

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0191]

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**Determination That Protamine Sulfate Injection and 26 Other Drug Products
Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 27 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) for the drug products, and it will allow FDA to continue to approve ANDAs for the products.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical

testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

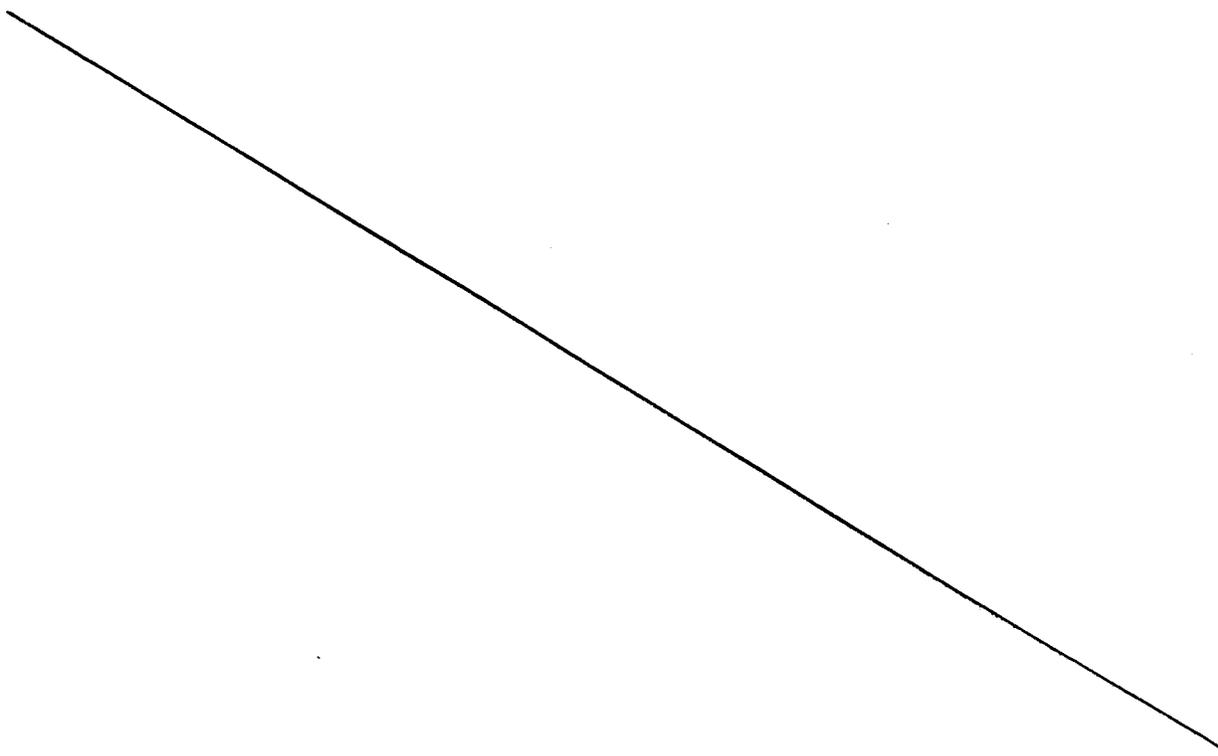
Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 6-460 for Protamine Sulfate Injection, NDA 18-675 for TAVIST Syrup, NDA 19-243 for PROVENTIL Inhalation Solution, NDA 19-471 for CARDIZEM SR Capsules, and NDA 19-817 for PERSANTINE

Injection in the **Federal Register** of March 4, 2005 (70 FR 10651), NDA 8-857 for PHENERGAN Injection in the **Federal Register** of May 5, 2004 (69 FR 25124), and NDA 13-400 for ALDOMET Tablets and NDA 13-401 for ALDOMET Injection in the **Federal Register** of June 16, 2006 (71 FR 34940)).

Application No.	Drug	Applicant
NDA 6-460	Protamine Sulfate Injection, 10 milligrams (mg)/milliliter (mL) in a 25-mL vial	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 6-773	ARTANE (trihexyphenidyl hydrochloride (HCl)) Tablets, 2 mg and 5 mg	Lederle, c/o Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 8-857	PHENERGAN (promethazine HCl) Injection, 25 mg/mL and 50 mg/mL in 1-mL vials	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101-8299
NDA 9-149	THORAZINE (chlorpromazine HCl) Tablets, 10, 25, 50, 100, and 200 mg	GlaxoSmithKline, 2301 Renaissance Blvd., King of Prussia, PA 19406
NDA 11-145	DIURIL (chlorothiazide) Tablets, 250 mg and 500 mg	Merck & Co., Inc., Sumneytown Pike, BLA-20, P.O. Box 4, West Point, PA 19486
NDA 11-664	DECADRON (dexamethasone) Tablets, 0.25, 4, and 6 mg	Do.
NDA 11-808	MELLARIL (thioridazine HCl) Tablets, 10, 15, 25, 50, 100, 150, and 200 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936
NDA 11-870	DIURIL (chlorothiazide) Suspension, 250 mg/5 mL	Merck & Co., Inc.
NDA 13-400	ALDOMET (methylodopa) Tablets, 125, 250, and 500 mg	Do.
NDA 13-401	ALDOMET (methylodopate HCl) Injection, 50 mg/mL	Do.
NDA 16-363	LASIX (furosemide) Injection, 10 mg/mL	Aventis Pharmaceuticals, Inc., 200 Crossing Blvd., Bridgewater, NJ 08807-0890
NDA 17-391	IMURAN (azathioprine) Injection, 100 mg base/vial	Prometheus Laboratories, 5739 Pacific Center Blvd., San Diego, CA 92121-4203
NDA 17-939	TAGAMET (cimetidine HCl) Injection, 300 mg/2 mL	GlaxoSmithKline
NDA 18-513	CHENIX (chenodiol) Tablets, 250 mg	Axcan Scandipharm, Inc., 22 Inverness Center Parkway, Birmingham, AL 35242-4814
NDA 18-675	TAVIST (clemastine fumarate) Oral Syrup, 0.5 mg/5 mL	Novartis Consumer Health, Inc., 200 Kimball Dr., Parsippany, NJ 07054-0622
NDA 18-922	LODINE (etodolac) Capsules, 200 mg; LODINE Tablets, 400 mg and 500 mg	Wyeth Pharmaceuticals, Inc.
NDA 19-201	VOLTAREN (diclofenac sodium) Delayed-Release Tablets, 25 mg and 50 mg	Novartis Pharmaceuticals, Inc.
NDA 19-243	PROVENTIL (albuterol sulfate) Inhalation Solution, 0.5% and 0.083%	Schering-Plough Corporation, 2000 Galloping Hill Rd., Kenilworth, NJ 07033
NDA 19-434	TAGAMET HCl (cimetidine HCl) in Sodium Chloride 0.9% in Plastic Container, EQ 6 mg/mL	GlaxoSmithKline
NDA 19-471	CARDIZEM SR (diltiazem HCl) Capsules, 60, 90, 120, and 180 mg	Biovail Laboratories, Inc., c/o Biovail Technologies Ltd., 700 Route 202/206 North, Bridgewater, NJ 08807-0980
NDA 19-817	PERSANTINE (dipyridamole) Injection, 5 mg/mL	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368
NDA 20-144	TRANSDERM-NITRO (nitroglycerin), 0.1 mg/hour (hr), 0.2 mg/hr, 0.4 mg/hr, 0.6 mg/hr, 0.8 mg/hr	Novartis Pharmaceuticals Corp.
NDA 20-584	LODINE (etodolac) XL Tablets, 600 mg	Wyeth Pharmaceuticals, Inc.
NDA 21-110	RAPAMUNE (sirolimus) Tablets, 5 mg	Wyeth Pharmaceuticals, Inc.
NDA 50-477	NEBCIN (tobramycin sulfate) Injection, 10 mg/mL	Eli Lilly and Co.
NDA 50-519	NEBCIN (tobramycin sulfate) Injection, 1.2 grams/vial	Do.
ANDA 62-008	NEBCIN (tobramycin sulfate) Injection, 40 mg/mL	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs and ANDA listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDA. Additional ANDAs for the products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.



Dated: 5/15/07
May 15, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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