4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801 and 830

[Docket No. FDA-2011-N-0090]

Unique Device Identification System; Editorial Provisions; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Unique Device Identification (UDI) System regulation to make editorial changes. This technical amendment updates the email address associated with FDA's UDI system, which allows FDA to obtain information and offer support and assistance on medical devices through their distribution and use, ensuring consistency with the requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This change is necessary to ensure that the UDI team continues to maintain regular email communications with device labelers.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Adaeze Teme, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5574, Silver Spring, MD 20993-0002, 240-402-0768.

SUPPLEMENTARY INFORMATION: FDA is updating the UDI email address in the following regulations that set forth the procedures for notifying the Agency when: (1) Requesting an exception from or alternative to a unique device identifier requirement (§ 801.55

(21 CFR 801.55)); (2) requesting continued use of legacy FDA identification numbers assigned to devices (§ 801.57 (21 CFR 801.57)); and (3) applying for accreditation as an issuing Agency (§ 830.110 (21 CFR 830.110)).

Specifically, the Agency is removing an old email address and replacing it with a new one, thereby maintaining consistency with the requirements of the FD&C Act (21 U.S.C. 321 et seq.).

In the Federal Register of September 24, 2013 (78 FR 58786), FDA issued a final rule to establish a system to adequately identify devices through distribution and use. The rule required the label of medical devices to include a UDI, except where an exception or alternative applies. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID). The final rule incorporated a direct avenue for the labeler to communicate with FDA's GUDID via a UDI email address. This rule updates §§ 801.55(b)(2), 801.57(c)(2), and 830.110(a) by replacing the old email address with a new one.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Incorporation by reference, Labeling, 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 parts 801and 830 are amended as follows:

PART 801--LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

2. In § 801.55, revise paragraph (b)(2) to read as follows:

§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

* * * * *

(b) * * *

(2) In all other cases, by email to: GUDIDSupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002.

* * * * *

3. In § 801.57, revise the second sentence of paragraph (c)(2) to read as follows:

§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

* * * * *

(c) * * *

(2) * * * A request for continued use of an assigned labeler code must be submitted by email to: GUDIDSupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002.

* * * * *

PART 830--UNIQUE DEVICE IDENTIFICATION

4. The authority citation for 21 CFR part 830 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

5. In § 830.110, revise paragraph (a)(1) to read as follows:

§ 830.110 Application for accreditation as an issuing agency.

(a) * * * (1) An applicant seeking initial FDA accreditation as an issuing agency shall notify FDA of its desire to be accredited by sending a notification by email to: GUDIDSupport@fda.hhs.gov, or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002.

* * * * *

Dated: February 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-04707 Filed: 3/3/2016 8:45 am; Publication Date: 3/4/2016]