

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