§ 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

withdrawal time for treated dairy cattle of breeding age is the same as that established for beef cattle in the original NADA 128–620.

Supplemental NADA's 128–620 and 132–872 are approved as of March 28, 1996, and §§ 520.905a and 520.905c are amended to reflect the approvals. Supplemental NADA 137–600 is approved as of (*insert date of publication in the* Federal Register), and § 558.258 is amended to reflect the approval. The basis for the approvals is discussed in the freedom of information summaries.

Approval of NADA 137–600 is for use of fenbendazole Type A medicated article to make Type C medicated feed. Fenbendazole is a Category II drug which, as provided in 21 CFR 558.4, requires an appproved Form FDA 1900 for making a Type C medicated feed. Therefore, use of fenbendazole Type A medicated articles to Type C medicated feeds as in NADA 137–600 requires an approved Form FDA 1900.

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)), summaries 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, 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)), these approvals for food-producing animals do not qualify for exclusivity because the supplemental applications do not contain new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant.

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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 520, 556, and 558 are 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).

§ 520.905a [Amended]

2. Section 520.905a *Fenbendazole suspension* is amended in paragraph (d)(2) by revising the paragraph heading to read ''*Beef and dairy cattle*'' and in paragraph (d)(2)(i)(B) by removing the third sentence.

§ 520.905c [Amended]

3. Section 520.905c *Fenbendazole paste* is amended in paragraph (d)(2) by revising the paragraph heading to read ''*Beef and dairy cattle*'' and in paragraph (d)(2)(iii) by removing the third sentence.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

5. Section 556.275 is amended by adding new paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(c) *Cattle milk*. A safe concentration of 1.67 parts per million is established for total fenbendazole residues. A tolerance of 0.6 part per million is established based on the fenbendazole sulfoxide metabolite (marker residue).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

6. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

7. Section 558.258 is amended by revising the introductory text of paragraph (c)(2), by removing the last sentence of paragraph (c)(2)(iii), by revising the introductory text of paragraph (c)(3) , and by removing the fourth sentence of paragraph (c)(3)(iii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(c) * * *

(2) It is used in the feed of beef and dairy cattle as follows:

* * * * *

(3) It is used in free-choice beef and dairy cattle feed as follows:

* * * * *

Dated: May 28, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14645 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride Sterile 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 new animal drug application (NADA) filed by The Upjohn Co. The NADA provides for use of ceftiofur hydrochloride sterile suspension for intramuscular injection in swine for treatment and control of certain forms of swine bacterial respiratory disease.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, is sponsor of NADA 140–890, which provides for use of Excenel® Sterile Suspension (ceftiofur hydrochloride equivalent to 50 milligrams (mg) per milliliter ceftiofur). The NADA provides for intramuscular injection in swine for treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus* (*Haemophilus*)