4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0620]

An Interactive Discussion on the Clinical Considerations of Risk in the Postmarket Environment; 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 "Clinical Considerations of Risk in the Postmarket Environment." The purpose of this workshop is to provide a forum for an interactive discussion on assessing changes in medical device risk as quality and safety situations arise in the postmarket setting when a patient, operator, or member of the public uses the device. FDA is interested in obtaining input from stakeholders about assessing risk postmarket when new hazards develop in the postmarket setting that were not present or not known at the time of clearance or approval or hazards were anticipated, but harm occurs at an unexpected rate or in unexpected populations or use environments. Comments and suggestions generated through this workshop will facilitate the assessment of risk in postmarket quality and safety situations.

Date and Time: The public workshop will be held on April 21, 2015, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Jean M. Cooper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5540, Silver Spring, MD 20993, 301-796-6141, email: Jean.Cooper@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m., April 13, 2015. 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 Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5231, Silver Spring, MD 20993-0002, 301-796-5661, email: susan.monahan@fda.hhs.gov no later than April 7, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this meeting/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 Susan Monahan (see Registration). Registrants will receive confirmation after they have been accepted and will be notified if they are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Web cast. Persons interested in viewing the Web cast must register online by 4 pm, April 13, 2015. 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 April 14, 2015. 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.)

Request to Speak: This public workshop includes a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to speak during a public comment session and which topic you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, FDA will determine the amount of time allotted to each speaker and will select and notify speakers by April 16, 2015. All requests to speak must be received by the close of registration on April 13,

2015. If selected to speak, any presentation materials must be emailed to Jean Cooper (see Contact Person) no later than April 13, 2015. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is seeking input from FDA staff, medical device industry, standards organizations, health care providers, academia, patients, and other stakeholders. 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 May 19, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify 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.

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 (see Comments). 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 the 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 approximately 45 days after the public workshop on the Internet at

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

There is a strong desire by FDA and industry to harmonize their practices regarding assessment of risk in postmarket quality and safety situations including, but not limited to, product defects, failures, faults, or shortages, and any resulting harm. When postmarket safety or quality issues arise, both the firm and FDA conduct risk analyses of the device in order to decide what actions to take. During this analysis, firms typically look for changes from their preproduction risk analysis to their postmarket experience and apply or update their risk management plan as appropriate. In contrast, FDA responds to the same issue by assessing information submitted in the firm's premarket submission and may consider other information such as information collected during an inspection when it is available. The result is that FDA and industry may base their decisions about postmarket quality and safety on different information.

Managing risk does not mean eliminating risk. The medical device industry, FDA, doctors, and patients recognize that medical devices cleared or approved for market may pose some inherent risk, even when used appropriately according to labeling. Examples include, but are not limited to, manufacturing problems, materials changes, unanticipated design flaws, regional differences in clinical practice, measurement inaccuracies, incomplete instructions, transport and storage factors, and incorrect installation.

FDA anticipates that principles and factors developed with public input will help bridge differences in understanding when conducting risk assessments.

II. Topics for Discussion at the Public Workshop

FDA held discussions in the Fall of 2014 with a working group of the Association of Advancement of Medical Instrumentation to develop a draft list of risk principles and factors to consider in analyzing postmarket risk. The draft principles and factors will be presented for discussion at the public meeting. The purpose of this workshop is to provide a forum for a collaborative discussion on postmarket risk principles and factors assessing risk when changes occur due to postmarket quality and safety situations. The following questions are provided to optimize the discussion.

- What factors are important to take into account when conducting risk assessments of safety and quality issues that occur with marketed medical devices? What principles best guide the risk assessment process to assure timely, consistent, and optimal results?
- Are there improvements that FDA and stakeholders could make to enhance risk assessments in recall and shortage situations with medical devices?
- Are there specific activities or issues related to postmarket quality, safety, or compliance activities where approaches used by FDA and industry currently differ enough to create confusion or delay or limit appropriate public health actions? Please identify them.
- In which activities and areas of postmarket quality, compliance, and safety would more detailed policies or guidance be most useful?

At this public workshop, participants will engage in open dialogue to discuss the responses to issues raised by the presenters and the questions in this Federal Register notice.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4

p.m., Monday through Friday. We have verified all Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.

1. FDA, "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices," 2014, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm

Dated: March 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-06278 Filed: 3/18/2015 08:45 am; Publication Date: 3/19/2015]