§ 526.365 [Amended]

2. Section 526.365 *Cephapirin sodium for intramammary infusion* is amended in paragraph (d)(3) by removing ''(8 milkings)''.

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9572 Filed 4–17–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Fenbendazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for establishing tolerances for residues of fenbendazole in edible tissues of swine. Technical corrections are also made.

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, filed a supplement to NADA 131–675 that provides for use of Safe-Guard® (20 percent fenbendazole) Type A medicated articles to make Type B and C medicated swine feeds. The supplement provides for establishing tolerances for parent fenbendazole in swine liver and muscle. The supplement is approved as of February 10, 2000, and § 556.275 (21 CFR 556.275) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 556.275 is further amended by deleting references to safe concentrations and by adding the previously established acceptable daily intake (ADI) of total residues of fenbendazole. The footnote for ''tolerance'' in that section is also removed.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action 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.

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 556

Animal drugs, Foods.

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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.275 is revised to read as follows:

§ 556.275 Fenbendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of fenbendazole is 40 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 part per million (ppm).

(ii) [Reserved]

(iii) *Milk.* The tolerance for fenbendazole sulfoxide metabolite (the marker residue in cattle milk) is 0.6 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 6 ppm.

(ii) *Muscle.* The tolerance for parent fenbendazole (the marker residue) is 2 ppm.

(3) *Goats*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 ppm.

(ii) [Reserved]

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9578 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 558

New Animal Drugs for Use in Animal Feeds; Bambermycins; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect the previously approved use level for bambermycins Type C medicated cattle feed. This document amends the regulations to state the correct use level is 2 to 40 grams (g) of bambermycins per ton of feed. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, is sponsor of NADA 141–034 that provides for use of GAINPRO® (bambermycins) Type A medicated articles to make Type B and Type C medicated cattle feeds. In its approval letter of October 17, 1994, the Center for Veterinary Medicine approved the use of Type C medicated feeds containing 2 to 40 g of bambermycins per ton of feed, used to provide 10 to 20 milligrams bambermycins per head per day for increased rate of weight gain in pasture cattle. At this time, 21 CFR 558.95(d)(4)(ii) is amended by removing ''4 to 20'' and adding in its place ''2 to 40'' to reflect the correct Type C medicated feed levels.

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 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