



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Chloramphenicol, Diethylcarbamazine Citrate, Hygromycin B, Methoxyflurane, Neomycin Sulfate, Penicillin G, Phenylbutazone, Pyrantel Tartrate, Tylosin Phosphate, and Sulfamethazine

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 withdrawal of approval of 20 new animal drug applications (NADAs).

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The sponsors of the 20 approved NADAs listed in

table 1 of this document have requested that FDA withdraw approval because the products are no longer manufactured or marketed:

Table 1.--Voluntary Requests for Withdrawal of Approval (WOA) of 20 NADAs

Application No.	Trade Name (drug)	Applicant
NADA 014-485	METOPHANE Inhalation (methoxyflurane)	Medical Developments, International, Ltd., P.O Box 21, Sandown Village, 3171 VIC Australia.
NADA 032-322	LIQUISONE F with Cerumene (hexamethyltetracosane, prednisolone, tetracaine, neomycin sulfate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 044-655	NEOMYCANE Ophthalmic Ointment (neomycin sulfate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 045-288	OPTISONE (neomycin sulfate, prednisolone acetate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 049-890	NORCO T-2 Pre-Pak (tylosin phosphate)	Norco Mills of Norfolk, Inc., ,P.O. Box 56, Norfolk, NE 68701.
NADA 055-034	CHLORASOL (chloramphenicol)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.

NADA 055-052	Chlora-Tabs 100 (chloramphenicol)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 065-158	CHLORICOL (chloramphenicol)	Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 065-259	CHLORASONE Ophthalmic Ointment (chloramphenicol, prednisolone acetate)	Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 065-488	BENZA-PEN (penicillin G benzathine, penicillin G procaine)	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.
NADA 095-953	MOORMABOOST TY 4000 Medicated (tylosin phosphate)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 100-689	DIFIL Syrup (diethylcarbamazine citrate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 100-690	DIFIL Tablets (diethylcarbamazine citrate)	Evsco Pharmaceuticals, An Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 107-957	TYLAN 20 Sulfa-G (tylosin phosphate and sulfamethazine)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.

NADA 111-069	TYLAN 40 Sulfa-G (tylosin phosphate and sulfamethazine)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 131-956	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 131-957	TYLAN 40 (tylosin phosphate)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 133-490	Ban-D-Wormer II BANMINTH (pyrantel tartrate)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 140-842	HYGROMIX 2.4 Premix (hygromycin B)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 140-958	EQUIPHEN Paste (phenylbutazone) 520.1720c	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.

In a notice published elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 014-485, 032-322, 044-655, 045-288, 049-890, 055-034, 055-052, 065-158, 065-259, 065-488, 095-953, 100-689, 100-690, 107-957, 111-069, 131-956, 131-957, 133-490, 140-842, and 140-958, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval and a current format.

Following these withdrawals of approval, Evsco Pharmaceuticals, an Affiliate of IGI, Inc.; Medical Developments International, Ltd.; and Norco Mills of Norfolk, Inc., are no longer

the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

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 520, 522, 524, and 529

Animal drugs.

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, 520, 522, 524, 529, 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.

§ 510.600 [Amended]

2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Evsco Pharmaceuticals, An Affiliate of IGI, Inc.”, “Medical Developments International, Ltd.”, and

“Norco Mills of Norfolk, Inc.”; and in the table in paragraph (c)(2), remove the entries for “017030”, “025245”, and “027190”.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

4. Revise § 520.390a to read as follows:

§ 520.390a Chloramphenicol tablets.

(a) Specifications. Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.

(b) Sponsors. See § 510.600(c) of this chapter:

(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:

(i) No. 000010 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;

(ii) No. 000856 for 100-, 250-, and 500-mg tablets;

(iii) No. 000069 for 250-mg tablets.

(2) For use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section:

(i) No. 061623 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;

(ii) [Reserved]

(c) Conditions of use in dogs--(1) Amount. Administer 25 mg per pound of body weight by mouth every 6 hours.

(2) Indications for use--(i) For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

§ 520.622a [Amended]

5. In § 520.622a, remove and reserve paragraph (a)(4).

§ 520.622b [Amended]

6. In § 520.622b, remove and reserve paragraph (b).

§ 520.1720c [Amended]

7. In § 520.1720c, in paragraph (b)(1), remove “Nos. 000061 and 010797” and in its place add “No. 000061”.

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

9. In § 522.1696a, revise paragraphs (b)(1), (b)(3), (d)(1)(iii), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(1) Nos. 000856, 055529, and 061623 for use as in paragraph (d)(1) of this section.

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(3) No. 000856 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) Limitations. Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) Limitations. Not for use within 30 days of slaughter. For Nos. 055529, 059130, and 061623: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

10. The authority citation for 21 CFR part 524 continues to read as follows:

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

11. Revise § 524.390 to read as follows:

§ 524.390 Chloramphenicol ophthalmic ointment.

(a) Specifications. Each gram contains 10 milligrams chloramphenicol.

(b) Sponsors. See Nos. 000856 and 025463 in §510.600(c) of this chapter.

(c) Conditions of use in dogs and cats--(1) Amount. Apply every 3 hours around the clock for 48 hours, after which night instillations may be omitted.

(2) Indications for use. For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§§ 524.390a, 524.390b, and 524.390d [Removed]

12. Remove §§ 524.390a, 524.390b, and 524.390d.

§§ 524.1484a, 524.1484j, and 524.1484k [Removed]

13. Remove 524.1484a, 524.1484j, and 524.1484k.

§§ 524.1880 [Removed]

14. Remove 524.1880.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

15. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1455 [Removed]

16. Remove 529.1455.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.274 [Amended]

18. In § 558.274, remove and reserve paragraph (a)(7); and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), in the “Sponsor” column, remove “012286”.

§ 558.485 [Amended]

19. In paragraph (b)(3) of § 558.485, remove “012286”.

§ 558.625 [Amended]

20. In § 558.625, remove and reserve paragraphs (b)(10), (b)(12), and (b)(67).

§ 558.630 [Amended]

21. In § 558.630, remove and reserve paragraph (b)(2) and in paragraph (b)(5), remove “012286”.

Dated: January 26, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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