DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 814 and 820

[Docket No. 2006N–0127]

Medical Device Reporting; Premarket Approval of Medical Devices; Quality System Regulation; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to correct some inadvertent typographical errors and other minor errors in certain device regulations. FDA intends for these corrections to improve the accuracy of the agency's regulations.

EFFECTIVE DATE: [*Insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–2343.

I. Highlights of Final Rule

FDA is making the following changes to correct typographical and other minor errors in certain device regulations:

1. FDA is amending 21 CFR 814.126(b)(1)(iv) to replace ''8dd'' with ''803.''

2. FDA is amending 21 CFR 820.198(a)(3) to eliminate a reference to part 804, a part that does not exist.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this action 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule corrects only typographical errors in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ‘‘any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more

(adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. The Technical Amendments

This rule corrects certain minor errors in existing regulations. This administrative action is limited to correcting typographical errors and eliminating a reference to a nonexistent Code of Federal Regulations (CFR) part. It makes no changes in substantive requirements.

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 makes technical administrative changes in the 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.

List of Subjects

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Institutional review board requirements, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

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 814 and 820 are amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 2. Amend paragraph (b)(1)(iv) of § 814.126 by removing ‘‘part 8dd’’ and adding in its place ‘‘part 803’’.

PART 820—QUALITY SYSTEM REGULATION

■ 3. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

■ 4. Amend paragraph (a)(3) of § 820.198 by removing ‘‘or 804’’.

Dated: March 24, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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