§ 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

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

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

feed efficiency and increased egg production.

The data submitted in support of this hybrid ANADA satisfy the requirements of section 512(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(b)(1) and (b)(2)) and the regulations in 21 CFR part 514. The hybrid ANADA has been defined in the Center's Seventh Generic Animal Drug Policy letter dated March 20, 1991. The hybrid ANADA relies on the approval of a listed (pioneer) animal drug and contains additional data needed to support the change in the generic product. The hybrid ANADA is thus relying on the approval of the listed animal drug to the extent that such reliance is allowed under section 512(n) of the act, to establish the safety and effectiveness of the underlying animal drug. An application that relies in part on the approval of a listed animal drug for this purpose is considered an application described in section 512(b)(2) of the act.

ALPHARMA, Inc.'s, hybrid ANADA 200–223 for bacitracin zinc is approved as a generic copy of Hoffmann-LaRoche's NADA 46–920. The hybrid ANADA is approved as of August 20, 1997, and the regulations are amended in 21 CFR 558.78 by revising paragraph (a)(1) to indicate additional approvals and in paragraph (d)(1) by removing the footnote to the table 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, 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(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 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 558.78 is amended by revising paragraph (a), and in paragraph (d)(1) by removing the footnote to the table to read as follows:

§ 558.78 Bacitracin zinc.

(a) *Approvals.* To sponsors listed in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) To 046573: 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(iv), and (d)(2) of this section.

(2) To 000004: 10, 25, 40, and 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(v), (d)(1)(vi), (d)(2), and (d)(3) of this section.

(3) To 000010: 5 and 50 grams per pound as in paragraph (d)(1)(i) of this section.

* * * * *

Dated: September 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–28015 Filed 10–22–97; 8:45 am]

BILLING CODE 4160–01–F

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Procedural Rules Governing Debt-Collection Procedures for Administrative Offset and Federal Income Tax Refund Offset

AGENCY: National Labor Relations Board.

ACTION: Final rule.

SUMMARY: The Debt Collection Act of 1982 (Pub. L. 97–365) amended the Federal Claims Collection Act of 1966 to authorize the federal government to employ various debt collection techniques commonly available to the private sector, including administrative offset and Federal income tax refund offset. In 1992 the Congress passed and the President signed into law the Cash Management Improvement Act Amendments of 1992 which requires federal agencies to participate in the Internal Revenue Service (IRS) income tax refund offset program for the collection of delinquent debts by offset from a federal income tax refund that may be due the delinquent debtor. This final rule establishes the procedures which the Board will follow in utilizing the debt collection procedures authorized by the above legislation.

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: John J. Toner, Executive Secretary, National Labor Relations Board, 1099 14th Street, NW, Room 11600, Washington, DC 20570. Telephone: (202) 273–1940.

SUPPLEMENTARY INFORMATION: The Debt Collection Act of 1982 (Pub. L. 97–365) amended the Federal Claims Collection Act of 1966 to authorize the Federal Government to employ various debt collection techniques commonly available to the private sector, including administrative offset and Federal income tax refund offset. In 1992 the Congress passed and the President signed into law the Cash Management Improvement Act Amendments of 1992 which requires federal agencies to participate in the Internal Revenue Service (IRS) income tax refund offset program in which federal agencies refer delinquent debt to the IRS for collection by offset from a federal income tax refund that may be due the delinquent debtor. On July 24, 1996, the National Labor Relations Board (Board) implemented interim regulations, set forth as new Subparts U (administrative offset), and V (Federal income tax refund offset), to part 102 of the Board's Rules and Regulations, Series 8, (published at 61 FR 38371 and 61 FR 38373, respectively), to enable the Board to utilize these debt collection procedures that have proven to be cost effective mechanisms for collection of delinquent debt.

These final rules establish the current interim rules as the means by which the Board will pursue debt collection permitted under the above statutes, with one minor change involving the clarification of a phrase appearing in § 102.160 of Subpart U, as discussed below.

When the Board published the interim rules on July 24, 1996, it determined that, because these rules merely implement a definite statutory scheme and its concomitant regulations, and relate to Agency procedure and practice, public comment on the rules was unnecessary. Nevertheless, the Board undertook to consider any public comments submitted to it on or before September 29, 1996, before issuing any final rules. The Board did receive comments from one organization which raised questions falling broadly within two categories: (1) Whether the regulations were needed, and (2) whether the application of the regulations was appropriate. We consider these comments seriatim.