DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

Indirect Food Additives: Paper and Paperboard Components

CFR Correction

In Title 21 of the Code of Federal Regulations, Parts 170 to 199, revised as of April 1, 2004, on page 207, in § 176.170, alphabetically add the following entry to the table in paragraph (b)(2):

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * *	* * *
Butanedioic acid, sulfo-1,4-di-(C_9-C_{11} alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093–88–9]).	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.
* * * *	* * *

* * * * *

In the same Title, revised as of the same date, on page 218, in § 176.180, alphabetically add the following entry to the table in paragraph (b)(2):

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * *	* * *
Butanedioic acid, sulfo-1,4-di-(C_9-C_{11} alkyl) ester, ammonium salt (also known as butanedioic acid, sulfo-1,4-diisodecyl ester, ammonium salt [CAS Reg. No. 144093–88–9]).	For use as a surface active agent in package coating inks at levels not to exceed 3 percent by weight of the coating ink.
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[FR Doc. 04–55521 Filed 12–28–04; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Pharmacia & Upjohn Co. to Pharmacia & Upjohn Co., a Division of Pfizer, Inc., and to correct the sponsor's mailing address.

DATES: This rule is effective December 29, 2004.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov.*

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, has informed FDA of a change of sponsor's name and mailing address to Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Pharmacia & Upjohn Co.'' and in the table in paragraph (c)(2) by revising the entry for ''000009'' to read as follows.

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017	000009
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
000009	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017
* *	* * *

Dated: December 10, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–28461 Filed 12–28–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 882

[Docket No. 2003N–0567]

Cardiovascular and Neurological Devices; Reclassification of Two Embolization Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify two embolization device types from class III (premarket approval) into class II (special controls). The agency is also changing the names and revising the identifications of these devices. The vascular embolization device (previously the arterial embolization device) is intended to control hemorrhaging due to aneurysms, certain types of tumors, and arteriovenous malformations. The neurovascular embolization device (previously the artificial embolization device) is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. FDA is reclassifying these devices on its own initiative on the basis of new information. FDA is taking this action 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 Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for these devices.

DATES: This rule is effective January 28, 2005.

FOR FURTHER INFORMATION CONTACT: Peter L. Hudson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*) 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 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures. FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.''

These devices are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. The devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) issues, under section 513(i) of the act, an order finding the device substantially equivalent to a predicate device that does not require premarket approval. As described in section 510(k) of the act (21 U.S.C. 360(k)) and under part 807 of the regulations (21 CFR part 807), FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act addresses the reclassification of classified devices. This section provides that FDA may, by rulemaking, reclassify a device based on ''new information.'' Under section 513(e) of the act, FDA can initiate reclassification or an interested person can petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the act, includes information developed after the date of the device's original classification. This information could include a reevalution of the original data or information from the time of the device's original classification that was not presented, available, or developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously used by FDA is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell*v. *Goddard*, supra, 366 F.2d at 181; *Ethicon*, Inc. v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Whether data before FDA are past or new data, the ''new information'' to support reclassification under section 513(e) of the act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Devices

In the **Federal Register** of February 25, 2004 (69 FR 8600), FDA issued a proposed rule to change the names, revise the identifications, and reclassify the two devices from class III (premarket