

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

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

#### Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of New Animal Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of 16 new animal drug applications (NADAs) and 1 abbreviated NADA (ANADA) because they are no longer manufactured or marketed. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of these NADAs.

**DATES:** This rule is effective [*insert date 10 days after date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Pamela K. Esposito, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7818, e-mail: [pesposit@cvm.fda.gov](mailto:pesposit@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** The following sponsors have requested that FDA withdraw approval of the 16 NADAs and 1 ANADA listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
Abbott Laboratories, North Chicago, IL 60064	NADA 99-568, FURANACE Caps (nifurpirinol)	529.1526 (000074)

TABLE 1.—Continued

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407	NADA 140–889, DERM–OTIC Ointment (neomycin sulfate; nystatin; thiostrepton; triamcinolone acetonide)	524.1600a (000332)
First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123	NADA 48–646, THERAZONE Injection (phenylbutazone)	522.1720 (058829)
Happy Jack, Inc., Snow Hill, NC 28580	NADA 121–556, Selenium Sulfide Suspension (selenium disulfide) NADA 121–723, Nitrofurazone Dressing NADA 125–137, FILARICIDE Capsules (diethylcarbamazine citrate)	524.2101 (023851) 524.1580b (023851) 520.622d (023851)
IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544	NADA 92–151, N-Butyl Chloride Canine Worming Caps NADA 65–065, Tetracycline HCl Caps NADA 138–900, Dichlorophene/Toluene	520.260 (000115) 520.2345a (000115) 520.580 (000115)
Jorgensen Laboratories, Inc., 1450 North Van Buren Ave., Loveland, CO 80538	NADA 10–481, SUREJETS (salicylic acid)	529.2090 (048087)
Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia	ANADA 200–232, GEOMYCIN 200 Injection (oxytetracycline)	522.1660a (011722)
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812	NADA 65–113 AUREO Sulfa Soluble Powder (chlor-tetracycline/sulfamethazine)	N/A (017800)
Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298	NADA 140–848, VETEEZE Injection (diazepam)	522.575 (063238)
Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960	NADA 131–806, Furosemide Tablets	520.1010 (000093)
Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	NADA 10–886, Purina Liquid Wormer (piperazine citrate)	N/A (051311)
Wyeth Laboratories, Division American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101	NADA 10–782, SPARINE Injection (promazine) NADA 55–008, BICILLIN Fortified (penicillin G benzathine and penicillin G procaine)	522.1962 (000008) 522.1696a (000008)

Following the withdrawal of approval of these NADAs, Biocraft Laboratories, Inc., IMPAX Laboratories, Inc., Jorgensen Laboratories, Inc., Pliva d.d., and Teva Pharmaceuticals USA are no longer sponsors of an approved application. Therefore, we are removing entries for these five sponsors from 21 CFR 510.600(c).

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals and a current format. In addition, FDA has noticed that the regulations do not reflect approved NADA 065–063 for Tetracycline Capsules sponsored by Eon Labs Manufacturing, Inc. At this time, the regulations in 21 CFR 520.2345a are amended to reflect this approved product.

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 Parts 520, 522, 524, and 529*

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, 522, 524, and 529 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. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entries for “Biocraft Laboratories, Inc.”, “IMPAX Laboratories, Inc.”, “Jorgensen Laboratories, Inc.”, “Pliva d.d.”, and “Teva Pharmaceuticals USA”; and in the table in paragraph (c)(2) by removing the entries for “000093”, “000115”, “000332”, “011722”, and “045087”.

**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.

**§ 520.260 [Amended]**

■ 4. Section 520.260 is amended in paragraph (b)(2) by removing “000115 or”; and by removing paragraph (c).

**§ 520.580 [Amended]**

■ 5. Section 520.580 is amended in paragraph (b)(1) by removing “, 000115”.

■ 6. Section 520.622d is revised to read as follows:

**§ 520.622d Diethylcarbamazine citrate capsules.**

(a) *Specifications.* Each capsule contains 12.5, 50, 200, or 400 milligrams (mg) diethylcarbamazine citrate.

(b) *Sponsor.* See No. 011014 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount/indications for use.* 3 mg per pound (/lb) body weight daily for prevention of heartworm disease (*Dirofilaria immitis*); 25 to 50 mg/lb body weight in a single dose as an aid in the treatment of ascarid infections (*Toxocara canis* and *Toxascaris leonina*).

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

**§ 520.1010 [Amended]**

■ 7. Section 520.1010 is amended by removing paragraph (b)(2); and by redesignating paragraphs (b)(3) and (b)(4) as paragraphs (b)(2) and (b)(3), respectively.

■ 8. Section 520.2345a is revised to read as follows

**§ 520.2345a Tetracycline hydrochloride capsules.**

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams (mg) tetracycline hydrochloride.

(b) *Sponsor.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000009: 250 mg per capsule.

(2) No. 000069: 125, 250, or 500 mg per capsule.

(3) No. 000185: 50, 100, 250, or 500 mg per capsule.

(c) *Conditions of use in dogs*—(1) *Amount*. 25 mg per pound of body weight per day in divided doses every 6 hours.

(2) *Indications for use*. For treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus spp.* and *E. coli*.

(3) *Limitations*. 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**

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

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

**§ 522.575** [Removed]

■ 10. Section 522.575 is removed.

**§ 522.1660a** [Amended]

■ 11. Section 522.1660a is amended in paragraph (b) by removing “, 011722”.

**§ 522.1696a** [Amended]

■ 12. Section 522.1696a is amended in paragraph (b)(1) by removing “000008,”.

**§ 522.1720** [Amended]

■ 13. Section 522.1720 is amended in paragraph (b)(1) by removing “, 058829”.

■ 14. Section 522.1962 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 522.1962** **Promazine hydrochloride.**

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(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 000856 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

(2) No. 061623 for use as in paragraphs (c)(1)(i)(B), (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*—(A) 0.2 to 0.5 milligrams per pounds (mg/lb) body weight intramuscularly or intravenously every 4 to 6 hours.

(B) 0.2 to 0.5 mg/lb body weight intravenously as required.

(ii) *Indications for use*—(A) For use as a tranquilizer, preanesthetic, or for minor operative procedures in conjunction with local anesthesia; and as adjunctive therapy for tetanus.

(B) For use as a tranquilizer and preanesthetic.

(iii) *Limitations*. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount*. 1 to 2 mg/lb body weight intramuscularly or intravenously every 4 to 6 hours.

(ii) *Indications for use*. For use as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic prior to worming; or to prevent motion sickness in dogs.

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

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

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

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

- 16. Section 524.1580b is amended by redesignating paragraph (c) as paragraph (d); by reserving new paragraph (c); and by revising paragraph (b) and newly redesignated paragraph (d) to read as follows:

**§ 524.1580b Nitrofurazone ointment.**

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(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) See Nos. 000010, 000069, 050749, 051259, 058005, and 061623 for use on dogs, cats, or horses.

(2) See No. 017135 for use on dogs and horses.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain on the lesion for at least 24 hours. Use of a bandage is optional.

(2) *Indications for use.* For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.

(3) *Limitations.* For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

**§ 524.1600a [Amended]**

- 17. Section 524.1600a is amended in paragraph (b) by removing “, 000332”.

■ 18. Section 524.2101 is amended by revising paragraphs (b) and (c) to read as follows:

**§ 524.2101     Selenium disulfide suspension.**

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(b) *Sponsors.* See Nos. 000061, 017135, and 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use on dogs—(1) Indications for use.* For use as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema, seborrhea, and nonspecific dermatoses.

(2) *Amount.* One to 2 ounces per application.

(3) *Limitations.* Use carefully around scrotum and eyes, covering scrotum with petrolatum. Allow the shampoo to remain for 5 to 15 minutes before thorough rinsing. Repeat treatment once or twice a week. If conditions persist or if rash or irritation develops, discontinue use and consult a veterinarian.

**PART 529—OTHER DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 529.1526     [Removed]**

■ 20. Section 529.1526 is removed.

**§ 529.2090 [Removed]**

■ 21. Section 529.2090 is removed.

Dated: June 30, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**