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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.95 [Amended]

2. Section 558.95 *Bambermycins* is amended in paragraph (d)(4)(ii) by removing ''4 to 20'' and adding in its place ''2 to 40''.

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9579 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 94P–0347]

Medical Devices; Reclassification and Codification of the Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to W. L. Gore and Associates, Inc., reclassifying the nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, from class III (premarket approval) to class II (special controls). Accordingly, the order is being codified in the Code of Federal Regulations (CFR).

EFFECTIVE DATES: The rule is effective May 18, 2000. The reclassification was effective September 9, 1999.

FOR FURTHER INFORMATION CONTACT: Anthony D. Watson, 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 (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the 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).

The 1976 amendments broadened the definition of ''device'' in 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, including the nonabsorbable ePTFE surgical suture, into class III. The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the **Federal Register** Of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including the nonabsorbable ePTFE surgical suture, to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 519 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the **Federal Register** of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act provides that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, in the **Federal Register** of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993, deadline.

Nevertheless, in accordance with sections 520(l)(5)(B) and 513(a) of the act, FDA is now reclassifying the nonabsorbable ePTFE surgical suture from class III to class II.

On September 14, 1994, FDA filed the reclassification petition submitted by W. L. Gore and Associates, Inc., requesting reclassification of the nonabsorbable ePTFE surgical suture from class III to class II.

FDA consulted with members of the General and Plastic Surgery Devices Panel (the Panel) of the Medical Devices Advisory Committee about the requested reclassification. The Panel members recommended that the nonabsorbable ePTFE surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, be reclassified from class III to class II. They also recommended FDA recognized consensus standards and device-specific labeling as the special controls for this device.

After reviewing the data in the petition and considering the Panel members' recommendations, FDA agreed with their recommendations to reclassify the device from class III into class II with the recommended special controls. Based on the available information, FDA issued an order to the petitioner on September 9, 1999, reclassifying the nonabsorbable ePTFE

surgical suture, and substantially equivalent devices of this generic type, from class III to class II.

FDA identified the following FDA recognized consensus standards and labeling as special controls for the device:

1. United States Pharmacopoeia (USP) 21:
a. Monograph for Nonabsorbable Surgical Sutures;
b. Suture—Diameter <861>;
c. Suture—Needle Attachment <871>; and
d. Tensile Strength <881>.
2. Labeling:
a. Contraindication: ''This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery.''
b. ''For Single Use Only.''
c. If the marketed suture has a different diameter than the diameter specified in USP 21—Suture Diameter <861>, then a tabular comparison of its diameter and USP suture sizes should be included in the labeling.

Accordingly, as required by 21 CFR 860.136(b)(6) of the regulations, FDA is announcing the reclassification of the generic nonabsorbable ePTFE surgical suture from class III into class II. In addition, FDA is codifying the reclassification of the device by adding new § 878.5040.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment.

Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the notice is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special controls do not require the respondent to submit additional information to the public. Therefore, no burden is placed on the public.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

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

2. Section 878.5035 is added to subpart E to read as follows:

§ 878.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture.

(a) *Identification*. Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

(b) *Classification*. Class II (special controls). FDA recognized consensus standards and device-specific labeling:
(1) United States Pharmacopoeia (USP) 21:
(i) Monograph for Nonabsorbable Surgical Sutures;
(ii) Sutures—Diameter <861>;
(iii) Sutures Needle Attachment <871>; and
(iv) Tensile Strength <881>.
(2) Labeling:
(i) Contraindication: ''This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery.''
(ii) ''For Single Use Only.''
(iii) If the marketed suture has a different diameter than the diameter specified in USP 21—Suture Diameter <861>, then a tabular comparison of its diameter and USP sizes should be included in the labeling.

Dated: April 5, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–9577 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. T–033]

Nevada State Plan; Final Approval Determination

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final State plan approval—Nevada.

SUMMARY: This document amends OSHA's regulations to reflect the Assistant Secretary's decision granting final approval to the Nevada State plan. As a result of this affirmative determination under section 18(e) of the Occupational Safety and Health Act of 1970, Federal OSHA's standards and enforcement authority no longer apply to occupational safety and health issues covered by the Nevada plan, and authority for Federal concurrent jurisdiction is relinquished. Federal enforcement jurisdiction is retained over any private sector maritime employment, private sector employers on Indian land, and any contractors or subcontractors on any Federal establishment where the land is exclusive Federal jurisdiction. Federal jurisdiction remains in effect with respect to Federal government employers and employees. Federal OSHA will also retain authority for coverage of the United States Postal