§ 558.485 [Amended]

■ 12. In paragraph (b)(3) of § 558.485, remove ''021930'' and in numerical sequence add ''012286''.

§ 558.625 [Amended]

■ 13. In paragraphs (b)(10) and (b)(12) of § 558.625, remove ''021930'' and in its place add ''No. 012286''.

§ 558.630 [Amended]

■ 14. In § 558.630, in paragraph (b)(2), remove ''021930'' and in its place add ''012286; and in paragraph (b)(5), remove ''021930'' and in numerical sequence add ''012286''.

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–14149 Filed 6–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. FDA–2008–N–0331]

Medical Devices; Change of Name; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to implement a nomenclature change and to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective June 23, 2008.

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

SUPPLEMENTARY INFORMATION:

I. Background

This document amends FDA's regulations to reflect a nomenclature change. It replaces the phrase ''good manufacturing practice regulations'' with the phrase ''good manufacturing practice requirements of the quality system regulation'' in 21 CFR parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these changes are nonsubstantive.

II. Environmental Impact

The agency 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.

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 makes only typographical and nonsubstantive changes 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 $127 million, using the most current (2006) 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.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PARTS 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892—[AMENDED]

■ 1. Parts 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended by removing the phrase ''good manufacturing practice regulations'' wherever it appears and by adding in its place the phrase ''good manufacturing practice requirements of the quality system regulation''.

Dated: June 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–14153 Filed 6–20–08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0321]

Special Local Regulation; Thunderboat Regatta; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.