

Dated: March 14, 2000.

Carolyn J. Russell,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention (CDC).*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0568]

FMC Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 8A4605) proposing that the food additive regulations be amended to provide for the safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 27, 1998 (63 FR 40126), FDA announced that a food additive petition (FAP 8A4605) had been filed by FMC Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 172.846 *Sodium stearoyl lactylate* (21 CFR 172.846) to provide for the expanded safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups. FMC Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: February 23, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-0988]

Lilly Research Laboratories et al.; Withdrawal of Approval of 22 New Drug Applications and 36 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 22 new drug applications (NDA's) and 36 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective April 19, 2000.

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 6-139	Surfacaine (cyclomethycaine).	Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 6-904	Terfonyl (trisulfapyrimidines) Tablets and Oral Suspension.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000.
NDA 9-357	Rau-Sed (reserpine) Tablets.	Do.
NDA 9-523	Tyzine 0.1% (tetrahydrozoline HCl).	Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755.
NDA 9-941	Tyzine 0.05% (tetrahydrozoline HCl) Pediatric Nasal Drops.	Do.
NDA 10-520	Leritine (anileridine HCl) Injection	Merck & Co., Inc., P.O. Box 4, BLA-20, West Point, PA 19486.
NDA 11-028	Hydeltrasol (prednisolone sodium phosphate) Sterile Ophthalmic Ointment, 0.25%.	Do.
NDA 11-178	Isuprel (isoproterenol hydrochloride) Mistometer.	Sanofi Winthrop, Inc., 90 Park Ave., New York, NY 10016-1389.
NDA 11-602	Kenalog (triamcinolone acetonide) Lotion.	Bristol-Myers Squibb Co.
NDA 12-335	Forhistal (dimethindene maleate) Tablets.	Novartis Pharmaceuticals Corp., 59 Route 10, East Hanover, NJ 07936-1080.
NDA 12-337	Forhistal (dimethindene maleate) Syrup.	Do.
NDA 12-338	Forhistal (dimethindene maleate) Pediatric Drops.	Do.
NDA 16-755	Diapid (Lypressin Nasal Solution USP) Nasal Spray.	Novartis Pharmaceuticals Corp.
NDA 16-990	Intal (Cromolyn Sodium for Inhalation USP) Capsules.	Rhone-Poulenc Rorer Pharmaceuticals, Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426-0107.
NDA 17-605	Xylo-Pfan (Xylose USP) Powder.	Savage Laboratories, 60 Baylis Rd., Melville, NY 11747.
NDA 19-215	FEMSTAT (butoconazole nitrate) 2% Vaginal Cream (prescription).	Hoffmann-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110-1199.
NDA 19-359	FEMSTAT (butoconazole nitrate) Suppositories, 100 milligrams (mg).	Do.