between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 172**

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

## PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.155 is amended by revising paragraph (c) to read as follows:

**§ 172.155 Natamycin (pimaricin).**

* * * * *

(c) The additive may be applied on cheese, as an antimycotic, in amounts not to exceed 20 milligrams per kilogram (20 parts per million) in the finished product as determined by International Dairy Federation (IDF) Standard 140A:1992, ''Cheese and Cheese Rind–Determination of Natamycin Content–Method by Molecular Absorption Spectrometry and by High-Performance Liquid Chromatography,'' which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy (HFS–206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: February 9, 2001.

**L. Robert Lake,**

*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

[FR Doc. 01–5612 Filed 3–7–01; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 510

### New Animal Drugs; Change of Sponsor's Name and Address

**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's name and address for Moorman Manufacturing Co.

**DATES:** This rule is effective March 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

**SUPPLEMENTARY INFORMATION:** Moorman Manufacturing Co., Quincy, IL 62301, has informed FDA of a change of name and address to MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305–3115. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the changes.

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 510**

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

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 510 is 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.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Moorman Manufacturing Co.'' and adding a new entry in alphabetical order and in the table in paragraph (c)(2) by revising the entry for ''021930'' to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|---|---|
| * * * * * * * | |
| MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305–3115 | 021930 |
| * * * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * * * * * | |
| 021930 | MoorMan's, Inc., 1000 North 30th St., Quincy, IL 62305–3115 |
| * * * * * * * | |

Dated: February 8, 2001.

**Claire M. Lathers,**

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

[FR Doc. 01–5682 Filed 3–7–01; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 520

### Oral Dosage Form New Animal Drugs; Clindamycin Hydrochloride Liquid

**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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for oral use of clindamycin hydrochloride liquid for treatment of soft tissue and dental infections in cats.

**DATES:** This rule is effective March 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed a supplement to approved ANADA 200–193 for Clindamycin Hydrochloride Oral Liquid. The supplemental ANADA provides for use of clindamycin hydrochloride liquid for treatment of soft tissue and dental infections in cats caused by or associated with susceptible strains of certain bacterial species. The supplemental application is approved as of December 27, 2000, and the regulations are amended in 21 CFR 520.447 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 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 520**

Animal drugs.

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 520 is amended as follows:

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 520.447 [Amended]**

2. Section 520.447 *Clindamycin hydrochloride liquid* is amended in paragraph (b) in the first sentence by removing ''No. 000009'' and adding in its place ''Nos. 000009 and 059130'' and by removing the second sentence.

Dated: January 30, 2001.

**Claire M. Lathers,**

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

[FR Doc. 01–5683 Filed 3–7–01; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 524

### Ophthalmic and Topical Dosage Form New Animal Drugs; Milbemycin Oxime Solution

**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 Novartis Animal Health US, Inc. The supplemental NADA provides for veterinary prescription use of milbemycin oxime solution to treat ear mite infestations in cats and kittens 4 weeks of age and older and for a repeat treatment, if necessary.

**DATES:** This rule is effective March 8, 2001.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to approved NADA 141–163 that provides for the veterinary prescription use of Milbemite ™ Otic Solution (0.1% milbemycin oxime) for the treatment of ear mite infestations in cats and kittens. The supplemental NADA provides for reducing the lower age limit from 8 weeks of age to 4 weeks of age and for repeating treatment one time, if necessary. The NADA is approved as of December 13, 2000, and the regulations are amended in 21 CFR 524.1446 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(1) 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.