4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1037]

Pilot Program for Center for Devices and Radiological Health Electronic Submission for Home Use Device Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) is announcing the availability of a CDRH electronic submissions Pilot Program database to house labeling for home use devices. Participation in the pilot is open to applicants who label their device(s) for home use. Participation in the pilot project is voluntary. Participants will be asked to navigate through the electronic submissions system and practice submitting labels and package inserts. The pilot project is intended to provide industry and CDRH staff the opportunity to evaluate the submissions process and system and to receive comments from industry participants.

DATES: FDA will accept applications for participation in the voluntary electronic submissions CDRH Home Use Device Labeling Pilot Program from May 1, 2015, through May 31, 2015. See the "Participation" section for instructions on how to submit a request to participate. The pilot project will occur July 1, 2015, through December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 rm. 5426, Silver Spring MD 20993, 301-796-6089, Mary.Brady@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring that medical devices are safe and effective when used for their intended purpose. Risks are inherent in all CDRH-regulated medical devices, and the Center plays a critical role in preventing injuries and deaths related to product use. CDRH minimizes risk through regulation, enforcement, and education. Risk minimization is accomplished, in part, through clear communication on the benefits and risks of the medical devices regulated by the Center, including communications by CDRH, product manufacturers, and product distributors. These communications include medical device labeling produced by manufacturers and distributors.

Medical device labeling provides safety information, instructions for use, and/or other necessary information to the user. This labeling can be essential for home-use devices, which are much more likely to be used by lay users, who frequently have not been trained to use such medical devices and who are especially reliant on the instructions for use and other information provided by the device label and package insert. When used in an environment where a healthcare professional is not available to provide supervision and assistance, these devices can present unique concerns and challenges. When a home-use device is used over a period of years, it becomes increasingly more likely that it may be separated from its original labeling or that its original labeling will not include current safety information or instructions for use. In contrast with use in professional healthcare settings, a patient or caregiver using a home-use device in a

setting without professional oversight may not have extensive experience in the use of a device and may not have ready access to the original packaging or to alternative sources of information about a device.

Home-use devices have significant public health importance to patients, caregivers, and healthcare professionals. Therefore, it is necessary to ensure that users are able to access necessary information for use, including safety information and instructions for use. Although many manufacturers have Internet sites that provide information concerning the devices they currently market, those sites typically focus on newer products and often do not provide any information on devices that they no longer actively market. Web sites also vary considerably in the types of information provided and may lack important details concerning their devices. Although some manufacturers' Web sites provide some labeling, FDA believes that most do not provide the label and package insert for all of their home-use devices listed with FDA.

II. CDRH Home Use Device Labeling Pilot

CDRH is developing an electronic submissions database, accessible to the public through FDA's Web site, of labels and package inserts for listed home-use devices. This database would fill an important gap in the information available to patients, caregivers, and the healthcare community concerning home-use devices. The database would allow both broad searches to identify legally marketed home-use devices that may fill a particular need and focused searches to obtain information concerning the use of a specific home-use device.

This electronic submissions database will be evaluated for usability through the CDRH Home Use Device Labeling Pilot Project. This pilot project will proceed for 6 months. Participation in the pilot is open to applicants who label their device(s) for home use. Participants will be asked to navigate through the electronic submissions system and practice

submitting labels and package inserts. The pilot project is intended to provide industry and CDRH staff the opportunity to evaluate the submissions process and system and to receive comments from industry participants. Comments received during the pilot project will be used to evaluate the usability of the database. FDA will not review the content of any labeling submitted to the pilot database for a regulatory purpose. The submitted labeling and the database will only be available to pilot participants.

A. Participation

Volunteers interested in participating in the pilot project should contact pilot staff by email at Mary.Brady@fda.hhs.gov. The following information should be included in the request: Contact name, contact phone number, and contact email address. FDA will contact interested applicants to discuss the pilot project. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot project.

B. Procedures

By following a series of prompts and instructions, pilot participants will submit a PDF version of their device labeling to the pilot database. The content of the submissions will not be reviewed by FDA for any regulatory purpose, nor will the pilot database be available to the public during this pilot project. During the pilot, CDRH staff will be available to answer any questions or concerns that may arise. Pilot project participants will be asked to comment on and discuss their experiences with the pilot submissions process. Their comments and discussions will assist CDRH in its development of this electronic submissions database.

III. Duration of the Home Use Device Labeling Pilot

FDA intends to accept requests for participation in the Home Use Device Labeling Pilot from May 1, 2015, through May 31, 2015. The pilot will proceed for 6 months, from July 1,

2015, through December 31, 2015. This pilot program may be extended as resources and needs allow.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit electronic comments regarding the Home Use Device Labeling Pilot 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. 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.

Dated: April 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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