

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 520**

[Docket No. FDA-2010-N-0002]

Oral Dosage Form New Animal Drugs; Tiamulin**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 Novartis Animal Health US, Inc. The supplemental NADA provides for use of an increased strength of tiamulin concentrate solution in the drinking water of swine for the treatment of certain bacterial respiratory and enteric diseases.

DATES: This rule is effective September 8, 2010.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 140-916 for DENAGARD (tiamulin) Liquid Concentrate administered in drinking water for the treatment of certain bacterial respiratory and enteric diseases in swine. The supplemental NADA provides for use of a 12.5 percent tiamulin concentrate solution. The supplemental NADA is approved as of June 14, 2010, and 21 CFR 520.2455 is amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 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 520

Animal drugs.

■ 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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.2455, revise paragraphs (a) and (b) to read as follows:

§ 520.2455 Tiamulin.

(a) *Specifications.* (1) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(2) Each milliliter (mL) of solution contains 125 mg (12.5 percent) tiamulin hydrogen fumarate.

(3) Each mL of solution contains 123 mg (12.3 percent) tiamulin hydrogen fumarate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 058198 for products described in paragraphs (a)(1) and (a)(2) of this section.

(2) No. 059130 for products described in paragraphs (a)(1) and (a)(3) of this section.

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Dated: September 1, 2010.

Elizabeth Rettie,

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

[FR Doc. 2010-22277 Filed 9-7-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 524**

[Docket No. FDA-2010-N-0002]

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin and Betamethasone Ophthalmic Solution**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to codify the conditions of use of an approved new animal drug application (NADA) for gentamicin sulfate and betamethasone acetate ophthalmic solution. This action is being taken to comply with the Federal Food, Drug, and Cosmetic Act and to improve the accuracy of the regulations.

DATES: This rule is effective September 8, 2010.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, email: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA has noticed that the approved conditions of use for GENTOCIN DURAFILM (gentamicin sulfate and betamethasone acetate) Ophthalmic Solution, sponsored by Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068 under NADA 34-267 are not codified. When this NADA was approved in 1967, codification of approved conditions of use for NADAs was not required. Accordingly, the regulations are amended in 21 CFR part 524 by adding § 524.1044i to reflect the approval. This action is being taken to comply with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and to improve the accuracy of the regulations.

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 524

Animal drugs.

■ 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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Add § 524.1044i to read as follows:

§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) *Specifications.* Each milliliter (mL) of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) of gentamicin base and 1 mg

betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use.* For treatment of external bacterial infections of the eye (conjunctiva and cornea).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 2010.

Elizabeth Rettie,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2000-P-0924] (formerly Docket No. FDA-2000-P-1533)

Cardiovascular Devices; Reclassification of Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the device type, standard percutaneous transluminal coronary angioplasty (PTCA) catheters, from class III (premarket approval) into class II (special controls). Cutting/scoring PTCA catheters remain in class III and continue to require premarket approval applications (PMAs). FDA is reclassifying these devices in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled “Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters” that will serve as the special control for the reclassified device type.

DATES: This final rule is effective October 8, 2010.

FOR FURTHER INFORMATION CONTACT: Kathryn O’Callaghan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 10903

New Hampshire Ave., Silver Spring, MD 20993, 301-796-6349.

SUPPLEMENTARY INFORMATION:

I. 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 (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 1976 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 (21 U.S.C. 360c(f)) 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 (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), 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 (510(k)) procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a 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 postamendments devices is governed by section 513(f)(3) of the act (21 U.S.C. 360c(f)(3)). This section states that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or that a manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA’s regulations in 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.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The PTCA catheter 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 unless it is subject to an approved premarket approval application (PMA) under section 515 of the act (21 U.S.C. 360e) or is reclassified.

On September 21, 2000, FDA filed a petition submitted under section 513(f)(3) of the act from COOK requesting reclassification of PTCA catheters from class III into class II. This reclassification petition did not include cutting or scoring PTCA catheters. In order to reclassify the PTCA catheter into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and