

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

SMB

Display Date	6-15-01
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Certifier	SRREESE

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 the change of sponsor for three approved new animal drug applications (NADAs) for oxytetracycline premixes from Pfizer, Inc., to Phibro Animal Health, Inc. The drug labeler code for Phibro Animal Health, Inc., is also being listed.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 8-804 for Terramycin® (oxytetracycline) Type A medicated articles, NADA 38-439 for Terramycin® (oxytetracycline) for fish, and NADA 95-143 for OXTC® (oxytetracycline) Type A medicated articles to Phibro Animal Health, Inc., One Parker Plaza, Fort Lee, NJ 07024. Accordingly, the agency is amending the regulations in 21 CFR 558.450 to reflect the transfer of ownership.

In addition, Phibro Animal Health, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c)(1) and (c)(2) is being amended to add entries for the firm.

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NADA 008-0804
NADA 038-0439
NADA 095-~~043~~
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This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

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: 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 alphabetically adding an entry for "Phibro Animal Health, Inc." and in the table in paragraph (c)(2) by numerically adding an entry for "066104" 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
Phibro Animal Health, Inc., One Parker Plaza, Fort Lee, NJ 07024	066104

(2) * * *

Drug labeler code	Firm name and address
066104	Phibro Animal Health, Inc., One Parker Plaza, Fort Lee, NJ 07024

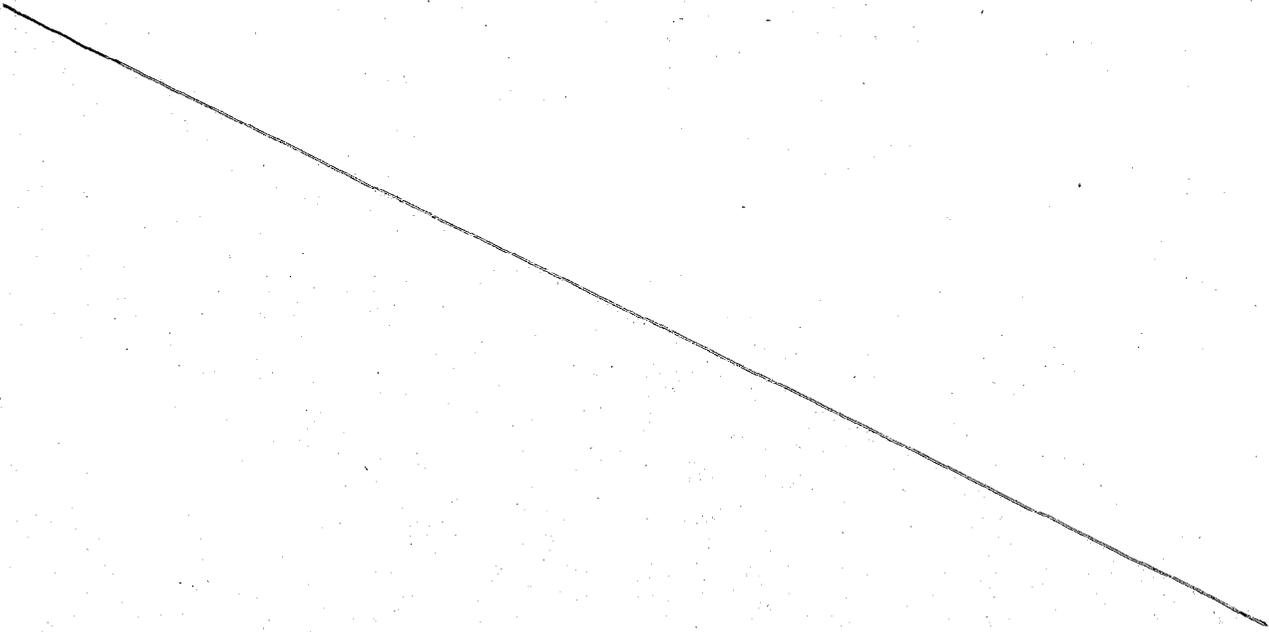
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

§ 558.450 [Amended]

4. Section 558.450 *Oxytetracycline* is amended in paragraph (a)(1) by removing “000069” and by adding in its place “066104”; and in table 1 in paragraphs (d)(1)(i), (d)(1)(v), (d)(1)(vii),



and (d)(1)(viii), under the "Sponsor" column, and in table 2 in paragraphs (d)(2)(i) through (d)(2)(iii), under the "Sponsor" column, by removing "000069" and by adding in its place "066104".

Dated: June 8, 2001
June 8, 2001.

Claire M. Lathers

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Suzette N. Reese