4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pediatric Clinical Investigator Training 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 the Center for Drug Evaluation and Research are announcing a 1-day public workshop entitled "Pediatric Clinical Investigator Training." The purpose of this workshop is to provide investigators with training and expertise in designing and conducting clinical trials in pediatric patients that will lead to appropriate labeling. The training course is intended to provide investigators with a clear understanding of some of the challenges of studying products in the pediatric population when the data are intended to be used to support product labeling, an overview of extrapolation as it relates to the pediatric population, a familiarity with FDA processes and timelines that are specific to pediatric product development, and an overview of ethically appropriate methods related to the design of clinical trials in the pediatric population.

DATES: The public workshop will be held on September 22, 2014, from 8 a.m. to 5:30 p.m.

ADDRESSES: The public workshop will be held at the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301-897-9400.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8646, FAX: 301-847-8640, email: terrie.crescenzi@fda.hhs.gov; or Betsy

Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8659, FAX: 301-847-8640, elizabeth.sanford@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) made permanent the pediatric initiatives, Best Pharmaceuticals for Children Act and Pediatric Research Equity Act, which have stimulated pediatric research over the past 15 years. Though much progress has been made, pediatric trials for the purpose of developing product use parameters and information are still performed much less frequently than adult trials. As such, current standards for trials are much more oriented to adult scientific, ethical, and clinical processes. This situation is due, in part, to the fact that pediatric trials have a number of unique attributes and requirements, which must be met if the data are to be accepted or used by FDA.

The development of safe and effective products in the pediatric population presents many challenges. These challenges include trial design, appropriate endpoints, extrapolation of data from adults, and ethical issues. It is extremely important that pediatric researchers recognize and understand the challenges and differences between the standards for adult trials and pediatric trials. Researchers are responsible for ensuring the safe and ethical treatment of pediatric patients and obtaining adequate and reliable data to support regulatory decisions. There is a critical need for further pediatric research on medical products to obtain additional data, which will help ensure that these products are safe and effective in the pediatric population. We are able to obtain data and information in older children; however, the challenge of obtaining data from non-verbal children and neonates is much more difficult. This need reinforces our responsibility to educate

clinical investigators to assure that children are only enrolled in research that is scientifically necessary, ethically sound, and designed to meet the challenges of review by FDA.

II. Participation in the Public Workshop

A. 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 by sending an email to OPT@fda.hhs.gov before September 8, 2014, and include the following information: Name, title, affiliation, email address, and telephone number. For those without Internet access, please contact Terrie L. Crescenzi or Betsy Sanford (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. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

Registration information, the agenda and additional background materials can be found at http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm.

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

B. Videotaping

The workshop will be videotaped and available on the Internet at http://wcms.fda.gov/FDAgov/NewsEvents/MeetingsConferencesWorkshops/ucm392506.htm?ssSourceSiteId=null&SSContributor=true, approximately 30 days after the workshop.

Dated: April 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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