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 the withdrawal of approval of those parts of a new animal drug application (NADA) for a tiamulin Type A medicated article that pertain to the production indications for use of increased rate of weight gain and improved feed efficiency in swine.

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, has requested that FDA withdraw approval of those parts of NADA 139-472 for DENAGARD (tiamulin) Type A medicated article pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. Novartis requested voluntary withdrawal of approval of these indications for use because the product is no longer marketed for these uses. Revised product labeling reflecting the withdrawal of these indications has been approved in a supplement to NADA 139-472.

Elsewhere in this issue of the Federal Register, FDA gave notice that the approval of those parts of NADA 139-472 pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine is withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided for in the regulatory text of this document, the animal drug regulations are amended to reflect this withdrawal of approval.

With the withdrawal of approval of the production indications for tiamulin, the lowest concentration of the drug in feed now has a preslaughter withdrawal period. In accordance with 21 CFR 558.3(b)(1)(ii), tiamulin is now a Category II drug, and the table in 21 CFR 558.4(d) is revised to reflect that change. However, the maximum concentration of tiamulin in Type B feeds is not being increased from the current 3.5 grams per pound (g/lb) because there is an approved 5-g/lb Type A medicated article.

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 Director of 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 I" table, remove the entry for "Tiamulin"; and in the "Category II" table, alphabetically add a new entry 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	113.4 g/lb, 100-108 5 and 10 g/lb, 90-115	3.5 g/lb (0.8%)	90-115 70-130
* * * * * * *			

1Percent of labeled amount.

2Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, 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 Type C medicated feed.

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§ 558.600 [Amended]

3. In § 558.600, in the table, remove and reserve paragraph (e)(1)(i).

Dated: March 21, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-9196 Filed 04/16/2012 at 8:45 am; Publication Date: 04/17/2012]