

genuine and substantial issue of fact that precludes the withdrawal of approval of the MFA's, or that the request for a hearing is not made in the required format or with the required analysis, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued as soon as practicable.

All submissions under this notice shall be filed in four copies and, except as provided in 21 CFR 10.20(j), may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act

(sec. 512 (21 U.S.C. 360b)) and under authority delegated to the Director, Center For Veterinary Medicine (21 CFR 5.84).

Dated: April 19, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-10274 Filed 4-25-95; 8:45 am]

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[Docket No. 95N-0101]

Warren Teed Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 107 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 107 abbreviated new drug applications (ANDA's). The holders of

the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: May 26, 1995.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Center for Drug Evaluation and Research (HFD-360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
83-076	Sulfasalazine, 500 milligrams (mg)	Warren Teed Pharmaceuticals, Inc., Columbus, OH 43215.
83-078	Chlorpheniramine Maleate Tablets, 4 mg	Anabolic, Inc., P.O. Box C-19508, Irvine, CA 92713.
83-135	Lidocaine Hydrochloride Injection, U.S.P., 1% and 2%	G. D. Searle and Co., P.O. Box 5110, Chicago, IL 60680.
83-168	Hydrocortisone Liquid, 1% and 2 1/2%	Dermik Laboratories, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426-0107.
83-169	Hydrocortisone Gel, 1% and 2 1/2%	Do.
83-184	Propoxyphene Hydrochloride Capsules, 65 mg	Smith, Kline & French, One Franklin Plaza, P.O. Box 7929, Philadelphia, PA 19101.
83-275	Diphenhydramine Hydrochloride Capsules, U.S.P., 50 mg	Anabolic, Inc.
83-301	Pentobarbital Sodium Capsules, 100 mg	Purepac Pharmaceutical, Co., 200 Elmora Ave., Elizabeth, NJ 07207.
83-313	Triamcinolone Acetonide Ointments, 0.025%, 0.1%, and 0.5%.	Dermik Laboratories, Inc.
83-314	Triamcinolone Acetonide Creams, 0.025%, 0.1%, and 0.5%.	Do.
83-363	Metaraminol Bitartrate Injection, U.S.P., 10 mg/milliliters (mL).	Elkins-Sinn, Inc., Two Esterbrook Lane, Cherry Hill, NJ 08003-4099.
83-554	Hydrochlorothiazide Tablets, 50 mg	Smith, Kline & French.
83-567	Diphenhydramine Hydrochloride Capsules, 50 mg	West-Ward Pharmaceutical Corp., 465 Industrial Way, West, Eatontown, NJ 07724.
83-625	Tripelennamine Hydrochloride Tablets, U.S.P., 25 mg	Warner-Lambert, 201 Tabor Rd., Morris Plains, NJ 07950.
83-626	Tripelennamine Hydrochloride Tablets, U.S.P., 50 mg	Do.
84-125	Dextroamphetamine Sulfate Tablets, 5 mg and 10 mg	Purepac Pharmaceutical, Co.
84-239	Hydrocortisone Tablets, 10 mg	Warner-Lambert.
84-240	Prednisone Tablets, 5 mg	Do.
84-242	Prednisolone Tablets, 5 mg	Do.
84-530	Aminophylline Tablets, 200 mg	The Vale Chemical Co., Inc., Allentown, PA 18102.
84-531	Aminophylline Tablets, 100 mg	Do.
84-601	Chlordiazepoxide Hydrochloride Capsules, 10 mg	Mylan Pharmaceuticals, Inc., P.O. Box 4310, 781 Chestnut Ridge Rd., Morgantown, WV 26505-4310.
84-699	Aminophylline Tablets, 100 mg	Purepac Pharmaceutical, Co.
84-739	Theophylline Elixir, 80 mg/15 mL	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
84-880	Hydrochlorothiazide Tablets, 25 mg and 50 mg	Mylan Pharmaceuticals, Inc.
85-112	Hydrochlorothiazide Tablets, 50 mg	Do.
85-195	Mecizine Hydrochloride Tablets, 12.5 mg	Circa Pharmaceuticals, 15 Grand Park Blvd., Athens, OH 45701.
85-375	Acetaminophen Capsules, 500 mg Oxycodone Hydrochloride Capsules, 4.5 mg Oxycodone Terephthalate Capsules, 0.38 mg.	McNeil Pharmaceutical, Welsh and Mckee Rds., Spring House, PA 19477-0776.
85-534	Sulfisoxazole Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hempstead, NY 11552.
85-564	Aminophylline Tablets, 200 mg	Do.
85-567	Aminophylline Tablets, 100 mg	Do.