4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

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

RIN 0910-AF86

Medical Device Reporting: Electronic Submission Requirements; Correcting Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation regarding postmarket electronic Medical Device Reporting (eMDR) to address the unintentional removal of certain provisions of the Unique Device Identification (UDI) System regulations and to update the contact information listed in the regulations.

DATES: This rule is effective August 14, 2015.

FOR FURTHER INFORMATION CONTACT: Sharon Kapsch, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3208, Silver Spring, MD 20993-0002, 301-796-6104, Sharon.Kapsch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 24, 2013 (78 FR 58786), FDA published the "Unique Device Identification System" final rule (UDI rule). The UDI rule, among other things, amended part 803 (21 CFR part 803). These amendments became effective on December 23, 2013.

In the Federal Register of February 14, 2014 (79 FR 8832), FDA published the "Medical Device Reporting: Electronic Submission Requirements" final rule (eMDR rule). The eMDR rule will become effective on August 14, 2015. The eMDR rule, among other things, revises part 803 in its entirety. As published in the Federal Register, the eMDR rule will, upon its effective date, unintentionally remove the amendments made by the UDI rule to part 803 of the Code of Federal Regulations (CFR), Title 21. This document addresses the unintentional removal by amending part 803 to include the UDI requirements.

When the eMDR rule goes into effect, it will require changes to the CFR citations of some provisions within part 803; consequently, some of the citations used by the UDI rule will have to be updated. The following table provides the "Original UDI Citation" (the citation used by the September 24, 2013, UDI rule) and the corresponding "Updated Citation" for provisions addressed in this document.

Table 1.--Citations in Part 803; UDI Citation and Corresponding Updated Citation

Provision	Original UDI Citation[1]	Updated Citation[2]
Amendment of 803.3--Definitions of human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device and unique device identifier (UDI).	Listed alphabetically within 803.3	803.3(aa) and 803.3(bb), respectively
Amendment of section 803.32	803.32(c)(6)	803.32(c)(4)
Amendment of section 803.33	803.33(a)(7)(iv)	803.33(b)(7)(iv)
Amendment of section 803.42	803.42(c)(6)	803.42(c)(4)
Amendment of section 803.52	803.52(c)(6)	803.52(c)(4)

[1] The "Original UDI Citation" is the citation within part 803, as amended by the UDI rule, which became effective on December 23, 2013.
[2] The "Updated Citation" is the citation within part 803, after the changes made by the eMDR rule go into effect on August 14, 2015, and after those changes are further amended by the correcting amendments in this document.

We are also updating the contact information listed in §§ 803.11 and 803.33 for the Division of International and Consumer Education (DICE) (formerly the Division of Small Manufacturers, International and Consumer Assistance (DSMICA)).

FDA is publishing this document as a final rule under the Administrative Procedures Act (5 U.S.C. 551, et seq.). FDA has determined that good cause exists to dispense with prior notice

and public comment under 5 U.S.C. 553(b)(3)(B) and 21 CFR 10.40(e)(1) because the provisions addressed in this document have already undergone notice and public comment. Additionally, the amendments to §§ 803.11 and 803.33, to provide updated contact information, are editorial in nature and are intended to improve the accuracy of the Agency's regulations.

FDA has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This final rule 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 (the PRA). The revised Form FDA 3500A is approved under OMB control number 0910-0291. The collections of information in part 803 have been approved under OMB control number 0910-0437. The collections of information in the UDI rule have been approved under OMB control number 0910-0720.

The information collection provisions in the eMDR rule have been submitted to OMB for review as required by section 3507(d) of the PRA (44 U.S.C. 3507(d)). Before the effective date of the final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 as amended by the Medical Device

Reporting: Electronic Submission Requirements final rule of February 14, 2014, 79 FR 8832, is further amended as follows:

PART 803--MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

2. Amend § 803.3 by adding paragraphs (aa) and (bb) to read as follows:

§ 803.3 How does FDA define the terms used in this part?

* * * * *

(aa) Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

(bb) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:

(1) A device identifier--a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A production identifier--a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

* * * * *

3. Amend § 803.11 by revising paragraph (d) to read as follows:

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

* * * * *

(d) Form FDA 3500A is available on the Internet at http://www.fda.gov/medwatch/getforms.htm or from Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4621, Silver Spring, MD 20993-0002, by email: DICE@fda.hhs.gov, FAX: 301-847-8149, or telephone: 800-638-2041.

4. Amend § 803.32 by revising paragraph (c)(4) to read as follows:

§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

5. Amend § 803.33 by revising paragraphs (a)(2) and (b)(7)(iv) to read as follows:

§ 803.33 If I am a user facility, what must I include when I submit an annual report?

* * * * *

(a) * * *

(2) Division of International and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4621, Silver Spring, MD 20993-0002, by email: DICE@fda.hhs.gov, FAX: 301-847-8149, or telephone: 800-638-2041.

* * * * *

(b) * * *

(7) * * *

(iv) Product model, catalog, serial, and lot number and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

6. Amend § 803.42 by revising paragraph (c)(4) to read as follows:

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

* * * * *

7. Amend § 803.52 by revising paragraph (c)(4) to read as follows:

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

* * * * *

(c) * * *

(4) Model number, catalog number, serial number, lot number, or other identifying number; expiration date; and unique device identifier (UDI) that appears on the device label or on the device package;

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Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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