

entities. Reclassification of the affected devices from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act, and may permit small potential competitors to enter the marketplace by lowering their costs. Although the final rule requires manufacturers of these devices to file an annual report with FDA for 3 consecutive years, this is less burdensome than the current premarket approval requirement that annual reports be submitted to FDA on an ongoing basis. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. In addition, the Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule because the rule will not impose costs of \$100 million or more on State, local, and tribal governments in the aggregate, or the private sector, in any one year (adjusted annually for inflation).

IX. Paperwork Reduction Act of 1995

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.

X. 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.

XI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition for reclassification of the Autopheresis-C System from class III to class II by Baxter Healthcare Corp., June 17, 1996.

2. Transcript of the Blood Products Advisory Committee, 52d Meeting, September 27, 1996.

3. Order to the petitioner, September 5, 2001.

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.9245 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively, by adding new paragraph (b), and by revising newly redesignated paragraphs (c) and (d) to read as follows:

§ 864.9245 Automated blood cell separator.

* * * * *

(b) *Classification of device operating by filtration separation principle.* Class II (special controls). The special controls for the device are that the manufacturer must file an annual report with FDA for 3 consecutive years. Each annual report must include the following:

(1) A summary of adverse donor reactions reported by the users to the manufacturer that do not meet the threshold for medical device reporting under part 803 of this chapter;

(2) Any change to the device, including but not limited to:

(i) New indications for use of the device;

(ii) Labeling changes, including operation manual changes;

(iii) Computer software changes, hardware changes, and disposable item changes, e.g., collection bags, tubing, filters;

(3) Equipment failures, including software, hardware, and disposable item failures, e.g., collection bags, tubing, filters.

(c) *Classification of device operating by centrifugal separation principle.* Class III (premarket approval).

(d) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device described in paragraph (c) of this section. See § 864.3.

Dated: February 4, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03-4690 Filed 2-27-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9021]

RIN 1545-AX68

Loans From a Qualified Employer Plan to Plan Participants or Beneficiaries; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Corrections to final regulations.

SUMMARY: This document contains corrections to final regulations that were published in the **Federal Register** on Tuesday, December 3, 2002 (67 FR 71821). This document contains final regulations relating to loans made from a qualified employer plan to plan participants or beneficiaries.

DATES: This correction is effective December 3, 2002.

FOR FURTHER INFORMATION CONTACT: Vernon S. Carter (202) 622-6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this corrections are under section 72 of Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9021) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 9021), which is the subject of FR. Doc. 02-29204, is corrected as follows:

§ 1.72(p)-1 [Corrected]

1. On page 71825, column 1, § 1.72(p)-1, A-19, paragraph (a), last 2 lines in the paragraph, the language “of the Internal Revenue Code. See Q&A 16 of this section”, is corrected to read “of the Internal Revenue Code. See Q&A-11 through Q&A-16 of this section”.

2. On page 71825, column 3, § 1.72(p)-1, A-20, paragraph (a)(2), lines 4 and 5, the language “section (including paragraph (a)(3) of this Q&A 20 and the amount limitations”, is

corrected to read "section (including the amount limitations)".

3. On page 71825, column 3, § 1.72(p)-1, A-20, paragraph (a)(2), the last line of the paragraph, the language "replaced loan.", is corrected to read "replacement loan."

Cynthia E. Grigsby,

Chief, Regulations Unit, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 03-4546 Filed 2-27-03; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 1, 3, 5, 45, 51, 52, 53, 66, 109, 114 and 120

46 CFR Parts 1 and 68

[USCG-2003-14505]

Coast Guard Transition to Department of Homeland Security; Technical Amendments Reflecting Organizational Changes

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This rule makes technical changes to various parts of titles 33 (Navigation and Navigable Waters) and 46 (Shipping) of the Code of Federal Regulations. These revisions coincide with the scheduled March 1, 2003, transfer of the Coast Guard from the Department of Transportation to the newly created Department of Homeland Security. This rule, which revises existing regulations to reflect organizational changes, has no substantive effect on the regulated public.

DATES: This rule is effective March 1, 2003.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the Docket Management Facility, (USCG-2003-14505), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC, 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call James McLeod, Project Manager, Office of Regulations and Administrative Law (G-LRA), Coast Guard, at 202-267-6233. If you have questions on viewing, or submitting material to, the docket, call Dorothy Beard, Chief, Dockets,

Department of Transportation, at 202-366-5149.

SUPPLEMENTARY INFORMATION: We did not publish a notice of proposed rulemaking (NPRM) for this rule. The rule consists entirely of agency organization, procedure and practice revisions to various regulations in titles 33 (Navigation and Navigable Waters) and 46 (Shipping) of the Code of Federal Regulations (CFR) in response to enactment of the Homeland Security Act of 2002 (HLSA), Public Law 107-296, 116 Stat. 2135 (2002). Congress has established the Department of Homeland Security (DHS) (section 101 of HLSA) and directed the transfer of the Coast Guard (sections 888 and 1512 of HLSA) from the Department of Transportation to DHS. As indicated in the Department of Homeland Security Reorganization Plan submitted on November 25, 2002, by the President to Congress (under section 1502 of the HLSA), the Coast Guard is scheduled to move to DHS on March 1, 2003.

Because it is technical in nature and relates only to agency organization, procedure and practice, under 5 U.S.C. 553(b)(A), the Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements. These changes will have no substantive effect on the public; therefore, it is not necessary for us to publish an NPRM and provide an opportunity for public comment. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that, for the same reasons, good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Discussion of the Rule

In this rule, we are changing "Department of Transportation" to the "Department of Homeland Security" in specified sections in 33 CFR Chapter I and 46 CFR Chapter I. We have also eliminated references to Department of Transportation delegation regulations (*i.e.*, 49 CFR 1.45 and 1.46) in the text of Coast Guard regulations. And we have updated our rulemaking regulations (33 CFR part 1, subpart 1.05) not only to reflect our transition to DHS but to reflect current agency practice and procedure.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of

the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. As this rule involves internal agency practices and procedures and non-substantive changes, it will not impose any costs on the public.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.