individual's record, the Privacy Act Officer, or, for records maintained by the Inspector General, the Inspector General, shall clearly note any portion of the record which is disputed and shall provide copies of the statement and, if the Commission deems it appropriate, copies of a concise statement of the reasons of the Commission for not making the amendments requested, to persons or other agencies to whom the disputed record has been disclosed.

§ 201.31 Fees.

(a) The Commission shall not charge any fee for the cost of searching for and reviewing an individual's records.

(b) Reproduction, duplication or copying of records by the Commission shall be at the rate of $0.10 per page. There shall be no charge, however, when the total amount does not exceed $25.00.

§ 201.32 Specific exemptions.

(a) Pursuant to 5 U.S.C. 552a(k)(2), and in order to protect the effectiveness of Inspector General investigations by preventing individuals who may be the subject of an investigation from obtaining access to the records and thus obtaining the opportunity to conceal or destroy evidence or to intimidate witnesses, records contained in the system titled Office of Inspector General Investigative Files (General), insofar as they include investigatory material compiled for law enforcement purposes, shall be exempt from this subpart and from subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) of the Privacy Act. However, if any individual is denied any right, privilege, or benefit to which he is otherwise entitled to under Federal law due to the maintenance of this material, such material shall be provided to such individual except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to government investigators under an express promise that the identity of the source would be held in confidence.

(b) Pursuant to 5 U.S.C. 552a(j)(2), and in order to protect the confidentiality and integrity of Inspector General investigations by preventing individuals who may be the subject of an investigation from obtaining access to the records and thus obtaining the opportunity to conceal or destroy evidence or to intimidate witnesses, records maintained in the Office of Inspector General Investigative Files (Criminal), insofar as they contain information pertaining to the enforcement of criminal laws, shall be exempt from this subpart and from the Privacy Act, except that subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11) and (i) shall still apply to these records.

(c) Pursuant to 5 U.S.C. 552a(k)(1), (5) and (6), records contained in the system entitled ''Personnel Security Investigative Files'' have been exempted from subsections (c)(3), (d), (e)(1), (e)(1)(G) through (I) and (f) of the Privacy Act. Pursuant to section 552a(k)(1) of the Privacy Act, the Commission exempts records that contain properly classified information that pertains to national defense or foreign policy and is obtained from other systems of records or another Federal agency. Application of exemption (k)(1) may be necessary to preclude the data subject's access to and amendment of such classified information under 5 U.S.C. 552a(d). All information about individuals in these records that meets the criteria stated in 5 U.S.C. 552a(k)(5) is also exempted because this system contains investigatory material compiled solely for determining suitability, eligibility, and qualifications for Federal civilian employment, Federal contracts or access to classified information. To the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence, or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence, the application of exemption (k)(5) will be required to honor such a promise should an individual request access to the accounting of disclosure, or access to or amendment of the record, that would reveal the identity of a confidential source. All information in these records that meets the criteria stated in 5 U.S.C. 552a(k)(6) is also exempt because portions of a case file record may relate to testing and examining material used solely to determine individual qualifications for appointment or promotion in the Federal service. Access to or amendment of this information by the data subject would compromise the objectivity and fairness of the testing or examining process.

§ 201.33 Employee conduct.

The Privacy Act Officer shall establish rules of conduct for persons involved in the design, development, operation, or maintenance of any system of records, or in maintaining any record, and periodically instruct each such person with respect to such rules and the requirements of the Privacy Act including the penalties for noncompliance.

PARTS 201 AND 205—[AMENDED]

8. In addition to the amendments set forth above, in 19 CFR parts 201 and 205 remove the words ''Special Representative for Trade Negotiations'' and add, in their place, the words ''United States Trade Representative'' in the following places:

a. Section 201.7(b); and

b. Section 205.3(a)(1), (a)(2), (b) and (d).

By order of the Commission.

Issued: May 22, 1998.

Donna R. Koehnke,

Secretary.

[FR Doc. 98–14140 Filed 5–28–98; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Milbemycin Oxime Tablet

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 supplemental new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The supplemental NADA provides for expanding the indications to include separate dosage and labeling for use of milbemycin oxime in cats.

EFFECTIVE DATE: May 29, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404–6402, filed supplemental NADA 140–915 that provides for oral administration of Interceptor® Flavor Tabs® (milbemycin oxime) tablets to cats 6 weeks of age or greater and 1.5 pounds of body weight or greater. The product is currently approved for the prevention of heartworm disease in both dogs and puppies 4 weeks of age or greater. The supplemental NADA provides for expanding the indications to include separate dosage and labeling for use of

the product in cats 6 weeks of age or greater and 1.5 pounds of body weight or greater. This supplemental NADA approval provides for 5.75, 11.5, and 23.0 milligram tablets, given orally, once a month, for the prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater. The supplemental NADA is approved as of April 13, 1998, and the regulations are amended in 21 CFR 520.1445 by revising paragraph (a) and the heading of paragraph (c) and by adding paragraph (d) to reflect the approval for cats. 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 13, 1998, because the application contains substantial evidence of effectiveness of the drug involved and studies of animal safety required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(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 520.1445 is amended by revising paragraph (a) and the heading of paragraph (c) and by adding paragraph (d) to read as follows:

§ 520.1445 Milbemycin oxime tablets.

(a) *Specifications*—(1) *Dogs.* Each tablet contains 2.3, 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

(2) *Cats.* Each tablet contains 5.75, 11.5, or 23.0 milligrams of milbemycin oxime.

* * * * *

(c) *Conditions of use in dogs.* * * *

(d) *Conditions of use in cats*—(l) *Amount.* 0.91 milligram per pound of body weight (2.0 milligrams per kilogram).

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.

(3) *Limitations.* Do not use in kittens less than 6 weeks of age or 1.5 pounds body weight. Administer once a month. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 11, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–14182 Filed 5–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Guaifenesin Injection

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 Phoenix Scientific, Inc. The ANADA provides for intravenous use of guaifenesin injection in horses as a skeletal muscle relaxant.

EFFECTIVE DATE: May 29, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–230 that provides for intravenous use of guaifenesin injection in horses as a skeletal muscle relaxant.

Approval of Phoenix Scientific, Inc.'s, ANADA 200–230 for guaifenesin injection is as a generic copy of Summit Hill Laboratories' NADA 48–854 for Gecolate (guaifenesin) Injection. The ANADA is approved as of April 8, 1998, and the regulations are amended in 21 CFR 522.1086(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, paragraph (c) is redesignated as paragraph (d) and paragraph (c) is reserved.

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(d)(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 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.

§ 522.1086 [Amended]

2. Section 522.1086 *Guaifenesin injection* is amended in paragraph (b) by removing ''No. 037990'' and adding in its place ''Nos. 037990 and 059130'', by redesignating paragraph (c) as paragraph (d), and by reserving paragraph (c).