4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4803]

Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"); Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')." FDA is issuing this guidance to describe the Center for Devices and Radiological Health's (CDRH) policy for notifying the public about medical device "emerging signals." This guidance describes the factors CDRH intends to consider in deciding whether to notify the public about an emerging signal and the processes and timelines it intends to follow in issuing and updating the notification. Timely notification about those emerging signals based on the factors described in this guidance document is intended to provide health care providers, patients, and consumers with access to the most current information concerning the performance and potential benefits and risks of marketed medical devices so that they can make informed patient management decisions about their treatment and diagnostic options.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-4803 for "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

SUPPLEMENTARY INFORMATION:

I. Background

All medical devices have benefits and risks. FDA weighs probable benefit to health from the use of the device against any probable risk of injury or illness from such use in determining

the safety and effectiveness of a device.[1] Once FDA has made its determination, health care providers, patients, and consumers must weigh these benefits and risks when making patient management decisions. However, not all information regarding benefits and risks for a given device may be known before the device reaches the market. New information about a device's safety and/or effectiveness, including unanticipated adverse events, may become available once the device is more widely distributed and used under real-world conditions and in broader patient populations than may have been studied in support of a marketing application. Also, subsequent changes made to the device, its manufacturing process, or supply chain might lead to new safety problems.

FDA is issuing this guidance to describe CDRH policy for notifying the public about medical device "emerging signals." For the purposes of this guidance, an emerging signal is new information about a marketed medical device: (1) That supports a new causal association or a new aspect of a known association between a device and an adverse event or set of adverse events and (2) for which the Agency has conducted an initial evaluation and determined that the information has the potential to impact patient management decisions and/or the known benefit-risk profile of the device. Information that is unconfirmed, unreliable, or lacks sufficient strength of evidence is not an emerging signal.

This guidance describes the factors CDRH intends to consider in deciding whether to notify the public about emerging signals and the processes and timelines it intends to follow in issuing and updating the notification. Timely notification about those emerging signals based on the factors described in this guidance document is intended to provide health care providers, patients, and consumers with access to the most current information concerning the performance

[1] See 21 U.S.C. 360c(a)(2) and 21 CFR 860.7.

and potential benefits and risks of marketed medical devices so that they can make informed patient management decisions about their treatment and diagnostic options.

In the Federal Register of December 31, 2015 (80 FR 81829), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by February 29, 2016. In the Federal Register of January 27, 2016 (81 FR 4632), FDA extended the comment period to March 29, 2016. FDA received and considered 21 sets of public comments and revised the guidance as appropriate. CDRH also intends to provide periodic public updates on the implementation of this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')" may send an email request to CDRH-Guidance@fda.hhs.gov to

receive an electronic copy of the document. Please use the document number 1500027 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance 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, regarding labeling, have been approved under OMB control number 0910-0485 and the collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control numbers 0910-0291, 0910-0437, and 0910-0471.

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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