4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0754]

Pediatric Medical Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue." The purpose of the public workshop is to receive public comment on the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.

The topics to be discussed are: The ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

Date and Time: The public workshop will be held on December 5, 2011, from 8:30 a.m. to 5 p.m. EST.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

Contact Person: Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5437, Silver Spring, MD 20993-0002, 301-796-3241, Carol.Krueger@fda.hhs.gov.

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on November 28, 2011. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Cynthia Garris (email: Cynthia.Garris@fda.hhs.gov or 301-796-5861) no later than November 28, 2011.

To register for the public workshop, please visit the following Web site: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (or go the FDA Medical Devices News & Events--Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Carol Krueger to register (see Contact Person). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Web Cast of the Public Workshop: This workshop will also be Web cast. Persons interested in viewing the Web cast must register online by 5 p.m. on November 28, 2011. Early registration is recommended because Web cast connections are limited. Organizations are requested to register all participants but to view using one connection per location. Web cast participants will be sent technical system requirements after registration and

will be sent connection access information after November 28th. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Workshop Format: This workshop is structured as topic-focused breakout sessions, intended to foster constructive dialogue between stakeholders with diverse perspectives. Moderators of each small group will summarize the group discussion and present it to the participants.

Comments: FDA is holding this public workshop to obtain information on a number of questions regarding factors affecting approval or clearance of devices for use with a pediatric population. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting written or electronic comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is January 5, 2012.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is necessary to send only one set of comments. It is no longer necessary to send two copies of mailed comments. Please identify written comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in

the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at http://www.regulations.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 2007, Congress passed the Pediatric Medical Device Safety and Improvement Act (the Act). The Act addresses pediatric device needs by providing financial incentives for development, production, approval and distribution of new devices for rare and unmet pediatric needs; allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device; and providing grants to pediatric device consortia that provide technical support and assistance to pediatric device innovators.

This workshop will support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. An important, but not the only, focus will be a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations.

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices treat or diagnose diseases and conditions occurring from birth through the 21st year of life. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Designing pediatric medical devices can be challenging; children are often smaller and more active than adults, body structures and functions change throughout childhood, and children may be long-term device users--bringing new concerns about device longevity and long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

Through this effort, FDA and stakeholders will take steps to increase awareness of a path for approval of pediatric devices that uses certain literature. FDA can advance this goal by collaborating with stakeholders, including medical device and health care industries, and the health care provider and consumer communities.

II. Topics for Discussion at the Public Workshop

The public workshop will be organized to discuss the following topic areas:

A. The use of existing scientific research data to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance,

B. The scientific and regulatory limitations and issues with the use of existing scientific research data, and

C. The methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a

Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: October 26, 2011.

Nancy K. Stade,

Deputy Director for Policy,

Center for Devices and Radiological Health.

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