§ 310.304 [Removed]

8. Section 310.304 *Drugs that are subjects of approved new drug applications and that require special studies, records, and reports* is removed.

Dated: June 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–14587 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

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 an abbreviated new animal drug application (ANADA) filed by Lambert-Kay, Div. of Carter-Wallace, Inc. The ANADA provides for oral use of pyrantel pamoate suspension 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: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Lambert-Kay, Div. of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512–0181, filed ANADA 200–028, which provides for oral use 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 product contains pyrantel pamoate equivalent to 2.27 milligrams of pyrantel base.

Approval of ANADA 200–028 for Lambert-Kay's pyrantel pamoate suspension is as a generic copy of Pfizer's NADA 100–237 Nemex™ (pyrantel pamoate). The ANADA is approved as of March 28, 1996, and the regulations in 21 CFR 520.2043(b)(2) are amended 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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 No. 000069 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 011615 for use of 2.27 milligrams per milliliter product.

* * * * *

Dated: May 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14647 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520, 556, and 558

Animal Drugs, Feeds, and Related Products; Fenbendazole-Containing Animal Drug and Feed Products

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 three supplemental new animal drug applications (NADA's) filed by Hoechst-Roussel Agri-Vet Co. The supplemental NADA's expand use of fenbendazole-containing suspension, paste, and medicated animal feed products to include use in dairy cattle of breeding age for the removal and control of gastrointestinal parasites and lungworm. They also provide for the establishment of a safe concentration and tolerance for fenbendazole residues in milk of treated dairy cattle and no requirement for discard of milk from the animals.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Rt. 202–206 North, P.O. Box 2500, Somerville, NJ 08876–1258, is the sponsor of NADA's which cover the following fenbendazole-containing animal drug and medicated feed products: 128–620 for 10 percent suspension, 132–872 for 10 percent paste, and 137–600 for 20 percent Type A medicated article, 0.5 percent pelleted top dressing, and 35 percent free-choice mineral feed. The firm holds approvals for use of the products in beef and dairy cattle not of breeding age for the removal and control of gastrointestinal parasites and lungworm (as provided for in §§ 520.905a, 520.905c, and 558.258 (21 CFR 520.905a, 520.905c, and 558.258)). The firm has submitted supplements to the NADA's providing for expanding use of the drug products to include use in dairy cattle of breeding age for the same uses currently approved for the above-mentioned production classes.

Safe concentrations for total fenbendazole residues in edible cattle tissues, a tolerance for parent fenbendazole in cattle liver (21 CFR 556.275), and a safe withdrawal time for treated beef cattle were established based on data and information submitted with the original NADA 128–620. Based on the evaluation of data generated by additional studies submitted with these supplements, the agency is establishing a safe concentration and tolerance for fenbendazole residues in milk of treated dairy cattle. Also, based on the data, no discard of milk (zero milk withdrawal) is required and the slaughter