may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals qualify for 3 years of marketing exclusivity beginning November 23, 2005. Exclusivity applies only to the effectiveness claim for adult Cylicocyclus radiatus and Petrovinema poculatus for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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.

§ 520.1452 [Amended]

■ 2. Section 520.1452 is amended in paragraph (d)(2) as follows:

a. By removing ''and *C. nassatus*;'' and adding in its place ''*C. nassatus*, and *C. radiatus*;'' and

b. By removing ''and *Gyalocephalus capitatus*;'' and adding in its place ''*Gyalocephalus capitatus*; and *Petrovinema poculatus*;''.

§ 520.1453 [Amended]

■ 3. Section 520.1453 is amended in paragraph (d)(2) as follows:

a. By removing ''and *C. nassatus*;'' and adding in its place ''*C. nassatus*, and *C. radiatus*;'' and

b. By removing ''and *Gyalocephalus capitatus*;'' and adding in its place ''*Gyalocephalus capitatus*; and *Petrovinema poculatus*;''.

Dated: December 8, 2005.

Bernadette A. Dunham,

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

[FR Doc. 05–24166 Filed 12–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

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 December 19, 2005.

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.

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: December 6, 2005.

Bernadette A. Dunham,

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

[FR Doc. 05–24165 Filed 12–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 1980N–0208]

Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule and final order.

SUMMARY: The Food and Drug Administration (FDA) proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the basis of findings and recommendations of the Panel on Review of Bacterial Vaccines and Toxoids (the Panel) on December 13, 1985. The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After the initial final rule and final order was vacated by the U.S. District Court for the District of Columbia on October 27, 2004, FDA published a new proposed rule and proposed order on December 29, 2004 (69 FR 78281). The purpose of this final rule and final order is to amend the biologics regulations, issue a final order in response to the report and recommendations of the Panel; and, respond to comments on the previously published proposed rule and proposed order submitted to the Division of Dockets Management. This final rule and final order does not address Anthrax Vaccine Adsorbed (AVA). The final order concerning AVA is published elsewhere in this issue of the **Federal Register**. FDA is classifying these products as Category I (safe, effective, and not misbranded), Category II (unsafe, ineffective, or misbranded), or Category IIIB (off the market pending completion of studies permitting a determination of effectiveness).

DATES: This rule is effective December 19, 2006. The final order on categorization of products is effective immediately.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

On December 13, 1985, FDA proposed to amend the biologics regulations and proposed to classify the bacterial vaccines and toxoids on the bases of findings and recommendations of the Panel. The Panel reviewed the safety, efficacy, and labeling of bacterial vaccines and toxoids with standards of potency, bacterial antitoxins, and immune globulins. After reviewing the Panel's report and comments on the proposal, FDA published a final rule and final order on January 5, 2004 (69 FR 255). On October 27, 2004, the U.S. District Court for the District of Columbia vacated the January 5, 2004, final rule and final order. On December 29, 2004, FDA published a withdrawal of the January 5, 2004, final rule and final order. Concurrently with the withdrawal of the final rule and final order, FDA published again a proposed rule and proposed order (69 FR 78281) to provide notice and to give interested persons an opportunity to comment.

The purpose of this document is to: (1) Categorize those bacterial vaccines