



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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 20 new animal drug applications (NADAs) at the sponsor's request 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:

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SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the 20 NADAs listed in table 1 of this document because the products are no longer manufactured or marketed:

Table 1.--NADAs for Which Approval Is Voluntarily Withdrawn

Application No.	Trade Name (drug)	Applicant
NADA 014-485	METOPHANE Inhalation (methoxyflurane)	Medical Developments, International Ltd., 556 Morris Ave., Summit, NJ 07901-1330.
NADA 032-322	LIQUIZONE 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)	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given 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 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 applications.

Dated: January 26, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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