

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 80 new drug applications (NDAs) and 75 abbreviated new drug applications (ANDAs). 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approval of the applications be withdrawn.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 17, 2003

**FOR FURTHER INFORMATION CONTACT:** Florine P. Purdie, 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 requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 0-159	Sulfapyridine Tablets.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 0-734	Histamine Phosphate Injection.	Do.
NDA 5-970	Sotradecol (sodium tetradecyl sulfate) Injection.	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 7-898	Benemid (probenecid) Tablets.	Merck & Co., Inc., Sunneytown Pike, P.O. Box 4, BLA-20, West Point, PA 19486.
NDA 8-048	Xylocaine (lidocaine) Ointment.	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803-8355.
NDA 8-228	Hydrocortone (hydrocortisone acetate) Acetate Injectable Suspension.	Merck & Co., Inc.
NDA 8-565	Thiosulfil (sulfamethizole) Tablets and Suspension.	Wyeth Pharmaceuticals.
NDA 9-489	Pathilon (tridehixethyl) Tablets.	Lederle Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 10-210	Metymid Ophthalmic (prednisolone acetate and sulfacetamide sodium).	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 10-220	Hypaque-M 75% and 90% Hypaque Compound (diatrizoate meglumine and diatrizoate sodium) Injection.	Amersham Health, 101 Carnegie Center, Princeton, NJ 08540-6231.
NDA 10-348	Sparine (promazine hydrochloride (HCl)) Tablets.	Wyeth Pharmaceuticals.
NDA 10-496	Xylocaine-MPF 5% Solution With Glucose 7.5% (lidocaine HCl and dextrose).	AstraZeneca Pharmaceuticals LP.
NDA 10-562	Hydeltra-T.B.A. (prednisolone tebutate).	Merck & Co., Inc.
NDA 10-753	Estradurin (polyestradiol phosphate) Injection.	Wyeth Pharmaceuticals.
NDA 10-942	Sparine (promazine HCl) Syrup and Concentrate.	Do.
NDA 11-338	Fluothane Inhalation (halothane USP).	Do.
NDA 11-418	Dimetane Ten Injectable (brompheniramine maleate).	Do.
NDA 11-673	Tepanil (diethylpropion HCl) Tablets.	3M Pharmaceuticals, 3M Center, Bldg. 270-3A-01, St. Paul, MN 55144-1000.
NDA 11-958	Hydropres (reserpine and hydrochlorothiazide).	Merck & Co., Inc.
NDA 12-383	ColBenemid (probenecid and colchicine) Tablets.	Do.
NDA 12-418	Akineton (biperiden lactate) Injection.	Abbott Laboratories, 200 Abbott Park Rd., Abbott Park, IL 60064-6157.
NDA 12-489	Exna (benzthiazide) Tablets.	Wyeth Pharmaceuticals.