§ 131.122 [Removed]

4. Section 131.122 *Sweetened condensed skimmed milk* is removed from subpart B.

§ 131.123 [Removed]

5. Section 131.123 *Lowfat dry milk* is removed from subpart B.

§ 131.132 [Removed]

6. Section 131.132 *Evaporated skimmed milk* is removed from subpart B.

§ 131.135 [Removed]

7. Section 131.135 *Lowfat milk* is removed from subpart B.

§ 131.136 [Removed]

8. Section 131.136 *Acidified lowfat milk* is removed from subpart B.

§ 131.138 [Removed]

9. Section 131.138 *Cultured lowfat milk* is removed from subpart B.

§ 131.143 [Removed]

10. Section 131.143 *Skim milk* is removed from subpart B.

§ 131.144 [Removed]

11. Section 131.144 *Acidified skim milk* is removed from subpart B.

§ 131.146 [Removed]

12. Section 131.146 *Cultured skim milk* is removed from subpart B.

13. Section 131.149 is amended by revising the second sentence of paragraph (a) to read as follows:

§ 131.149 Dry cream.

(a) * * * Alternatively, dry cream may be obtained by blending dry milks as defined in §§ 131.125(a) and 131.147(a) with dry cream as appropriate: *Provided*, That the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. * * *

* * * * *

§ 131.185 [Removed]

14. Section 131.185 *Sour half-and-half* is removed from subpart B.

§ 131.187 [Removed]

15. Section 131.187 *Acidified sour half-and-half* is removed from subpart B.

PART 133—CHEESE AND RELATED CHEESE PRODUCTS

16. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 133.131 [Removed]

17. Section 133.131 *Lowfat cottage cheese* is removed from subpart B.

Dated: November 12, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–29485 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510, 520, and 522

Animal Drugs, Feeds, and Related Products; Clindamycin Hydrochloride Liquid

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 Pharmacia & Upjohn Co. The supplemental NADA provides for expanding the use of clindamycin hydrochloride liquid by adding indications for the treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with certain, susceptible stains of bacteria in cats.

EFFECTIVE DATE: November 20, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, is sponsor of NADA 135–940, which provides for use of Antirobe® Aquadrops Liquid (clindamycin hydrochloride) in dogs for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by or associated with certain, susceptible strains of aerobic or anaerobic bacteria in accordance with § 520.447 (21 CFR 520.447). The firm has filed a supplemental NADA that expands use of the drug product to cats by providing for treatment of: (1) Soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of the aerobic bacteria *Staphylococcus aureus, S. intermedius*, and *Streptococcus spp.*, and (2) soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of the anaerobic bacteria *Clostridium perfringens* and *Bacteroides fragilis*. The supplemental NADA is approved as of October 7, 1996, and the regulations are amended in § 520.447 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the existing ''Limitations'' paragraph for use of the drug in dogs (§ 520.447(c)(3)) is being revised to add chinchillas and ruminating animals to the list of animals for which the drug product is contraindicated.

Also, the regulations are amended in 21 CFR 510.600(c)(1) and (c)(2) and § 522.1145(a) (21 CFR 522.1145(a)) to reflect a change of sponsor resulting from the merger of The Upjohn Co. and Pharmacia, Inc. The new sponsor, Pharmacia & Upjohn Co., informed FDA of the change and subsequently requested that the agency amend the regulation in § 522.1145(a) that provides for use of Pharmacia's Hylartin V Injection (hyaluronate sodium, NADA 112–048) to indicate the new sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), approval for use in cats qualifies for 3 years of marketing exclusivity beginning October 7, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval 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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 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 parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for ''Pharmacia, Inc.,'' and ''The Upjohn Co.'' and by alphabetically adding a new entry for ''Pharmacia & Upjohn Co.'' and in the table in paragraph (c)(2) by removing the entry for ''000016'' and by revising the entry for ''000009'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	* *
Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199	000009
* * * * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * * * *
000009	Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199
* *	* * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. 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).

4. Section 520.447 is amended by revising the third sentence in paragraph (c)(3) and by adding new paragraph (d) to read as follows:

§ 520.447 Clindamycin hydrochloride liquid.

* * * * *

(c) * * *

(3) * * * Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. * * *

(d) *Conditions of use in cats*—(1) *Amount.* 5.0 to 10.0 milligrams per pound of body weight every 24 hours for a maximum of 14 days (11 to 22 milligrams per kilogram of body weight per day).

(2) *Indications for use.* Aerobic bacteria: Treatment of soft tissue infections (wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Staphylococcus aureus, S. intermedius, and Streptococcus spp.* Anaerobic bacteria: Treatment of soft tissue infections (deep wounds and abscesses) and dental infections caused by or associated with susceptible strains of *Clostridium perfringens and Bacteroides fragilis.*

(3) *Limitations.* Wound infections, abscesses, and dental infections: Do not use for more than 4 days if no improvement of acute infection is observed. Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas, or ruminating animals. Use with caution in animals receiving neuromuscular blocking agents, because clindamycin may potentiate their action. Prescribe with caution in atopic animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1145 [Amended]

6. Section 522.1145 *Hyaluronate sodium injection* is amended in paragraph (a)(2) by removing ''000016'' and adding in its place ''000009''.

Dated: November 6, 1996.

Robert C. Livingston,

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

[FR Doc. 96–29696 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin With Pyrantel Pamoate

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 Merck Research Laboratories, Division of Merck & Co., Inc., for chewable tablets containing ivermectin with pyrantel pamoate. The product is used to prevent canine heartworm disease and to treat and control ascarid and hookworm