4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0743]

Medical Device Reporting for Manufacturers; 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) is announcing the availability of the guidance entitled "Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff." This guidance document is intended to assist medical device manufacturers meet applicable reporting and recordkeeping requirements for certain device-related adverse events and malfunctions.

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-2013-D-0743 for "Medical Device Reporting for Manufacturers". 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 "Medical Device Reporting for Manufacturers" 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: Isaac Chang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3114, Silver Spring, MD 20993-0002, 301-796-2789.

SUPPLEMENTARY INFORMATION:

I. Background

Medical device reporting under section 519(a) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 360i(a)) provides a mechanism that allows FDA and device manufacturers, user facilities, and importer of medical devices to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving your medical devices. The goal is to detect and correct problems in a timely manner. This guidance updates FDA's policy and clarifies FDA's interpretations of the regulatory requirements under part 803 (21 CFR part 803) and includes a section on common reporting errors.

The draft of this guidance was made available in the Federal Register on July 9, 2013 (78 FR 41069), and the comment period closed October 7, 2013. FDA reviewed and considered all public comments received and revised the guidance as appropriate.

This document supersedes the draft entitled, "Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff," dated July 9, 2013, and the previous guidance on this topic, "Medical Device Reporting for Manufacturers," issued March 1997.

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 medical device reporting. 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 "Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1828 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 and 809, regarding labeling, have been approved under OMB control number 0910-0485; the collections of information in part 803, regarding medical device reporting, have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 806, regarding corrections and removals, have been approved under OMB control number 0910-0359; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812, regarding investigational device exemptions, have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910-0073; the collections of information regarding MedWatch: The Food and Drug Administration Medical Products Reporting Program have been approved under OMB control number 0910-0291; and the collections of information regarding the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)) have been approved under OMB control number 0910-0471.

Dated: November 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-26933 Filed: 11/7/2016 8:45 am; Publication Date: 11/8/2016]