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Kathy Kutch,

Manager, System Support Group, Eastern Service Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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. The supplemental NADA revises the concentration of monensin in Type C medicated feeds used for improved feed efficiency, and for the prevention and control of coccidiosis in cattle fed in confinement for slaughter.

DATES: This rule is effective January 8, 2007.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *eric.dubbin@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 80 (monensin) Type A medicated articles. The supplement revises the concentration of monensin in Type C medicated feeds used for improved feed efficiency, and for the prevention and control of coccidiosis in cattle fed in confinement for slaughter. The supplemental NADA is approved as of December 1, 2006, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), 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.

FDA has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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. Section 558.355 is amended as follows:

a. Revise paragraph (d)(2);

b. Revise the introductory text of paragraphs (f)(3)(i) and (f)(3)(vii);

c. Revise paragraph (f)(3)(vii)(*b*);

d. Amend paragraph (f)(3)(i)(*b*)(*1*) by revising the second sentence and adding a new third sentence.

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(2) Type C cattle feeds containing 40 grams or less monensin per ton shall bear an expiration date of 30 days after its date of manufacture.

(f) * * *

(3) * * *

(i) [*Amount per ton*]. Monensin, 5 to 40 grams.

(*b*) * * *

(*1*) *Limitations.* * * * Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day). * * *

* * * * *

(vii) *Amount per ton.* Monensin, 10 to 40 grams.

* * * * *

(*b*) *Limitations.* For cattle fed in confinement for slaughter, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.

* * * * *

Dated: December 19, 2006.

Steven D. Vaughn,

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

[FR Doc. E7–4 Filed 1–5–07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2006–0648; FRL–8266–1]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Identification of the Northern Virginia PM2.5 Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Virginia State Implementation Plan (SIP). The revision consists of the addition of counties in Northern Virginia which were designated as nonattainment for the fine particulate (PM2.5) national ambient air quality standard (NAAQS). EPA is approving this revision in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on March 9, 2007 without further notice, unless EPA receives adverse written comment by February 7, 2007. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR–2006–0648 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. E-mail: *miller.linda@epa.gov.*

C. Mail: EPA–R03–OAR–2006–0648, Linda Miller, Acting Chief, Air Quality Planning and Analysis Branch,