4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0067]

Medical Device Patient Labeling; Request for Comments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration is announcing the following public workshop entitled "Medical Device Patient Labeling". The purpose of the public workshop is to discuss issues associated with the development and use of medical device patient labeling including content, testing, use, access, human factors, emerging media formats, and promotion and advertising. The Center for Devices and Radiological Health (CDRH) is seeking input into these topics from patients and advocacy groups, academic and professional organizations, industry, standards organizations, and governmental Agencies. Ideas generated during this workshop will help facilitate development or revision of guidances and/or standards for medical device patient labeling.

Date and Time: The workshop will be held on September 29, 2015, from 8 a.m. to 5 p.m. and September 30, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non- FDA employees) is through

Building 1 where routine security check procedures will be performed. For parking and security information, please visit the following Web site: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm

Contact Person: Antoinette (Tosia) Hazlett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5424, Silver Spring, MD 20993-0002, 301-796-6119, Tosia.Hazlett@fda.hhs gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the "Medical Device Patient Labeling" public workshop must register online by 4 p.m. on September 21, 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 permit, onsite registration on the days of the public workshop will be provided beginning at 7 a.m. If you need special accommodations due to a disability, please contact Susan Monahan at least 7 days in advance of the meeting.

To register for the public workshop, please visit CDRH's Workshops and Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan 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 Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on September 21, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 25, 2015. If you have never attended a Connect Pro event before, test your connections at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. (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.)

Comments: FDA is holding this public workshop to obtain stakeholder input on medical device patient labeling. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop. The deadline for submitting comments regarding this public workshop is October 30, 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 topics as outlined in "Topics for Discussion", please identify the topic 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

The CDRH Guidance on Medical Device Patient Labeling (available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070782.htm) serves to assist manufacturers in their development of patient labeling and to assist Center reviewers in their review and evaluation of the manufacturers' labeling. Medical device patient labeling includes any medical device information that is intended for a lay audience. It is intended to help assure that the device is used safely and effectively. This labeling may pertain to therapeutic, restorative, diagnostic, or cosmetic devices. Medical device patient labeling is supplied in many formats, for example: As patient brochures, patient leaflets, user manuals, videos or audio recording, and through physical or online media. This labeling is intended to be supplied to or available to patients or their lay caregivers for their use with or without accompanying professional counseling. While some patients receive labeling from their healthcare practitioners or device suppliers, others receive it in the packaging of over-the-counter

devices. CDRH is collecting public comment to use in updating the Medical Device Patient Labeling Guidance.

FDA is committed to supporting the development and availability of patient labeling which supports the safe and effective use of medical devices by patients. To inform FDA in their efforts, they are seeking input on the topics identified in section II.

II. Topics for Discussion

FDA seeks to address and receive comments on the following topics:

A. Current Medical Device Patient Labeling:

1) The current use and practice trends of medical device patient labeling development and use. For example: When is medical device patient labeling used? How much medical device patient labeling exists? How much modification and revision of existing medical device patient labeling occurs, and under what circumstances? What is the role of voluntary consensus standards in developing medical device patient labeling?
2) What risks or adverse outcomes have been reported in association with the use of medical device patient labeling? What communication barriers have been encountered, and how can they be mitigated?
3) Is there any part of the medical device patient labeling development process that presents a barrier to receiving approval or clearance from CDRH? If so, please provide examples of the specific issues, how frequently this occurs, and suggestions which constructively address these barriers.

4) What are the best ways to foster efficient networking with patients and advocacy groups, academic and professional organizations, industry, standards organizations, and government Agencies to address medical device patient labeling needs?

B. Medical Device Patient Labeling Needs Assessment:

1) Describe the parameters that should be used in determining priority areas of development of medical device patient labeling, including both therapeutic and diagnostic devices.

2) What are best practices for conducting a needs assessment of medical device patient labeling?

C. Advancing Development:

1) What could advance the development and use of medical device patient labeling?

2) How should patient labeling be considered in the development stages of all medical device labeling?

3) What resources (e.g., registries, industry, or patient advocacy groups,) could be tapped to advance the development of medical device patient labeling?

4) What are potential changes to guidances and regulations, or advances in current science that may help develop and enhance medical device patient labeling to address the needs of medical device manufacturers, device suppliers, and device users?

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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