

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0149]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 16 new animal drug applications (NADAs) and 1 abbreviated NADA (ANADA) because the products are no longer manufactured or marketed. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of the NADAs.

DATES: Withdrawal of approval 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-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7818, or 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)

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, thioestrepton, triamcinolone acetanide)	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 (oxy-tetracycline)	522.1660a (011722)
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812	NADA 10–886 Purina Liquid Wormer (piperazine citrate)	n/a (051311)
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 65–113, AUREO Sulfa Soluble Powder (chlortetracycline/sulfamethazine)	520.445a (051311)
Wyeth Laboratories, Division of 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)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 10–481, 10–782, 10–886, 48–646, 55–008, 65–065, 65–113, 99–568, 121–556, 121–723, 125–137, 131–806, 138–900, 140–848, 140–889, and ANADA 200–232, and all supplements and amendments thereto, is hereby withdrawn, effective [insert date 10 days after date of publication in the **Federal Register**].

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these NADAs.

Dated: July 5, 2005.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

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

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