

should be sent to the Document Control Unit, Center for Veterinary Medicine (HFV-199), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

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writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.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.

Appication no.	Drug	Applicant
ANDA 89-222 .....	Hydralazine Hydrochloride Tablets, U.S.P., 50 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 89-252 .....	Isoetharine Hydrochloride Inhalation Solution, U.S.P., 1%.	Dey Laboratories, 2751 Napa Valley Corporate Dr., Napa, CA 94558.
ANDA 89-554 .....	Hydrocodone Bitartrate and Acetaminophen Tablets, U.S.P., 5 mg/500 mg.	Halsey Drug Co., Inc.

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 and supplements thereto, is hereby withdrawn, effective August 21, 1995.

Dated: July 5, 1995.

**Murray M. Lumpkin,**

*Deputy Director, Center for Drug Evaluation and Research.*

[FR Doc. 95-17923 Filed 7-20-95; 8:45 am]

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#### Advisory Committees; Notice of Meetings

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

**ACTION:** Notice.

**SUMMARY:** This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETINGS:** The following advisory committee meetings are announced:

#### Dental Drug Products Panel Plaque Subcommittee (Nonprescription Drugs) of the Medical Devices Advisory Committee

*Date, time, and place.* August 14 and 15, 1995, 9 a.m., Parklawn Bldg., conference room G, 5600 Fishers Lane, Rockville, MD.

*Type of meeting and contact person.* Open public hearing, August 14, 1995, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; open public hearing, August 15, 1995, 9 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 5 p.m.; Jeanne L. Ripperer or Stephanie A. Mason, Center for Drug Evaluation and Research (HFD-813), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-1003, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Dental Products Panel of the Medical Devices Advisory Committee, code 12518.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

The Dental Products Panel of the Medical Devices Advisory Committee functions at times as a nonprescription drug advisory panel. As such, the panel reviews and evaluates available data concerning the safety and effectiveness of active ingredients, and combinations thereof, of various currently marketed nonprescription drug products for human use, the adequacy of their labeling, and advises the Commissioner of Food and Drugs on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on the general issues pending before the subcommittee. Those desiring to make formal presentations should

notify the contact person before August 9, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

*Open committee discussion.* The subcommittee will continue with its discussion begun during the December 5 through 7, 1994, meeting, and continued at the April 10 through 12, 1995, meeting on developing general guidelines for determining the safety and effectiveness of antiplaque and antiplaque-related drug products. The subcommittee will also begin discussion on the safety and effectiveness of the ingredient cetylpyridinium chloride and a product containing an enzyme blend (amylase, protease, and lipase) with aloe vera for antiplaque and antiplaque-related uses.

#### Cardiovascular and Renal Drugs Advisory Committee

*Date, time, and place.* August 28, 1995, 9 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

*Type of meeting and contact person.* Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or Valerie M. Mealy, Advisors and Consultants Staff (HFD-9), 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the