## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

### § 520.1484 [Amended]

4. Section 520.1484 *Neomycin sulfate soluble powder* is amended in paragraph (b) by removing ''047864'' and adding in its place ''046573'' and in paragraph (c)(3) by revising the words in the last sentence ''for sponsors 000009, 000069, 050604'' to read as ''for sponsors 000009, 000069, 046573, 050604''.

### § 520.1696b [Amended]

5. Section 520.1696b *Penicillin G potassium in drinking water* is amended in paragraph (b) by removing ''047864, and'' and adding in its place ''046573,''.

### § 520.2345d [Amended]

6. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraphs (a)(1), (d)(1)(iii), and (d)(2)(iii) by removing ''047864'', and adding in its place ''046573'' and in paragraph (a)(4) by removing ''047863'' and adding in its place ''046573''.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

### § 558.274 [Amended]

8. Section 558.274 *Hygromycin B* is amended in paragraph (a)(8) by removing ''047863'' and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), under the ''sponsor'' column, by removing ''047863'' and numerically adding ''046573''.

Dated: September 9, 1997.

**Robert C. Livingston,**

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

[FR Doc. 97–28011 Filed 10–22–97; 8:45 am]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Parts 520, 524, 556, and 558

## Animal Drugs, Feeds, and Related Products; Famphur

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to specify the tolerance for residues of famphur in cattle products. The residue tolerances were originally issued in FDA's regulations under tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities, and subsequently moved to the Environmental Protection Agency's (EPA's) regulations for residues of pesticides. Subsequent FDA new animal drug approvals with the same tolerances, instead of stating the tolerances, cross-referenced EPA's regulations. This action is being taken because EPA has removed the tolerance from its regulations.

**EFFECTIVE DATE:** October 23, 1997.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

**SUPPLEMENTARY INFORMATION:** FDA has several approved new animal drug applications (NADA's) providing for use of various famphur products. Three NADA's sponsored by Mallinckrodt Veterinary, Inc., Mundelein, IL 60060, are:

NADA 34–266: Famix Famphur Type A article (for Type C cattle feed).

NADA 34–697: Warbex Famphur Cattle Pour-On/Bo-Anna Famphur Cattle Insecticide.

NADA 139–858: Tramisol-X-Tra (Famphur/Levamisole) Cattle Anthelmintic and Ectoparasite Paste.

One NADA sponsored by PM Resources, Inc., 13001 St. Charles Rock Rd., Bridgeton, MO 63044, is:

NADA 43–215: Purina Grub-Kill (Famphur).

Tolerances for residues of famphur including its oxygen analog in or on the raw agricultural commodities meat, fat, and meat byproducts of cattle had been established under 21 CFR 120.233 (33 FR 2935, February 14, 1968). Those provisions were subsequently transferred to EPA and redesignated as 40 CFR 180.233 (36 FR 424, January 13, 1971, interim rule; and 36 FR 22369 at 22564, November 25, 1971, final rule) at 0.1 part per million. FDA, in its approvals of famphur as a new animal drug, established the same tolerance for residues of the drug. Instead of specifying the tolerance in the regulations reflecting the new animal drug approvals, the regulations cross-referenced to 40 CFR 180.233. EPA has revoked the tolerance for residues of famphur in or on certain raw agricultural commodities because the pesticide no longer was covered by EPA's food use registrations (59 FR 17754, April 14, 1994, proposed rule; and 60 FR 49798, September 27, 1995, final rule). Because EPA has removed 40 CFR 180.233, FDA is amending its regulations in 21 CFR 556.273 to establish the tolerances for residues of famphur including its oxygen analog.

In addition, the tolerance citations in 21 CFR 520.1242g(e), 524.900(e), and 558.254(c) are amended to replace the cross-reference to 40 CFR 180.233 with a reference to the residue tolerance specified in 21 CFR part 556.

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.

### List of Subjects

*21 CFR Part 520*

Animal drugs.

*21 CFR Part 524*

Animal drugs.

*21 CFR Part 556*

Animal drugs, Food, Residues.

*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 520, 524, 556, and 558 are 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.

### § 520.1242g [Amended]

2. Section 520.1242g *Levamisole resinate and famphur paste* is amended in paragraph (e) by removing ''40 CFR 180.233 (under the chemical name)'' and adding in its place ''§ 556.273 of this chapter.''

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

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

**§ 524.900 [Amended]**

4. Section 524.900 *Famphur* is amended in paragraph (e) by removing ''40 CFR 180.233 under the chemical name'' and adding in its place ''§ 556.273 of this chapter.''

## PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

5. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

6. Section 556.273 is added to subpart B to read as follows:

**§ 556.273 Famphur.**

Tolerances are established for residues of famphur including its oxygen analog in or on meat, fat, or meat byproducts of cattle at 0.1 part per million.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

**§ 558.254 [Amended]**

8. Section 558.254 *Famphur* is amended in paragraph (c) by removing ''40 CFR 180.233'' and adding in its place ''§ 556.273 of this chapter.''

Dated: September 9, 1997.

**Robert C. Livingston,**

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

[FR Doc. 97–28016 Filed 10–22–97; 8:45 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 524

### Ophthalmic and Topical Dosage Form New Animal Drugs; Miconazole Nitrate Lotion and Spray

**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 an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of miconazole nitrate lotion and spray as topical antifungal agents to treat certain infections of dogs and cats.

**EFFECTIVE DATE:** October 23, 1997.

**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.

**SUPPLEMENTARY INFORMATION:** Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, filed ANADA 200–196, which provides for use of miconazole nitrate lotion 1 percent and miconazole nitrate spray 1 percent as antifungal agents for topical treatment of infections in dogs and cats caused by *Microsporum canis*, *M. gypseum*, and *Trichophyton mentagrophytes*.

Med-Pharmex's ANADA 200–196 is approved as a generic copy of Mallinckrodt Veterinary's Conofite® miconazole nitrate 1 percent lotion and spray, NADA 95–184. ANADA 200–196 is approved as of August 4, 1997, and the regulations are amended in 21 CFR 524.1443(b) to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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.

### List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.1443 is amended by revising paragraph (b) to read as follows:

**§ 524.1443 Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.**

* * * * *

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter for use of cream, lotion, and spray; see No. 051259 in § 510.600(c) of this chapter for use of lotion and spray.

* * * * *

Dated: September 10, 1997.

**Michael J. Blackwell,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. 97–28014 Filed 10–22–97; 8:45 am]

BILLING CODE 4160–01–F

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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; Bacitracin Zinc

**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 hybrid abbreviated new animal drug application (ANADA) filed by ALPHARMA, Inc. The hybrid ANADA provides for the use of bacitracin zinc Type A medicated articles to make Type C medicated feeds for cattle, broiler chickens, turkeys, pheasants, growing quail, and growing and finishing swine, for increased rate of weight gain and improved feed efficiency, and for laying chickens for improved feed efficiency and increased egg production.

**EFFECTIVE DATE:** October 15, 1997.

**FOR FURTHER INFORMATION CONTACT:** Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

**SUPPLEMENTARY INFORMATION:** ALPHARMA, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of hybrid ANADA 200–223 that provides for use of bacitracin zinc Type A medicated articles (bacitracin zinc equivalent to 50 grams (g) of bacitracin per pound) to make Type C medicated feeds for cattle when fed at 35 to 70 milligrams per head per day, for growing broiler chickens, turkeys, and pheasants fed at 4 to 50 g per ton (g/t), for growing quail up to 5 weeks of age fed at 5 to 20 g/t, for growing and finishing swine fed at 10 to 50 g/t, for increased rate of weight gain and improved feed efficiency, and for laying chickens fed at 10 to 25 g/t for improved