Thunder Bay National Marine Sanctuary and Underwater Preserve, which were the subject of FR Doc. 00-15638, (65 FR 39042), is corrected as follows:

§ 922.3 [Corrected]

1. On page 39055, in the first column, amendatory instruction 3 is corrected to read as follows:

3. Section 922.3 is amended by revising the definition for ''Sanctuary resource'' to read as follows:

2. On page 39055, beginning in the first column, in § 922.3, add five asterisks before and after the definition of ''Sanctuary resource''.

§ 922.50 [Corrected]

3. On page 39056, in the third column, in § 922.50, correct the paragraph designation (b) to read (a)(2).

Dated: October 4, 2000.

Margaret A. Davidson,

Acting Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 00–25938 Filed 10–4–00; 1:57 pm]

BILLING CODE 3510–08–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor 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 name and address for Rhone-Poulenc, Inc.

DATES: This rule is effective October 10, 2000.

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: Rhone-Poulenc, Inc., P.O. Box 125, Black Horse Lane, Monmouth Junction, NJ 08852, has informed FDA of a change of sponsor name and address to Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005–8891. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change of sponsor name and address.

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 removing the entry for ''Rhone-Poulenc, Inc.'' and alphabetically adding an entry for ''Aventis Animal Nutrition, Inc.'' and in the table in paragraph (c)(2) by revising the entry for ''011526'' to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005–8891	011526
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
011526	Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005–8891
* * * * * * *	

Dated: September 28, 2000.

Claire M. Lathers,

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

[FR Doc. 00–25965 Filed 10–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 98N–0753]

Dental Products Devices; Reclassification of Endosseous Dental Implant Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the manually powered drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, trial abutments, and other manually powered endosseous dental implant accessories from class III to class I. These devices are intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than an hour. FDA is also exempting these devices from premarket notification. This reclassification is on the Secretary of Health and Human Services' own initiative based on new information. This action is being taken 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).

DATES: This rule is effective November 9, 2000.

FOR FURTHER INFORMATION CONTACT: Angela Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

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 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) 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 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not 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 before the agency 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.) Regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''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. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' FDA has considered the endosseous dental implant accessories in accordance with the reserved criteria and determined that