affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency believes that this interim rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires that if a rule has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options to minimize the economic impact on small entities. The agency certifies that this interim rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires an agency to prepare a budgetary impact statement before promulgating any rule likely to result in a Federal mandate that may result in expenditures by State, local, and tribal governments or the private sector of $100 million (adjusted annually for inflation) in any 1 year. The elimination of the ''successful defense'' provision of § 314.107(c)(1), and the related provision in § 314.107(c)(4), will not result in any significant increased expenditures by State, local, and tribal governments or the private sector. Because this interim rule will not result in an expenditure of $100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

This interim rule is intended to bring FDA's regulations into conformance with the *Granutec* and *Mova* court decisions. The agency believes that this interim rule is necessary and that it is consistent with the principles of Executive Order 12866; that it is not a significant regulatory action under that Order; that it will not have a significant economic impact on a substantial number of small entities; and that it is not likely to result in an annual expenditure in excess of $100 million.

IV. Paperwork Reduction Act of 1995

This interim rule contains no collections of information, therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Effective Date

The agency is issuing these amendments as an interim rule effective November 10, 1998. This action is being issued to remove the ''successful defense'' provision of § 314.107(c)(1), and the related provision in § 314.107(c)(4). This action is necessary because both the *Granutec* and *Mova* courts have found the ''successful defense'' provision to be without support in the act. Indeed, the *Mova* court has ordered FDA not to enforce the ''successful defense'' provision of § 314.107(c)(1). These decisions have rendered the ''successful defense'' provision, and the related provision in § 314.107(c)(4), a nullity, and FDA can find no reason to retain the provisions in its regulations. For the foregoing reasons, FDA finds, for good cause, that notice and public procedure would be impracticable, unnecessary, and contrary to the public interest; therefore, a public comment period before the establishment of this interim rule may be dispensed with under 5 U.S.C. 553(b)(B) and § 10.40(e)(1) (21 CFR 10.40(e)(1)). In addition, the Commissioner of Food and Drugs finds good cause under 5 U.S.C. 553(d)(3) and § 10.40(c)(4)(ii) for making this interim rule effective in less than 30 days.

VI. Opportunity for Public Comment

Interested persons may, on or before February 3, 1999, submit to the Dockets Management Branch (address above) written comments regarding this interim rule. FDA will use any comments received to determine whether this interim rule should be modified or revoked. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

1. The authority citation for 21 CFR part 314 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

§ 314.107 [Amended]

2. Section 314.107 *Effective date of approval of a 505(b)(2) application or abbreviated new drug application under section 505(j) of the act* is amended in paragraph (c)(1) by removing the phrase ''and the applicant submitting the first application has successfully defended against a suit for patent infringement brought within 45 days of the patent owner's receipt of notice submitted under § 314.95'' and in paragraph (c)(4) by removing the phrase ''if sued for patent infringement''.

Dated: October 30, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29610 Filed 11–2–98; 11:57 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; Levamisole Hydrochloride Soluble Drench Powder

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 Agri Laboratories, Ltd. The ANADA provides for use of levamisole hydrochloride soluble drench powder for use in water as an anthelmintic for cattle and sheep.

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: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503–0103, filed ANADA 200–225 that provides for use of Prohibit™ (levamisole hydrochloride) soluble drench powder, in 46.8 and 544.5 gram packages, in water, as an anthelmintic for cattle and sheep. Levamisole cattle and sheep drench is used to treat infections of stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) (*Chabertia,* sheep only), and lung worms (*Dictyocaulus*). Agri Laboratories, Ltd.'s ANADA 200–225 is approved as a generic copy of the Schering–Plough Corp.'s NADA 112–051 Levasole® (levamisole) soluble drench. ANADA 200–225 is approved as

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,