4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0393]

Questions and Answers About Electronic Medical Device Reporting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Questions and Answers About eMDR--Electronic Medical Device Reporting." FDA has published a final rule that requires device manufacturers and importers to submit mandatory reports of individual medical device adverse events, also known as medical device reports (MDRs), to the Agency in an electronic format that FDA can process, review and archive. This guidance provides general information regarding how to prepare and send an electronic postmarket medical device report to the Center for Devices and Radiological Health (CDRH) in FDA. The guidance also identifies where to find more detailed information on the preparation and transmission of the reports.

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: Submit written requests for single copies of the guidance document entitled "Questions and Answers About eMDR--Electronic Medical Device Reporting" 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. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the 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: Tahseen Mirza, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2312, Silver Spring, MD 20993-0002, 301-796-7645.

SUPPLEMENTARY INFORMATION:

I. Background

Section 519 of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) is FDA's authorization to issue a regulation to require mandatory reporting of device-related adverse events. The Medical Device Reporting (MDR) regulation, 21 CFR part 803, effective December 13, 1984, contained reporting requirements for device manufacturers and importers. Amendments to the FD&C Act under the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992 introduced mandatory reporting by device user facilities and changed the requirements for device manufacturers, importers and distributors. FDA revised the MDR regulation (part 803) effective July 31, 1996, to address the reporting changes. On February 28, 2005, FDA revised the MDR regulation into plain language.

On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit MDRs to the Agency in an electronic format. Because of concerns over the cost of implementation for user facilities, and the relatively low volume of reports FDA receives from such facilities, the final rule does not require user facilities to adopt electronic reporting. Although FDA encourages user facilities to file reports electronically, they may continue to use only paper forms for MDR reporting. The final rule for electronic submission of MDRs to FDA anticipates that there will be a reduction in costs and time associated with the submission of MDR reports, elimination of transcription errors associated with paper reports, and both expedited access to safety information and enhanced ability to communicate information about suspected problems. This question and answer guidance provides general information on how to prepare and send an electronic postmarket medical device report to FDA and identifies where to find more detailed information on how to prepare and transmit eMDRs.

The draft eMDR guidance document was published in the Federal Register of August 21, 2009. No significant comments were received.

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 Agency's current thinking on electronic MDR reporting. 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 guidance may do so by using the Internet. To receive "Questions and Answers about eMDR--Electronic Medical Device Reporting," you may either send an e-mail 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 1679 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov.

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 part 803 have been approved under OMB control numbers 0910-0291 and 0910-0437.

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 (see ADDRESSES). 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: February 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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