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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]
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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".