

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0179]

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Certifier	<i>Deborah Oliver</i>

Purina Mills, Inc., et al.; 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 11 new animal drug applications (NADAs) listed below. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove the portions reflecting approval of the NADAs because the products are no longer manufactured or marketed.

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, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

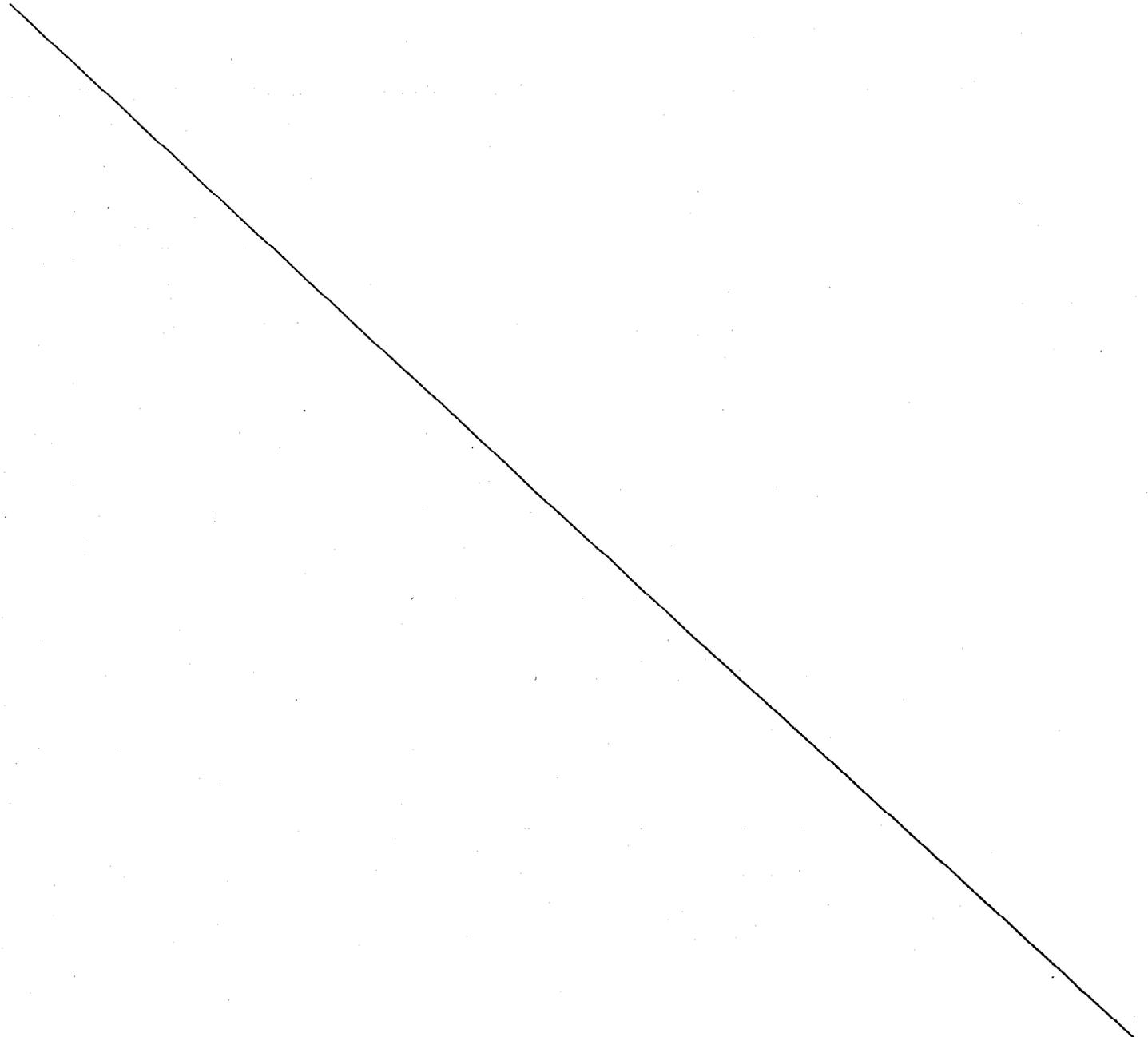
SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA No. Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812.	NADA 48-915 Purina® Bot Control (trichlorfon)	520.2520a (017800)
Golden Sun Feeds, Inc., 111 South Fifth St., Estherville, IA 51334.	NADA 97-567 Tylan® 10 Premix (tylosin phosphate).	558.625(b)(17) (021780)
.....	NADA 97-615 Swine Med-A-Mix TS 8000 Premix, Tylan® 5, 10, 20, 40 Sulfa-G (tylosin phosphate and sulfamethazine).	558.630(b)(4) and (b)(10) (021780)
Quali-Tech Products, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318-1093.	NADA 110-440 Hygromix Hygrowormer Hyanthelmix (hygromycin B).	558.274(a)(2), (a)(3), (a)(4), (c)(1)(i), and (c)(1)(ii) (016968)
Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043-4705.	NADA 44-585 Oxytocin Injection	522.1680 (000402)
.....	NADA 45-578 Lidocaine Hydrochloride with Epinephrine Injection 2%.	522.1258 (000402)
.....	NADA 45-737 Sodium Pentobarbital Injection	522.1704(b) (000402)
.....	NADA 45-848 Phenylbutazone Injection	522.1720 (000402)
.....	NADA 110-349 Dexamethasone Injection	522.540(c)(2) (000402)
.....	NADA 110-350 Dexamethasone Injection	522.540(b)(2)(ii) (000402)

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Sponsor	NADA No. Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
.....	NADA 117-973 Prednisolone Sodium Succinate for Injection.	522.1884(c) (000402)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), re delegated 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 44-585, 45-578, 45-737, 45-848, 48-915, 97-567, 97-615, 110-349, 110-350, 110-440, and 117-973, 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: 5/2/01
May 2, 2001.

Stephen F. Sundlof
Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Wanda Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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