4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 806

[Docket No. FDA-2014-N-0011]

Medical Devices; Reports of Corrections and Removals; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation regarding reports of corrections to and removals of medical devices to address a minor change as a result of the enactment of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This action is technical in nature and is intended to provide accuracy to the Agency's regulation.

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

FOR FURTHER INFORMATION CONTACT: Deborah Yoder, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2676, Silver Spring, MD, 20993-0002, 301-796-6109, Deborah.Yoder@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 806.1(a) (21 CFR 806.1(a)) refers to a subsection of the Federal Food, Drug, and Cosmetic Act that was redesignated as a result of FDAAA (Public Law 110-85). FDA is amending § 806.1(a) to update the obsolete reference.

FDA is publishing the 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) since such notice and comment are unnecessary because this amendment to the regulation provides only a technical change to update an obsolete citation. In addition, FDA finds good cause to provide for this regulation to be effective immediately upon publication under 5 U.S.C. 553(d)(3).

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 contains information collection provisions that 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 806 have been approved under OMB control number 0910-0359, which expires May 31, 2014.

List of Subjects in 21 CFR Part 806

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 806 is amended as follows:

PART 806--MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

1. The authority citation for 21 CFR part 806 continues to read as follows:

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

§ 806.1 [Amended]

2. Amend § 806.1(a) by removing "section 519(f)" and adding in its place "section 519(g)".

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-03581 Filed 02/18/2014 at 8:45 am; Publication Date: 02/19/2014]