inform patients and patient advocacy organizations about FDA's:
    - regulatory authorities and processes;
    - initiatives;
    - public meetings;
    - ways to comment on FDA draft guidances; and
- provide a venue for patient advocacy involvement within the FDA.

In addition to an annual meeting, the FDA Patient Network consists of:

- The FDA Patient Network Web site (www.patientnetwork.fda.gov)--a patient-centered Web site that contains:
    - educational modules and FDA webinars;
    - centralized agency information for patients;
    - periodic LiveChat and listening discussions between patient advocates and FDA staff; and
- The biweekly FDA Patient Network News email newsletter informs the community on current FDA-related information on medical product:
    - medical approvals;
    - safety labeling changes;
    - safety warnings;
    - ways to participate on upcoming public meetings;
    - ways to comment on proposed regulatory guidances;
    - information on food safety; and

- other information of interest to patient and patient advocates.

To sign up for the FDA Patient Network News, visit http://www.patientnetwork.fda.gov/get-involved/get-newsletter.

FDA will post the agenda 5 days before the meeting at http://patientnetwork.fda.gov/3rd-annual-patient-network.

Dated: July 11, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014-16714 Filed 07/15/2014 at 8:45 am; Publication Date: 07/16/2014]