

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

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New Animal Drugs; Change of Sponsor; 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 a change of sponsor for four approved new animal drug applications (NADAs) for oral dosage forms and feed uses of tiamulin from Boehringer Ingelheim Vetmedica, Inc., to Novartis Animal Health US, Inc.

DATES: This rule is effective [insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, has informed FDA that it has transferred ownership of, and all rights and interest in, the following four approved NADAs, to Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408:

NADA Number	Trade Name
134-644	DENAGARD (tiamulin) Soluble Antibiotic
139-472	DENAGARD (tiamulin) 25% Premixes
140-916	DENAGARD (tiamulin) Liquid Concentrate
141-011	DENAGARD (tiamulin)/chlortetracycline

Accordingly, the agency is amending the regulations in 21 CFR 520.2455, 520.2456, and 558.600 to reflect the transfer of ownership and a current format.
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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

21 CFR Part 520

Animal drugs.

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 parts 520 and 558 are 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. Revise § 520.2455 to read as follows:

§ 520.2455 Tiamulin.

(a) *Specifications.* (1) Each ounce of concentrate solution contains 3.64 grams (12.3 percent) tiamulin hydrogen fumarate.

(2) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(b) *Sponsors.* See Nos. 058198 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.738 of this chapter.

(d) *Special considerations.* (1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur.

(2) Do not use in swine weighing over 250 pounds (lb).

(e) *Conditions of use in swine—(1) Amounts and indications for use.*

Administer in drinking water for 5 consecutive days:

(i) 3.5 mg per (/) lb of body weight daily for treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin.

(ii) 10.5 mg/lb of body weight daily for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(2) *Limitations.* Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Prepare fresh medicated water daily. Use as only source of drinking water.

§ 520.2456 [Removed]

■ 3. Remove § 520.2456.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.600 [Amended]

■ 5. Amend § 558.600 in paragraph (b) and in the table in paragraphs (e)(1)(i) through (e)(1)(iv) in the “Sponsor” column by removing “000010” and by adding in its place “058198”.

Dated: Dec. 6/2005
December 6, 2005.

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