includes the chasuble, dalmatic, alb, stole, girdle, maniple, rochet, musette, mitre, and bonnet. Size varies according to garment.

Inapplicability of Notice and Delayed Effective Date

Because the amendments to the Customs Regulations contained in this document merely remove reference to expired import restrictions and impose import restrictions on the above-listed cultural property of Bolivia in response to a bilateral agreement entered into in furtherance of a foreign affairs function of the United States, pursuant to the Administrative Procedure Act (5 U.S.C. 553(a)(1)), no notice of proposed rulemaking or public procedure is necessary and a delayed effective date is not required.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Accordingly, this final rule is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

This amendment does not meet the criteria of a ''significant regulatory action'' as described in E.O. 12866.

Drafting Information

The principal author of this document was Bill Conrad, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 12

Customs duties and inspections, Imports, Cultural property.

Amendment to the Regulations

Accordingly, Part 12 of the Customs Regulations (19 CFR Part 12) is amended as set forth below:

PART 12—[AMENDED]

1. The general authority and specific authority citations for Part 12, in part, continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

2. In § 12.104g, paragraph (a), the list of agreements imposing import restrictions on described articles of cultural property of State Parties, is amended by adding Bolivia in appropriate alphabetical order, as follows, and paragraph (b), the list of emergency actions imposing import restrictions, is amended by removing the entry for ''Bolivia'':

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(2) * * *

State party	Cultural property	T.D. No.
Bolivia	Archaeological and Ethnological Material from Bolivia.	T.D. 01–86
* * * *	* *	*

* * * * *

Dated: December 4, 2001.

Robert C. Bonner,

Commissioner of Customs.

Timothy E. Skud,

Acting Deputy Assistant Secretary of the Treasury.

[FR Doc. 01–30417 Filed 12–5–01; 10:36 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for six approved new animal drug applications (NADAs) from Koffolk, Inc., to Phibro Animal Health.

DATES: This rule is effective December 7, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067, has informed FDA that it has transferred ownership of, and all rights and interest in, the following NADAs to Phibro Animal Health, 710 Rte. 46 East, suite 401, Fairfield, NJ 07004.

NADA Number	Established Names of Ingredients
9–476	Nicarbazin
98–378	Nicarbazin/Bacitracin Methylene Disalicylate
107–997	Nicarbazin/Lincomycin/Roxarsone
108–115	Nicarbazin/Roxarsone
108–116	Nicarbazin/Lincomycin
141–146	Nicarbazin/Bacitracin Zinc

Accordingly, the agency is amending the regulations in 21 CFR 558.366 to reflect the transfer of ownership.

Following the change of sponsor of these NADAs, Koffolk, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove the entries for this sponsor.

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.

* * * * *

Dated: November 15, 2001.

Claire M. Lathers,

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

[FR Doc. 01–30299 Filed 12–6–01; 8:45 am]

BILLING CODE 4160–01–S

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*.

* * * * *

Dated: November 8, 2001.

Claire M. Lathers,

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

[FR Doc. 01–30298 Filed 12–6–01; 8:45 am]

BILLING CODE 4160–01–S