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Dated: July 18, 1995,

**William B. Schultz,**

*Deputy Commissioner for Policy.*

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[Docket No. 95N-0207]

**Owen/Galderma, et al.; Withdrawal of Approval of 1 New Drug Application, 23 Abbreviated New Drug Applications, and 5 Abbreviated Antibiotic Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 1 new drug application (NDA), 23 abbreviated new drug applications (ANDA's), and 5 abbreviated antibiotic applications (AADA'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writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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:** August 21, 1995.

**FOR FURTHER INFORMATION CONTACT:** Lola Batson, 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 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.

Appication no.	Drug	Applicant
ANDA 18-795 .....	Hydrocortisone Butyrate Cream, 0.1% .....	Owen/Galderma, 6201 South Freeway, P.O. Box 6600, Forth Worth, TX 76115.
NDA 50-610 .....	Erythromycin U.S.P. for Extemporaneous Compounding of Topical Solutions.	Paddock Laboratories, Inc., P.O. Box 27286, Minneapolis, MN 55427.
AADA 62-656 .....	Nystatin and Triamcinolone Acetonide Ointment, U.S.P.	Pharmafair, Inc., 8500 Hidden River Pkwy., Tampa, FL 33637.
AADA 62-657 .....	Nystatin and Triamcinolone Acetonide Cream, U.S.P.	Do.
AADA 63-183 .....	Cefamandole Naftate for Injection, U.S.P., bulk ...	Richmar International, Inc., 1706 Birch Rd., McLean, VA 22101.
AADA 63-184 .....	Sterile Cefamandole Naftate, U.S.P. ....	Do.
AADA 64-018 .....	Amikacin Sulfate, U.S.P., nonsterile bulk .....	Do.
ANDA 70-077 .....	Nitroglycerin Injection, U.S.P., 5 milligrams (mg)/milliliter (mL).	Fujisawa USA, Inc., 3 Parkway North, 3rd floor, Deerfield, IL 60015-2548.
ANDA 70-524 .....	Dephenhydramine Hydrochloride Syrup, 12.5 mg/5 mL.	The Procter and Gamble Co., Sharon Woods Technical Center, 11450 Grooms Rd., Cincinnati, OH 45242-1434.
ANDA 70-648 .....	Naloxone Hydrochloride Injection, U.S.P., 0.02 mg/mL.	Fujisawa USA, Inc.
ANDA 70-649 .....	Naloxone Hydrochloride Injection, U.S.P., 0.04 mg/mL.	Do.
ANDA 72-191 .....	Clofibrate Capsules, U.S.P., 500 mg .....	Geneva Pharmaceuticals, Inc., 2555 West Midway Blvd., P.O. Box 446, Broomfield, CO 80038-0446.
ANDA 83-951 .....	Acetaminophen and Codeine Phosphate Tablets, U.S.P., 300 mg/30 mg and 300 mg/60 mg.	Burroughs Wellcome Co., 3030 Cornwallis Rd., P.O. Box 12700, Research Triangle Park, NC 27709-2700.
ANDA 83-963 .....	Quinidine Sulfate Tablets, U.S.P., 200 mg .....	Vintage Pharmaceuticals, Inc., 3241 Woodpark Blvd., Charlotte, NC 28206.
ANDA 84-301 .....	Hydralazine Hydrochloride Tablets, U.S.P., 25 mg	Lemmon Co., Inc., 650 Cathill Rd., Sellersville, PA 18960.
ANDA 84-969 .....	Hydrocortisone Ointment, U.S.P., 0.5% .....	Clay-Park Labs., 1700 Bathgate Ave., Bronx, NY 10457.
ANDA 84-970 .....	Hydrocortisone Cream, U.S.P., 0.5% .....	Do.
ANDA 85-026 .....	Hydrocortisone Cream, U.S.P., 1% .....	Do.
ANDA 85-500 .....	Phentermine Hydrochloride Tablets, U.S.P., 8 mg	Lemmon Co.
ANDA 85-662 .....	Hydrocortisone Lotion, U.S.P., 0.5% .....	Clay-Park Labs.
ANDA 86-095 .....	Chlorpheniramine Maleate Injection, U.S.P., 100 mg/mL.	Steris Laboratories, Inc., P.O. Box 23160, Phoenix, AZ 85063-3160.
ANDA 86-606 .....	Aminophylline Injection, U.S.P., 25 mg/mL .....	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620.
ANDA 88-123 .....	Isosorbide Dinitrate Tablets, U.S.P., 10 mg, sublingual.	Zeneca Pharmaceuticals, 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437.
ANDA 88-407 .....	Aminophylline Injection, U.S.P., 25 mg/mL, 100 mL vials.	Fujisawa USA, Inc.
ANDA 88-448 .....	Dexamethasone Sodium Phosphate Injection, U.S.P., 4 mg/mL, vials.	Do.
ANDA 88-645 .....	Dicyclomine Hydrochloride Capsules, U.S.P., 20 mg.	Lemmon Co.