

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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry "Koffolk, Inc.," and in the table in paragraph (c)(2) by removing the entry "063271".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.366 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively; by revising paragraph (a); by adding a new paragraph (b); and in the newly redesignated paragraph (d), in the table, under the headings "Limitations" and "Sponsor" by removing "063271" wherever it appears and by adding in its place "066104" to read as follows:

§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Approvals.* See Nos. 000986, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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Dated: November 15, 2001.
Claire M. Lathers,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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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 MoorMan's, Inc. The supplemental NADA provides for use of approved monensin Type A medicated articles to make free-choice, medicated feed blocks used for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle.

DATES: This rule is effective December 7, 2001.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223.

SUPPLEMENTARY INFORMATION: MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305-3115, filed a supplement to NADA 115-581 that provides for use of monensin Type A medicated articles to make free-choice, medicated protein/mineral blocks (MoorMan's Mintrate Blonde Block RU and MoorMan's Mintrate Red Block RU) used for increased rate of weight gain in cattle on pasture (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) which may require supplemental feed. The supplemental NADA provides for use of these medicated feed blocks for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle. The supplemental NADA is approved as of September 27, 2001, and the regulations are amended in 21 CFR 558.355 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 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 Dockets Management Branch (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(a)(1) that these actions are of a type that do 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. Section 558.355 is amended by revising paragraph (f)(3)(v)(a) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(v) * * *

(a) *Indications for use.* For increased rate of weight gain and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

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Dated: November 8, 2001.

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