[FR Doc. 97–7676 Filed 3–25–97; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor from TRINADA, Inc., to ALPHARMA INC.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: TRINADA, Inc. (a wholly owned subsidiary of A. L. Pharma, Inc.), One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024 has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 91–668 (*Chlortetracycline*, *procaine penicillin*, and *sulfamethazine*) to ALPHARMA INC., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024. Accordingly, the agency is amending the regulations in 21 CFR 558.145 to reflect the change of sponsor and also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing TRINADA, Inc., because the firm is no longer the sponsor of any approved NADA's.

List of Subjects

21 CFR Part 510

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

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 510 and 558 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).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry ''TRINADA, Inc.'', and in the table in paragraph (c)(2) by removing the entry ''058690''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. 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).

§ 558.145 [Amended]

4. Section 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* is amended in paragraph (a)(1) by removing the number ''058690'' and adding in its place ''046573''.

Dated: March 17, 1997.

Robert C. Livingston,

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

[FR Doc. 97–7548 Filed 3–25–97; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Hygromycin B, Pyrantel Tartrate, and Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of the two new animal drug applications (NADA's) held by Land O'Lakes, Inc., (one for use of tylosin and one for tylosin/sulfamethazine Type A medicated articles), and three NADA's held by ADM Animal Health and Nutrition Div. (one for use of pyrantel tartrate, one for hygromycin B, and one for tylosin/sulfamethazine Type A medicated articles). In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADA's. The sponsors requested the withdrawal of approval of the NADA's.

EFFECTIVE DATE: April 2, 1997.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: Land O'Lakes, Inc., Agricultural Services, 2827 Eighth Avenue South, Fort Dodge, IA 50501, is the sponsor of NADA's 42–489 tylosin (see 21 CFR 558.625(b)(53)) and 98–156 tylosin/sulfamethazine (see § 558.630(b)(3) (21 CFR 558.630(b)(3)). ADM Animal Health and Nutrition Div., P.O. Box 2508, Fort Wayne, IN 46801–2508, is the sponsor of NADA 118–874 pyrantel tartrate (see 21 CFR 558.485(a)(4)) (formerly held by Henwood Feed Additives, Inc.), NADA 127–825 hygromycin B (see 21 CFR 558.274(a)(4) and (c)(1)(i) and (c)(1)(ii)), and NADA 127–826 tylosin/sulfamethazine (see § 558.630(b)(10)) (both formerly held by Music City Supplement Co.). The sponsors requested withdrawal of approval of the NADA's. The animal drug regulations are amended to remove those portions which reflect approval of these NADA's.

Also, with the withdrawal of approval of these NADA's, Land O'Lakes and Music City Supplement Co. are no longer sponsors of approved NADA's. Therefore, 21 CFR 510.600(c)(1) and (c)(2) are amended to remove entries for these firms.

List of Subjects

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 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).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) by removing the entries for ''Land O'Lakes, Inc.,'' and ''Music City Supplement Co.'', and in paragraph (c)(2) by removing the entries for ''017519'' and ''034500''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. 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).

§ 558.274 [Amended]

4. Section 558.274 *Hygromycin B* is amended in paragraphs (a)(4) and (c)(1)(i) and (c)(1)(ii) by removing the number ''017519,''.

§ 558.485 [Amended]

5. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraph (a)(4).

§ 558.625 [Amended]

6. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(53).

§ 558.630 [Amended]

7. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(3) by removing the number ''034500'' and in paragraph (b)(10) by removing the number ''017519,''.

Dated: March 13, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–7541 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron 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 Ciba-Geigy Animal Health Corp. The NADA provides for oral administration of lufenuron tablets to cats and kittens 6 weeks of age and older for the control of flea populations.

EFFECTIVE DATE: March 26, 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.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health Corp., P.O. Box 18300, Greensboro, NC 27419–8300, filed NADA 141–062, which provides for oral administration of Program® (Lufenuron) Cat Flavor Tablets for cats and kittens 6 weeks of age or older, for the control of flea populations. The drug is given orally, once a month, at a minimum of 13.6 milligrams (mg) of lufenuron per pound of body weight (30 mg/kilogram), in tablets containing 135 or 270 mg lufenuron each. Lufenuron has no deleterious effect on adult fleas, but it prevents most flea eggs from hatching or maturing into adults. The NADA is approved as of March 3, 1997, and the regulations are amended in 21 CFR 520.1288(a) and (d) 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 3, 1997, because the NADA contains substantial evidence of effectiveness of the drug involved or any studies of animal safety, required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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 520.1288 is amended by revising paragraphs (a), (d) (1), and (d) (3) to read as follows:

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) *Dogs.* Each tablet contains either 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron.

(2) *Cats.* Each regular tablet contains either 90 or 204.9 mg lufenuron, each flavor tablet contains 135 or 270 mg lufenuron.

* * * * *

(d) *Conditions of use in cats*—(1) *Amount.* Minimum of 13.6 mg lufenuron per pound (lb) of body weight (30 mg per kilogram). Recommended 90 mg regular tablet for cats up to 6 lb of body weight, 204.9 mg regular tablet for 7 to 15 lb, 135 mg flavor tablet for up to 10 lb, 270 mg flavor tablet for 11 to 20 lb. Cats over 15 lb (regular tablet) or over 20 lb (flavor tablet) are provided the appropriate combination of tablets.

* * * * *

(3) *Limitations.* For oral use in cats or kittens 6 weeks of age or older, once a month, directly or broken and mixed with wet food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

Dated: March 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–7549 Filed 3–25–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin and Clorsulon

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. The supplemental NADA provides for persistent control of gastrointestinal roundworms and lungworms following use of ivermectin and clorsulon injection for cattle.

EFFECTIVE DATE: March 26, 1997.

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