4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Medical Device Reporting for Manufacturers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Medical Device Reporting for Manufacturers." This draft guidance describes and explains the current FDA regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events. This draft guidance is intended to update FDA's policy and to further clarify FDA's interpretations of the regulation requirements and, when final, will supersede the previous manufacturer guidances issued in 1988 and 1997. This draft guidance also provides answers to frequently asked questions and includes a section on common reporting errors. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Medical Device Reporting for Manufacturers" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. Please use the document number 1828 to identify the guidance you are requesting. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara Myklebust, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2312, Silver Spring, MD 20993-0002, 301-796-6005.

SUPPLEMENTARY INFORMATION:

I. Background

The first Medical Device Reporting (MDR) regulation became effective December 13, 1984, with mandatory device-related adverse event reporting obligations for manufacturers and importers. FDA published "Medical Device Reporting Questions and Answers" as part of its Compliance Guidance Series in February 1988. Subsequent changes to the reporting requirements, including mandatory reporting by domestic distributors and device user facilities,

resulted from amendments to the Federal Food Drug and Cosmetic Act (the FD&C Act) in 1990 and 1992.

The MDR regulation was revised significantly after the 1990 and 1992 amendments to the FD&C Act. The amended MDR regulation was published with significant revisions on December 11, 1995, and effective on July 31, 1996. FDA published a guidance document "Medical Device Reporting for Manufacturers" in March 1997 to clarify the changes to reporting requirements under the new regulation. The FD&C Act was further modified by amendments in 1997, 2002, and 2007, requiring further changes to the regulation. A plain language version of the MDR regulation was published on February 28, 2005, effective (in part) on July 13, 2005.

This draft guidance describes and explains the current FDA regulation that addresses reporting and recordkeeping requirements applicable to manufacturers of medical devices for certain device-related adverse events. This draft guidance is intended to update FDA's policy and to further clarify FDA's interpretations of the regulation requirements and, when final, will supersede the previous manufacturer guidances issued in 1988 and 1997. The draft guidance also provides answers to frequently asked questions and includes a section on common reporting errors.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on medical device reporting for manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using 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. To receive "Medical Device Reporting for Manufacturers," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1828 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 collection of information in 21 CFR part 803 subparts A to E have been approved under OMB 0910-0437 (expires August 31, 2015), and the collection of information in 21 CFR 803.11 and 803.20 have been approved under OMB control number 0910-0291 (expires June 30, 2015).

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management. It is necessary to send only 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: July 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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