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 provides for approval of free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers).

DATES: This rule is effective January 27, 2012.

FOR FURTHER INFORMATION CONTACT: Suzanne Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8105, email: *suzanne.sechen@fda.hhs.gov.*

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) Type A medicated article in free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) for increased rate of weight gain and for prevention and control of coccidiosis. The supplemental NADA is approved as of November 18, 2011, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application 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.

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 § 558.355, add paragraph (f)(3)(iv); and in paragraph (f)(3)(x)(*c*), remove the last sentence.

The addition reads as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(iv) *Amount.* Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.

(*a*) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

(*b*) *Limitations.* During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

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Dated: January 23, 2012.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2012–1755 Filed 1–26–12; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1303, 1304, 1305, 1306, 1308, 1309, 1310, 1312, 1313, 1314, 1316

[Docket No. DEA–356]

Technical Amendments and Corrections to DEA Regulations

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule updates the Code of Federal Regulations pertaining to DEA by alphabetizing definitions and eliminating the numeric listings in those definitions in order to simplify future rulemakings where additional definitions are added or deleted. This rule also corrects typographic errors, reflects organizational changes, and updates cross-reference listings in the CFR. This action makes no substantive changes to the affected rules.

DATES: The effective date of this rule is January 27, 2012.

FOR FURTHER INFORMATION CONTACT: Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Background

DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 through 1321.

The Administrative Procedure Act (5 U.S.C. 553) does not require notice and the opportunity for public comment where the agency for good cause finds that notice and public comment are unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(B) or on rules affecting agency organization, procedure, or practice under 5 U.S.C. 553(b)(A). This rule contains technical corrections and updates organizational changes in agency regulations; it imposes no new or substantive requirement on the public or DEA registrants. As such, DEA has determined that notice and