of August 27, 1998, and § 520.1242a (21 CFR 520.1242a) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In the regulations, § 520.1242a provides for use of levamisole hydrochloride soluble powder in a drench as an anthelmintic for cattle and sheep against stomach worms, intestinal worms, and lung worms, and in drinking water as an anthelmintic for swine against large roundworms, nodular worms, intestinal threadworms, and lungworms. The regulation states the drug's chemical name and assay, information that FDA has determined is better provided by other references. In addition, the rule fails to properly reflect the dosage. Thus, FDA is amending § 520.1242a to remove the chemical name and assay and to better reflect the package sizes and dosage. Finally, FDA also is redesignating the paragraphs to reflect current style format.

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.

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.

2. Section 520.1242a is amended by removing paragraphs (a) and (d), by redesignating paragraphs (b), (c), (e), and (f) as paragraphs (a), (b), (c), and (d), respectively, by revising newly redesignated paragraphs (a), (b), (c), (d)(1)(i), (d)(1)(iii), (d)(2)(i), and by adding newly designated paragraph (d)(2)(iii) to read as follows:

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) *Specifications.* Each package contains either 9.075, 11.7, 18.15, 46.8, or 544.5 grams of levamisole hydrochloride.

(b) *Sponsors.* Approval for sponsors in 21 CFR 510.600(c) for use as in paragraph (d) of this section as follows:

(1) See 043781 for use of 46.8 gram package as in paragraph (d)(1) of this section, for 11.7 and 46.8 gram packages as in paragraph (d)(2) of this section, and for 9.075 and 18.15 gram packages as in paragraph (d)(3) of this section.

(2) See 000061 for use of 46.8 and 544.5 gram packages as in paragraph (d)(1) of this section, for 11.7, 46.8, and 544.5 gram packages as in paragraph (d)(2) of this section, and for 18.15 gram package as in paragraph (d)(3) of this section.

(3) See 057561 for use of 46.8 and 544.5 gram packages as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used as an anthelmintic at 0.365 gram per 100 pounds of body weight as follows:

(1) *Cattle*—(i) *Amount.* As a single oral dose drench using 46.8 or 544.5 gram packet.

* * * * *

(iii) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 46.8 gram package in water to provide 1 quart (32 fluid ounces) of drench solution and administer as a drench at 1/4 ounce per 100 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in water to provide 8.75 fluid ounces of concentrate solution and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose by syringe.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(2) *Sheep*—(i) *Amount.* As a single oral dose drench using 11.7, 46.8, or 544.5 gram packet.

* * * * *

(iii) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 11.7 gram package in 1 quart (32 ounces) of water and administer as a drench at 1 ounce per 100 pounds of body weight, or dissolve in 10.9 fluid ounces of water and administer as a drench at 1 milliliter per 10 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in 128 fluid ounces (1 gallon) of water and administer as a drench at 1 ounce per 100 pounds of body weight as a single oral dose.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

* * * * *

Dated: October 23, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–29613 Filed 11–4–98; 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; Sulfadimethoxine Soluble Powder and Oral 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 two abbreviated new animal drug applications (ANADA's) filed by Med–Pharmex, Inc. One ANADA provides for the use of sulfadimethoxine soluble powder for use in drinking water or as a drench, and the second ANADA provides for the use of the oral solution in drinking water or as a drench, for the treatment of chickens,

turkeys, and dairy calves, dairy heifers, and beef cattle.

EFFECTIVE DATE: November 5, 1998.

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 91767–1861, has filed both ANADA 200–238 that provides for the use of Sulfasol® (sulfadimethoxine) soluble powder, and ANADA 200–251 that provides for use of Sulforal® (sulfadimethoxine) concentrated solution, both for use in drinking water or as a drench for the treatment of disease outbreaks as follows: Coccidiosis, fowl cholera, and infectious coryza in chickens; coccidiosis and fowl cholera in meat-producing turkeys; and shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine, and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine in dairy calves, dairy heifers, and beef cattle.

ANADA 200–238 is approved as a generic copy of Pfizer, Inc.'s NADA 46–285 for Albon® (sulfadimethoxine soluble powder). ANADA 200–238 is approved as of July 28, 1998.

ANADA 200–251 is approved as a generic copy of Pfizer, Inc.'s NADA 31–205 for Albon® (sulfadimethoxine 12.5% concentrated solution). ANADA 200–251 is approved as of August 3, 1998.

Currently the regulations in § 520.2220a (21 CFR 520.2220a) do not specify which sponsors have approval for the oral solution or the soluble powder. The section is amended to combine paragraphs (a) and (b) to specify the approvals, including the new approvals. The basis for approval is discussed in the freedom of information summaries.

In amending § 520.2220a paragraph (a) is revised, paragraph (b) is removed, and paragraphs (c) through (e) are redesignated as paragraphs (b) through (d), respectively.

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 these applications 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.

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.

2. Section 520.2220a is amended by revising paragraph (a), by removing paragraph (b), and by redesignating paragraphs (c) through (e) as paragraphs (b) through (d), respectively, to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) *Approvals.* (1) For oral solution containing 12.5 percent (3.75 grams per ounce) sulfadimethoxine, see Nos. 000010, 000069, 051259, 057561, and 059130 in § 510.600(c).

(2) For soluble powder, each package containing the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt), see Nos. 000069, 051259, and 057561 in § 510.600(c).

* * * * *

Dated: October 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–29612 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Animal Drugs, Feeds, and Related Products; Change of Sponsor; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct sponsor for an approved new animal drug application. The sponsor that is currently specified in the regulations is incorrect. This document amends the regulations to correct that error.

EFFECTIVE DATE: November 5, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has become incorporated into the agency's regulations for animal drugs, feeds, and related products. An amendment published on June 30, 1997 (62 FR 35075), amended § 522.1044 (21 CFR 522.1044) in paragraph (b)(3) by removing ''054273'' and adding in its place ''000010''. However, § 522.1044(b)(3) was not added to the agency's regulations until August 26, 1997 (62 FR 45157). Because § 522.1044(b)(3) did not exist when the amendment was made, the regulations were not amended and therefore the regulations are incorrect. This document corrects that error.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1044 [Amended]

2. Section 522.1044 *Gentamicin sulfate injection* is amended in paragraph (b)(3) by removing ''054273'' and adding in its place ''000010''.

Dated: October 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–29611 Filed 11–4–98; 8:45 am]

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