

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 15 CFR Part 280, Subpart D

Application for Insignia.

■ For the reasons set forth in the preamble, the National Institute of Standards and Technology and the United States Patent and Trademark Office amend 15 CFR Part 280, Subpart D, as follows:

PART 280—[AMENDED]

■ 1. The authority citation for Part 280 continues to read:

Authority: 15 U.S.C. 5401 *et seq.*

■ 2. Section 280.310 is amended by revising paragraph (d) to read as follows:

§ 280.310 Application for insignia.

* * * * *

(d) Applications and other documents should be addressed to: Director, United States Patent and Trademark Office, P.O. Box 16471, Arlington, VA 22215–1471 Attn: FQA

Dated: August 10, 2005.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

William Jeffrey,

Director, National Institute of Standards and Technology.

[FR Doc. 05–17020 Filed 8–25–05; 8:45 am]

BILLING CODE 3510–16–P

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.

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 September 6, 2005.

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.

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)
Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407	NADA 140–889, DERM–OTIC Ointment (neomycin sulfate; nystatin; thiostrepton; triamcinolone acetone)	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 (chlortetracycline/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)

TABLE 1.—Continued

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
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)	522.1962 (000008)
	NADA 55–008, BICILLIN Fortified (penicillin G benzathine and penicillin G procaine)	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.

* * * * *

(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.

* * * * *

(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.

* * * * *

(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. 05-16995 Filed 8-25-05; 8:45 am]

BILLING CODE 4160-01-S

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 226

[Aid Reg 226]

RIN 0412-AA55

Administration of Assistance Awards to U.S. Non-Governmental Organizations; Marking Requirements

AGENCY: Agency for International Development (USAID).

ACTION: Final rule.

SUMMARY: This final rule implements the statutory requirement that all USAID programs be marked appropriately overseas as “American Aid.” It does so by adding a USAID regulation that requires recipients of USAID funded grants and cooperative agreements and other assistance awards—with certain Presumptive Exceptions and subject to a waiver if warranted by specific conditions in the cooperating country—to mark programs, projects, activities, public communications, and commodities with the USAID Standard Graphic Identity (USAID Identity, defined below).

EFFECTIVE DATES: January 2, 2006.

FOR FURTHER INFORMATION CONTACT: John Niemeyer (or designee), Assistant General Counsel, Office of the General Counsel, USAID, Rm. 6.06.95, 1300 Pennsylvania Ave., NW., Washington, DC 20523; telephone: (202) 712-4776 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On December 20, 2004, USAID published in the *Federal Register* (69 FR 75885-75887) a proposed rule to implement fully Section 641 of the Foreign Assistance Act of 1961, as amended. The Agency provided a forty five (45)-day public comment period on the proposed rule, which ended on February 3, 2005. The Agency also offered the public the opportunity to submit comments by surface mail, e-mail or fax.

I. Background

The marking of foreign aid as assistance from the U.S. Government was first required during the Marshall Plan when Congress became concerned about poorly marked U.S. foreign aid donations to European countries. USAID’s framework legislation, the Foreign Assistance Act of 1961, as amended, section 641, requires that all programs under the Foreign Assistance Act, including assistance awards, be identified appropriately overseas as “American Aid.” While USAID has required its contractors to mark U.S.