modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (e) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required within 25 hours time-in-service (TIS) after the effective date of this AD, unless accomplished previously.

To prevent fatigue failure of the carrier, which could result in failure of the main transmission and subsequent loss of control of the helicopter, accomplish the following:

(a) Create a component history card or equivalent record for the carrier, P/N 214–040–077–007 or –101.

(b) Determine and record the accumulated Retirement Index Number (RIN) to date on the carrier as follows (if the multiplication results in a fraction, round the results up to the next whole number):

(1) For Model 214B or B–1 helicopters:

(i) Multiply the high-power event total to date by 2, or

(ii) If the actual operating hours are *known*, and:

(A) If the type of operation is internal load lift operations only, multiply each operating hour by 7;

(B) If the type of operation involves any external load lift operations and the number of external load lift operations is known, use the table below and multiply the appropriate factor for the average number of external load lift operations by the number of actual operating hours:

Average number of external load lift operations per hour	Factor [1]
0–2.00	7
2.01–5.00	7
5.01–16.00	14
16.01–27.00	21
above 27.00	28

[1] RIN = Factor × Actual Operating Hours.

(C) If the type of operation involves any external load lift operations and the number of external load lift operations is unknown, multiply each actual operating hour by 21; or

(D) If the type of operation is unknown, multiply each actual operating hour by 21.

(iii) If the actual operating hours are *unknown*, assume 900 operating hours per calendar year. Prorate the assumed operating hours for partial years.

(A) If the type of operation is internal only, multiply the assumed operating hours by 7.

(B) If the type of operation involves any external load lift operations and the number of external load lift operations is known, use the table in paragraph (b)(1)(ii)(B) and multiply the appropriate factor for the average number of external load lift operations by the number of assumed operating hours.

(C) If the type of operation involves any external load lift operations and the number of external load lift operations is unknown, multiply each assumed operating hour by 21.

(D) If the type of operation is unknown, multiply each assumed operating hour by 21.

(2) For Model 214ST helicopters:

(i) Multiply the high-power event total to-date by 2, or

(ii) Multiply the factored flight hour total to-date by 12.

Note 2: BHTI Alert Service Bulletin (ASB) 214–94–52, which is applicable to Model 214B helicopters, and ASB 214ST–94–66, which is applicable to Model 214ST helicopters, both of which are dated November 7, 1994, pertain to this subject.

(c) After compliance with paragraphs (a) and (b) of this AD, and during each operation thereafter, maintain a count of each lift or takeoff performed and at the end of each day's operations, increase the accumulated RIN on the component history card or equivalent record as follows:

(1) For Model 214B and 214B–1 helicopters,

(i) Increase the RIN by 1 for each takeoff.

(ii) Increase the RIN by 1 for each external load lift operation; or, increase the RIN by 2 for each external load lift operation in which the load is picked up at a higher elevation and released at a lower elevation, and the difference in the elevation between the pick up point and the release point is 200 feet or greater.

(2) For Model 214ST helicopters,

(i) Increase the RIN by 2 for each takeoff.

(ii) Increase the RIN by 2 for each external load lift operation; or, increase the RIN by 4 for each external load lift in which the load is picked up at a higher elevation and released at a lower elevation and the difference in elevation between the pick up point and the release point is 200 feet or greater.

(d) Remove the carrier, P/N's 214–040–077–007 or –101, from service on or before attaining an accumulated RIN of 120,000. The carrier is no longer retired based upon flight hours. This AD revises the Airworthiness Limitations section of the maintenance manual by establishing a new retirement life for the carrier of 120,000 RIN.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Certification Office, FAA, Rotorcraft Directorate. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Certification Office.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(g) This amendment becomes effective on August 19, 1997.

Issued in Fort Worth, Texas, on July 8, 1997.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–18499 Filed 7–14–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

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 abbreviated new animal drug application (ANADA) filed by Lambert-Kay, Division of Carter-Wallace, Inc. The supplemental ANADA provides for oral use 4.54 milligrams per milliliter (mg/mL) pyrantel pamoate suspension in addition to the 2.27 mg/mL product for removal of large roundworms and hookworms in puppies and dogs and to prevent reinfections of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

EFFECTIVE DATE: July 15, 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: Lambert-Kay, Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512–0181, filed a supplement to ANADA 200–028 that provides for oral use of 4.54 mg/mL of Evict®, Lassie®, and Vet's Own® (pyrantel pamoate) liquid wormer for removal of large roundworms (*T. canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in puppies and dogs and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping. The supplemental ANADA provides for use of 4.54 mg/mL pyrantel pamoate suspension in addition to 2.27 mg/mL suspension.

Approval of supplemental ANADA 200–028 for Lambert-Kay's pyrantel

pamoate suspension is as a generic copy of Pfizer's NADA 100–237 Nemex-2™ (pyrantel pamoate) suspension. The supplemental ANADA is approved as of June 4, 1997, and the regulations are amended in 21 CFR 520.2043(b)(2) 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 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.2043 is amended by revising paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) *Sponsors.* See Nos. 000069 and 011615 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 023851 for use of 4.54 milligrams per milliliter product.

* * * * *

Dated: June 20, 1997.

Robert C. Livingston,

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

[FR Doc. 97–18459 Filed 7–14–97; 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; Sulfaquinoxaline Drinking Water

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 Solvay Animal Health, Inc. The supplemental NADA provides for revised conditions of use of sulfaquinoxaline sodium in the drinking water of chickens and turkeys to reflect compliance with the results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Implementation (DESI) evaluation of the product and FDA's conclusions based on that evaluation.

EFFECTIVE DATE: July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Solvay Animal Health, Inc., 1201 Northland Dr., Mendota Heights, MN 55120–1149, filed supplemental NADA 6–707 that provides for use of 28.62-percent sulfaquinoxaline sodium solution to make 0.025- or 0.04-percent solution used in the drinking water of chickens and turkeys for control of coccidiosis, acute fowl cholera, and fowl typhoid.

The supplement is approved as of June 2, 1997, and the regulations are amended by adding new 21 CFR 520.2325a(a)(4) to reflect the approval.

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 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.2325a is amended by adding new paragraph (a)(4) to read as follows:

§ 520.2325a Sulfaquinoxaline drinking water.

(a) * * *

(4) No. 053501 for use of a 28.62-percent sulfaquinoxaline sodium solution as provided in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

* * * * *

Dated: June 20, 1997.

Robert C. Livingston,

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

[FR Doc. 97–18458 Filed 7–14–97; 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; Moxidectin Tablets

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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral use of moxidectin tablets for dogs to prevent canine heartworm infections and subsequent development of canine heartworm disease.

EFFECTIVE DATE: July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.