4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs for Use in Animal Feeds; 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 approval of a new concentration of a Type A medicated article.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc. (Novartis), 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 139-472 for DENAGARD (tiamulin hydrogen fumarate) Type A medicated articles for use of a new product formulation in medicated swine feed. The supplemental NADA is approved as of January 6, 2012, and the regulations in 21 CFR 558.4 and 558.600 are amended to reflect the approval.

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 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.

2. In paragraph (d) of § 558.4, in the "Category II" table, revise the entries for "Tiamulin" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

Category II

Drug	Assay limits percent[1] Type A	Type B maximum (100x)	Assay limits percent[1] Type B/C[2]
* *	* *	* * *	* *
Tiamulin hydrogen fumarate	90-115	10 g/lb	90-115/70-130
* *	* *	* * *	* *

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

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3. In § 558.600, revise paragraph (a) and the heading of the first column in the table in paragraph (e)(1) to read as follows:

§ 558.600 Tiamulin.

(a) Specifications. Type A article containing 363.2 grams of tiamulin hydrogen fumarate per pound.

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(e) * * *

(1) * * *

Tiamulin hydrogen fumarate in grams per ton	* * *	* * *	* * *	* * *

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Dated: April 17, 2012.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.

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