

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 99N-4004]

**Wallace Laboratories et al.; Withdrawal of Approval of 18 New Drug Applications and 44 Abbreviated New Drug Applications**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 18 new drug applications (NDA's) and 44 abbreviated new drug applications (ANDA's). The holders of the applications 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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:** September 22, 1999.**FOR FURTHER INFORMATION CONTACT:**

Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food

and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of the applications 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.

Application No.	Drug	Applicant
NDA 4-253	Davitamin Tablets	Wallace Laboratories, 301B College Rd., East, Princeton, NJ 08540.
NDA 5-932	5% Aminosol	Abbott Laboratories, One Abbott Park Rd., Abbott Park, IL 60064-3500.
NDA 6-668	Redisol (cyanocobalamin) Tablets and Injection.	Merck & Co., Inc., 5 Sentry Pkwy., East (BLA-10), Blue Bell, PA 19422.
NDA 7-842	Flaxedil (gallamine triethiodide injection), 20 milligrams (mg)/milliliter (mL).	Kendall Healthcare Products Co., 15 Hampshire St., Mansfield, MA 02048.
NDA 9-295	Vibazine (buclizine hydrochloride) Tablets.	Pfizer Pharmaceuticals, 235 East 42d St., New York, NY 10017-5755.
NDA 10-460	Preludin (phenmetrazine hydrochloride) Tablets.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 10-639	Hydeltrasol (prednisolone sodium phosphate ophthalmic solution) Sterile Ophthalmic Solution.	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486.
NDA 11-612	Daricon (oxyphenylcyclamine hydrochloride) Tablets.	Pfizer Pharmaceuticals.
NDA 11-752	Preludin (phenmetrazine hydrochloride) Endurets.	Boehringer Ingelheim Pharmaceuticals, Inc.
NDA 17-497	Synthetic Calcimar (calcitonin-salmon) for Injection.	Rhone-Poulenc Rorer Pharmaceuticals, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426-0107.
NDA 18-208	Pfi-Lith (lithium carbonate) Capsules.	Pfizer Pharmaceuticals.
NDA 18-237	Calciparine (heparin calcium) Injection.	Sanofi Pharmaceuticals, Inc., 90 Park Ave., New York, NY 10019.
NDA 18-342	Wellcovorin (leucovorin calcium) Tablets.	Glaxo Wellcome, Inc., 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709.
NDA 18-499	Lactated Ringer's and Dextrose Injection USP.	Miles, Inc., Pharmaceutical Div., 4th and Parker Sts., P.O. Box 1986, Berkeley, CA 94701.
NDA 18-933	MVI-12 Powder	Astra USA, Inc., P.O. Box 4500, Westborough, MA 01581-4500.
NDA 19-498	Parathar (teriparatide acetate) for Injection.	Rhone-Poulenc Rorer Pharmaceuticals, Inc.
NDA 20-841	Lotemax (loteprednol etabonate ophthalmic suspension), 0.5% Ophthalmic Suspension.	Pharmos Corp., c/o Bausch & Lomb Pharmaceuticals, Inc., 8500 Hidden River Pkwy., Tampa, FL 33637.
NDA 50-762	Trovan/Zithromax Compliance Pak (trovafloxacin mesylate/azithromycin for oral suspension).	Pfizer Pharmaceuticals.
ANDA 60-082	Tetracycline (tetracycline) Capsules.	Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755.
ANDA 60-290	Tetracycline Hydro-chloride Capsules USP, 250 mg and 500mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 60-458	Terramycin (oxytetracycline with polymyxin B sulfate) Topical Powder with Polymyxin B Sulfate.	Pfizer, Inc.
ANDA 60-586	Terramycin (oxytetracycline) IV.	Do.
ANDA 60-595	Terramycin (oxytetracycline) Syrup.	Do.
ANDA 60-731	Bacitracin Neomycin-Polymyxin with Hydrocortisone Acetate Ophthalmic Ointment 1%.	Altana, Inc., 60 Baylis Rd., Melville, NY 11747.
ANDA 61-009	Terra-Poly (oxytetracycline, polymyxin B sulfate) Vaginal Tablets.	Pfizer, Inc.
ANDA 61-010	Terramycin (oxytetracycline) Tablets.	Do.
ANDA 61-277	Penicillin G Potassium Tablets for Oral Solution USP.	Teva Pharmaceuticals, USA, 1510 Delp Dr., Kulpville, PA 19443.
ANDA 61-841	Terramycin (oxytetracycline) with Polymyxin B Sulfate Otic Ointment.	Pfizer, Inc.
ANDA 62-288	Gentamicin Sulfate Injection, 40 mg/mL.	Bristol Laboratories, P.O. Box 4755, Syracuse, NY 13221-4755.
ANDA 62-289	Gentamicin Sulfate Injection USP.	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
ANDA 62-598	Neomycin Sulfate-Triamcinolone Acetonide Cream.	Savage Laboratories, Inc., Division of Altana Inc., 60 Baylis Rd., Melville, NY 11747.
ANDA 62-607	Neomycin Sulfate-Triamcinolone Acetonide Ointment.	Pharmaderm, Division of Altana, Inc., 60 Baylis Rd., Melville, NY 11747.

Application No.	Drug	Applicant
ANDA 70-656	Dopamine Hydrochloride Injection USP, 40 mg/mL.	Abbott Laboratories.
ANDA 70-657	Dopamine Hydrochloride Injection USP, 80 mg/mL.	Do.
ANDA 73-611	Diphenhydramine Hydrochloride Cough Syrup, 12.5 mg/5 mL.	Cumberland-Swan, Inc., 1 Swan Dr., Smyrna, TN 37167.
ANDA 80-195	Potassium Chloride Injection.	Miles, Inc.
ANDA 80-211	Prednisolone Tablets, 5 mg.	Private Formulations, Inc., 460 Plainfield Ave., Edison, NJ 08818.
ANDA 80-830	Vitamin A Capsules USP, 15 mg.	Del Ray Labs, Inc., 22-20th Ave., NW., Birmingham, AL 35215.
ANDA 83-021	Sulfacetamide Sodium Ophthalmic Solution USP, 10%, 15%, and 30%.	AKORN, Inc., 1222 West Grand, Decatur, IL 62526.
ANDA 83-256	Alcohol in Dextrose Injection USP, 5%/5%.	Baxter Healthcare Corp., Rte. 120 and Wilson Rd., Round Lake, IL 60073-0490.
ANDA 84-652	Chlorotrianisene Capsules USP, 12 mg.	Banner Pharmacaps, 200730 Dearborn St., P.O. Box 2157, Chatsworth, CA 91313-2157.
ANDA 84-708	Triamcinolone Tablets, 2 mg.	Roxane Laboratories, Inc., P.O. Box 16532, Columbus, OH 43216-6532.
ANDA 84-775	Triamcinolone Tablets, 4 mg.	Teva Pharmaceuticals, USA.
ANDA 85-697	Phendimetrazine Tartrate Tablets, 35 mg (pink).	Private Formulations, Inc.
ANDA 85-914	Phendimetrazine Tartrate Tablets, 35mg.	Manufacturing Chemist, Inc., c/o Integrity Pharmaceutical Corp., 5767 Thunderbird Rd., Indianapolis, IN 46236.
ANDA 86-192	Hydrochlorothiazide Tablets, 25 mg and 50 mg.	M. M. Mast & Co., 4152 Ruple Rd., Cleveland, OH 44121.
ANDA 86-217	Chlordiazepoxide Capsules, 10 mg.	Do.
ANDA 86-259	Trichlormethiazide, 4 mg.	Do.
ANDA 86-521	Dextroamphetamine Sulfate Tablets, 5 mg.	Do.
ANDA 86-523	Phenazine Capsules, 35 mg.	Do.
ANDA 86-524	Phenazine Capsules, 35 mg.	Do.
ANDA 86-525	Phenazine Capsules, 35 mg.	Do.
ANDA 86-787	Sustac (nitroglycerin) Extended-release Oral Tablets, 10 mg.	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022-4731.
ANDA 87-255	Quinidine Sulfate Tablets, 200 mg.	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
ANDA 87-229	Nitrobon (nitroglycerin extended-release capsules) Capsules.	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022-4731.
ANDA 87-305	Phendimetrazine Tartrate Tablets, 35 mg.	M. M. Mast & Co.
ANDA 87-544	Nitrobon (nitroglycerin extended-release capsules) Capsules.	Inwood Laboratories, Inc.
ANDA 87-917	Theophylline Syrup, 80 mg/15 mL.	Ferndale Laboratories, Inc., 780 West Eight Mile Rd., Ferndale, MI 48220.
ANDA 89-577	Hydrocortisone Sodium Succinate for Injection USP, 100 mg/mL.	Abbott Laboratories.
ANDA 89-578	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 250 mg/vial.	Do.
ANDA 89-579	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 500 mg/vial.	Do.
ANDA 89-580	A-Hydrocort (Hydrocortisone Sodium Succinate for Injection USP), 1 gram/vial.	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective September 22, 1999.

Dated: September 8, 1999.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cardiovascular and Renal Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and

recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 14, 1999, 9 a.m. to 5:30 p.m.

*Location:* National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8-15 minutes during rush hour and every 15 minutes at other times.

*Contact Person:* Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5630 Fishers Lane,