4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advancing the Development of Pediatric Therapeutics: Successes and Challenges of Performing Long-Term Pediatric Safety Studies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Office of Pediatric Therapeutics (OPT) and Center for Drug Evaluation and Research are announcing a 2-day public workshop entitled "Advancing the Development of Pediatric Therapeutics (ADEPT): Successes and Challenges of Performing Long-Term Pediatric Safety Studies." The purpose of this 2-day public workshop is for FDA to have an open discussion with experts in the field examining the need and path forward for long-term pediatric safety studies. Day 1 of the public workshop will focus on an exposition of the successes and challenges of long-term safety studies in children. Day 2 of the public workshop will focus on suggestions for the future on study design and implementation of long-term safety studies in children. Viewpoints of patient representatives of children with chronic conditions and industry will be included.

DATES: The public workshop will be held on April 13 and 14, 2016, from 8 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at The DoubleTree by Hilton Hotel--Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Renan A. Bonnel, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8654, FAX: 301-847-8640, email: renan.bonnel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Medical product safety studies in children are usually performed for 6 months or less. In children, measurement of long-term outcomes is particularly challenging since, compared to adults, children are undergoing dramatic growth and developmental changes. This 2-day public workshop will focus on the challenges of long-term follow-up in children receiving medical products. The first day of the public workshop will focus on the problems or barriers, including; challenges with study design, data capture, infrastructure, and endpoints. Viewpoints of parents and industry will be represented. The second day of the public workshop will include panel discussions to propose solutions to the problems posed on day one and to discuss the epidemiological challenges posed by the collection of data on different types of adverse events. On both days of the public workshop there will be a certain amount of time on the agenda for attendee questions or comments.

II. Participation in the Public Workshop

Registration: There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at: http://pediatricsafety.eventbrite.com before April 7, 2016. For those without Internet access, please contact Renan A. Bonnel (see FOR FURTHER INFORMATION CONTACT) to register. In the event that a minimum number

of participants have not registered, the workshop will be postponed. Registered participants will be notified of any change. Onsite registration will be available if seating permits it. Registration information, the agenda, and additional background materials can be found at http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm.

If you need special accommodations due to a disability, please contact Renan A. Bonnel (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Web cast: The live Web cast on April 13, 2016, will be available at: https://event.webcasts.com/starthere.jsp?ei=1093258. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): https://event.webcasts.com/starthere.jsp?ei=1093259. On April 14, 2016, the live Web cast will be available at: https://event.webcasts.com/starthere.jsp?ei=1093263. After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (note that it is different from the morning's session): https://event.webcasts.com/starthere.jsp?ei=1093265.
The Web cast will only be for listening and there will not be an opportunity for Web cast participants to speak.

The videocast will be posted after the workshop at http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm477639.htm.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852, and at http://www.regulations.gov approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information. The Freedom of Information address is available on the Agency's Web site at http://www.fda.gov. Send faxed requests to 301-827-9267.

Dated: March 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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