

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

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Medical Device Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device reporting regulations to reflect a change in address for agency contacts for reporting a public health emergency. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Howard A. Press, Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ-530), 1350 Piccard Dr., Rockville, MD 20850, 301-827-2983.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 803.12(c) to reflect a reorganization affecting the agency contacts for reporting public health emergencies. The current address for reporting a public health emergency to FDA is the FDA Emergency Operations Branch (HFC-162), Office of Regional Operations, at 301-443-1240, followed by the submission of a fax to 301-443-3757. The new contact is the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240. This report can be followed by an e-mail to

emergency.operations@fda.hhs.gov or a fax report sent to 301-827-3333. This document is published as a final rule with the effective date given previously.

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Because the final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely updates contact information included in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Medical device reporting, 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 is 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.

*per OFR
Kent Giles
1-5-04
mg*

■ 2. Section 803.12 is amended by revising paragraph (c) to read as follows:

§ 803.12 Where ~~to submit reports.~~ *and how do I submit reports and additional information*

* * * * *

(c) If an entity is confronted with a public health emergency, this can be brought to FDA’s attention by contacting the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240, followed by the submission of an e-mail to *emergency.operations@fda.hhs.gov* or a fax report to 301-827-3333.

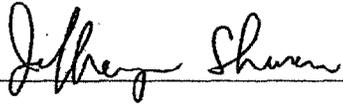
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Dated: _____

January 3, 2006.

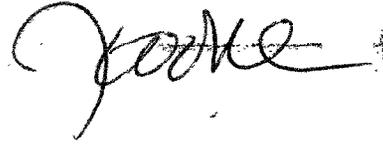


Jeffrey Shuren,
Assistant Commissioner for Policy.

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