final rule that appeared in the **Federal Register** of June 27, 1997 (62 FR 34631). The document amended the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Deprenyl Animal Health, Inc. The NADA provides for oral use of selegiline hydrochloride tables for dogs for the control of clinical signs associated with uncomplicated pituitary-dependent hyperadrenocorticism. The approved use in dogs was inadvertently omitted from the document. This document corrects that error.

EFFECTIVE DATE: June 27, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

In FR Doc. 97–16791, appearing on page 34631 in the **Federal Register** of Friday, June 27, 1997, the following corrections are made:

1. On page 34631, in the first column, in the heading ''*Tablet*'' is corrected to read ''*Tablets*''.

§ 520.2098 [Corrected]

2. On page 34632, in the first column, in § 520.2098 *Selegiline hydrochloride tablets*, in paragraph (d), the heading ''(d) *Conditions of use—*'' is corrected to read ''(d) *Conditions of use—Dogs—*''; and in paragraph (d)(2), in the 4th line, ''hyperadrenocorticism.'' is corrected to read ''hyperadrenocorticism in dogs.''

Dated: September 8, 1997.

Robert C. Livingston,

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

[FR Doc. 97–28017 Filed 10–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

New Animal Drugs and Related Products; 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 three new animal drug applications (NADA's) and three abbreviated new animal drug applications (ANADA's) from Wade-Jones Co., Inc., and its manufacturing subsidiary Arkansas Micro Specialties, Inc., to Alpharma Inc. The agency is also correcting a final rule that appeared in the **Federal Register** of June 20, 1996 (61 FR 31398).

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Wade-Jones Co., Inc., 409 North Bloomington, Lowell, AR 72745, and its manufacturing subsidiary Arkansas Micro Specialties, Inc., P.O. Box 308, Highway 71 North, Lowell, AR 72745, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's and ANADA's to Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024.

NADA/ANADA	Ingredient
065–140	Tetracycline Hcl Soluble Powder
140–443	Hygromycin B Type A Medicated Articles
140–578	Tetracycline Hcl Soluble Powder
200–122	Penicillin G Potassium Soluble Powder
200–130	Neomycin Sulfate Soluble Powder
200–233	Lincomycin Hcl Soluble Powder

The agency is amending parts 510, 520, and 558 (21 CFR parts 510, 520 and 558) to reflect the change of sponsor. The agency is amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for Wade-Jones Co., Inc., and Arkansas Micro Specialties, Inc., because the firm no longer is the holder of any approved NADA's.

The agency is also correcting a final rule that appeared in the **Federal Register** of June 20, 1996 (61 FR 31398). This document amended the animal drug regulations to reflect approval of a supplemental NADA filed by The Upjohn Co., and two supplemental ANADA's, one filed by Pfizer, Inc., and the other filed by Rhone Merieux, Inc, respectively. In § 520.1484(c)(3), the drug labeler code (047864) for Wade-Jones Co., Inc., was inadvertently omitted from the document. After that document published, Wade-Jones Co., Inc., transferred ownership of and all rights and interest to Alpharma Inc. Accordingly, this document adds a drug labeler code for Alpharma Inc. and, thereby, corrects the error in the final rule (61 FR 31398).

List of Subjects

21 CFR Part 510

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

21 CFR Part 520

Animal drugs.

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, 520, 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 entries for ''Arkansas Micro Specialties, Inc.''and ''Wade-Jones'' and in the table in paragraph (c)(2) by removing the entries ''047863'' and ''047864''.

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

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.