

Labeling, Reporting and recordkeeping requirements.

Accordingly, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, 21 CFR part 530 is amended as follows:

PART 530--EXTRALABEL DRUG USE IN ANIMALS

1. The authority citation for 21 CFR part 530 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

§ 530.41 [Amended]

2. Section 530.41 is amended by adding paragraph (a)(12) to read as follows:

§ 530.41 Drugs prohibited for extralabel use in animals.

- (a) * * *
- (12) Phenylbutazone.
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Dated: February 13, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 96P-0484]

Medical Devices; Hematology and Pathology Devices; Reclassification of Automated Blood Cell Separator Device Operating by Filtration Principle from Class III to Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the automated blood cell separator (ABCS) device operating by filtration principle, intended for routine collection of blood and blood components, from class III to class II (special controls). The special control requirement for this device is an annual report with emphasis on adverse reactions to be filed by the manufacturer for a minimum of 3 years. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act)

as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency is reclassifying the automated blood cell separator devices operating by filtration principle into class II (special controls) because special controls, in addition to general controls, are capable of providing a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective March 31, 2003.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94-295), the SMDA (Public Law 101-629), and FDAMA (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(f)(1) of the act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the 1976 amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807.

Under section 513(f)(3) of the act, FDA may initiate the reclassification of a device classified into class III under section 513(f)(1), or the manufacturer or importer of a device may petition the Secretary of Health and Human Services

for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

II. Regulatory History of the Device

The AUTOPHERESIS-C SYSTEM, an ABCS, intended for the routine collection of blood and blood components, is a postamendments device classified into class III under section 513(f)(1) of the act. Therefore, the device cannot be placed in commercial distribution for the routine collection of blood and blood components unless it is reclassified under section 513(f)(3) of the act, or subject to an approved premarket approval application (PMA) under section 515 of the act (21 USC 360e). FDA is taking this action under section 513(f)(3) of the act and § 860.134, based on information submitted in a petition by Baxter Healthcare Corp. (Baxter) on June 17, 1996, requesting reclassification of the AUTOPHERESIS-C SYSTEM, intended for routine collection of blood and blood components, from class III to class II (Ref. 1). Although Baxter submitted its petition for reclassification under section 513(e) of the act, the request should have been submitted under section 513(f)(3), and therefore FDA has considered the petition filed under section 513(f)(3). Consistent with section 513(f)(3) of the act and § 860.134, FDA referred the petition to the Blood Products Advisory Committee, Medical Devices Panel (the Panel) for its recommendation on the requested change in classification. The Panel met on September 26, 1996, at a public meeting (Ref. 2).

III. Device Description

The AUTOPHERESIS-C SYSTEM, intended for routine collection of blood and blood components, is an automated plasmapheresis system. It utilizes a spinning membrane separation device to achieve rapid and gentle separation by filtration of whole blood into concentrated cellular components for reinfusion and into plasma for collection.

The instrument uses a system of pumps and sensors controlled by a microprocessor and it incorporates a variety of safety and alarm system