

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:

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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.

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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:

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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