4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2011-N-0003]

New Animal Drugs For Use in Animal Feeds; Monensin

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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA revises a manufacturing specification for monensin free-choice Type C medicated feed for growing cattle on pasture or in dry lot.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95-735 that provides for use of RUMENSIN 90 (monensin, USP) Type A medicated article in a free-choice Type C medicated feed for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers). The supplement revises the percent monensin Type A medicated article in the codified free-choice feed specifications to reflect use of a product containing 90.7 grams of monensin per pound. The supplemental NADA is approved as of May 24, 2011, and the regulations in 21 CFR 558.355 are 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 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 § 558.355, revise paragraph (f)(3)(x) introductory text and paragraph (f)(3)(x)(b) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(x) Amount per ton. 1,620 grams monensin, USP.

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(b) Specifications. Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed no.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.37	6-04-152
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632
Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix[1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1]Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

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Dated: December 9, 2011.

Steven D. Vaughn,

Director,

Office of New Animal Drug Evaluation,

Center for Veterinary Medicine.

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