DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0035]

Ashland Chemical Co.; 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 6A4490) proposing that the food additive regulations be amended to provide for the safe use of polypropylene glycol with a molecular weight of 1,200 to 3,000 as a defoaming agent in water for sliced potatoes.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 3, 1997 (62 FR 5011), FDA announced that a food additive petition (FAP 6A4490) had been filed by Ashland Chemical Co., One Drew Plaza, Boonton, NJ 07005. The petition proposed to amend the food additive regulations in § 173.340 Defoaming agents (21 CFR 173.340) to provide for the safe use of polypropylene glycol with a molecular weight of 1,200 to 3,000 as a component of defoaming agents in wash water for sliced potatoes. Ashland Chemical Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 10, 1997.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval.

[FR Doc. 97–31215 Filed 11–26–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0479]

Parke-Davis et al.; Withdrawal of Approval of 18 New Drug Applications, 7 Abbreviated Antibiotic Applications, and 53 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 18 new drug applications (NDA's), 7 abbreviated antibiotic applications (AADA's), and 53 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agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: December 29, 1997.

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 6–413	Super Anahist (neohetramine hydrochloride)	Parke-Davis, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 7–812	Inhiston-APC (aspirin 3.5 grains (gr), caffeine 0.5 gr, phenacetin 2.5 gr, pheniramine maleate 10 milligrams (mg).	Plough, Inc., P.O. Box 377, Memphis, TN 38151.
NDA 9–108	Rauval (rauwolfia serpentina) Tablets	Glenwood-Palisades, P.O. Box 369, One New England Ave., Piscataway, NY 08855.
NDA 11–760	Normacol (polycarbophil) Tablets	Schering Corp., 2000 Galloping Hill Rd., Kenilworth, NY 07033.
NDA 11–935	Actifed (pseudoephedrine hydrochloride and triprolidine hydrochloride) Syrup.	Glaxo Wellcome Inc., Five Moore Dr., Research Triangle Park, NC 27709.
NDA 11–936	Actifed (pseudoephedrine hydrochloride and triprolidine hydrochloride) Tablets.	Do.
NDA 11–950	Tacaryl (methdilazine hydrochloride) Syrup, 4 mg/15 milliliters (mL).	Westwood-Squibb Pharmaceuticals, Inc., 100 Forest Ave., Buffalo, NY 14213–1091.
NDA 12–939	Neutrapen (penicillinase injectable)	3M Pharmaceuticals, Bldg. 260–6A–22, 3M Center, St. Paul, MN 55144–1000.
NDA 15–438	Meprobamate Tablets USP, 200 mg, 400 mg	Zenith Goldline Pharmaceuticals, 140 Legrand Ave., Northvale, NJ 07647.
NDA 16–649	Feminone Tablets	Pharmacia & Upjohn, 7000 Portage Rd., Kalamazoo, MI 49001–0199.
NDA 17–369	Teldrin (chlorpheniramine maleate extended release) Spansules.	SmithKline Beecham Consumer Healthcare, 1500 Littleton Rd., Parsippany, NY 07054–3884.
NDA 17–906	Lactulose Syrup	Solvay Pharmaceuticals, Inc., 901 Sawyer Rd., Marietta, GA 30062.
NDA 19–014	Benylin Decongestant Cough Formula (diphenhydramine hydrocholoride and pseudoephedrine hydrochloride).	Warner-Lambert Co., 170 Tabor Rd., Morris Plains, NJ 07950.
NDA 50–125	Tablets Remanden-250 (Potassium Penicillin G with Probenecid).	Merck & Co., Inc., BLA–30, West Point, PA 19486.
NDA 50–137	Cer-O-Cillin Sodium (crystalline sodium penicillin O).	Pharmacia & Upjohn

Application No.	Drug	Applicant
NDA 50–298	Pyopen (sterile carbenicillin disodium) Injection	SmithKline Beecham Pharmaceuticals, P.O. Box 7929, Philadelphia, PA 19101–7929.
NDA 50–375	Cremomycin Oral Suspension	Merck & Co., Inc.
NDA 50–566	Sterile Cefazolin Sodium Injection in PL146 Plastic Container.	Baxter Healthcare Corp., Rt. 120 and Wilson Rd., Round Lake, IL 60073–0490.
AADA 60–571	MYCOSTATIN (Nystatin) Ointment 100,000 USP units per gram (g).	Westwood-Squibb Pharmaceuticals, Inc.
AADA 60–634	Oxytetracycline Hydrochloride Capsules USP, 250 mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
AADA 62–471	Gentamicin Sulfate Cream, USP 0.1%	Alpharma, U.S. Pharmaceuticals Div., Johns Hopkins Bayview Center, 333 Cassell Dr., suite 3500, Baltimore, MD 21224.
AADA 62–496	Gentamicin Sulfate Ointment, USP 0.1%	Do.
AADA 62–583	Bacitracin (sterile)	Alpharma AS, U.S. Agent: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024.
AADA 62–584	Bacitracin Zinc (nonsterile)	Do.
AADA 63–250	Amoxicillin Trihydrate, nonsterile bulk	Ranbaxy Laboratories Ltd., U.S. Agent: Ranbaxy Pharmaceuticals, Inc., 4600 Marriott Dr., suite 100, Raleigh, NC 27612.
ANDA 70–136	Propranolol Hydrochloride Injection USP, 1 mg/mL (syringe).	SoloPak Laboratories, 1845 Tonne Rd., Elk Grove Village, IL 60007–5125.
ANDA 70–579	Allopurinol Tablets USP, 100 mg	Purepac Pharmaceutical Co.
ANDA 70–688	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/25 mg.	Do.
ANDA 70–695	Verapamil Hydrochloride Injection USP, 2.5 mg/mL (syringe).	SoloPak Laboratories
ANDA 70–800	Haloperidol Injection USP, 5 mg/mL (syringe)	Do.
ANDA 70–853	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/15 mg.	Purepac Pharmaceutical Co.
ANDA 70–854	Methyldopa and Hydrochlorothiazide Tablets USP, 250 mg/30 mg.	Do.
ANDA 71–000	Amantadine Hydrochloride Capsules USP, 100 mg.	Solvay Pharmaceuticals, Inc.
ANDA 71–123	Ibuprofen Tablets USP, 300 mg	Purepac Pharmaceutical Co.
ANDA 71–124	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 71–125	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 71–672	Naloxone Hydrochloride Injection USP, 0.02 mg/mL (syringe).	SoloPak Laboratories
ANDA 71–683	Naloxone Hydrochloride Injection USP, 0.4 mg/mL (syringe).	Do.
ANDA 72–110	Doxepin Hydrochloride Capsules USP, 100 mg	Purepac Pharmaceutical Co.
ANDA 72–330	Clorazepate Dipotassium Tablets, 3.75 mg	Do.
ANDA 72–331	Clorazepate Dipotassium Tablets, 7.5 mg	Do.
ANDA 72–332	Clorazepate Dipotassium Tablets, 15 mg	Do.
ANDA 72–386	Doxepin Hydrochloride Capsules USP, 75 mg	Do.
ANDA 72–387	Doxepin Hydrochloride Capsules USP, 150 mg	Do.
ANDA 80–493	Cortisone Acetate Tablets USP, 25 mg	Do.
ANDA 80–842	Rauwolfia Serpentina Tablets USP, 50 mg and 100 mg.	Do.
ANDA 80–845	Diphenhydramine Hydrochloride Capsules USP, 25 mg and 50 mg.	Eon Labs Manufacturing, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
ANDA 84–138	Phendimetrazine Tartrate Tablets, 35 mg (Pink)	KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144–2555.
ANDA 84–141	Phendimetrazine Tartrate Tablets, 35 mg	Do.
ANDA 84–479	Dicyclomine Hydrochloride Syrup USP, 10 mg/5 mL.	Alpharma, U.S. Pharmaceuticals Div.
ANDA 84–932	Quinidine Sulfate USP, 200 mg (Tablets)	Solvay Pharmaceuticals, Inc.
ANDA 85–296	Quinidine Sulfate USP, 200 mg (Capsules)	Do.
ANDA 85–297	Quinidine Sulfate USP, 300 mg (Capsules)	Do.
ANDA 85–298	Quinidine Sulfate USP, 300 mg (Tablets)	Do.
ANDA 85–299	Quinidine Sulfate USP, 100 mg (Tablets)	Do.
ANDA 86–298	UNIPRES (Reserpine, Hydralazine Hydrochloride, and Hydrochlorothiazide Tablets, USP) 0.1 mg/25 mg/15 mg.	Do.
ANDA 86–822	Hydroxyzine Hydrochloride Injection USP, 25 mg/mL (syringe).	SoloPak Laboratories
ANDA 87–043	Heparin Sodium Injection USP, 1,000 units/mL (syringe).	Do.
ANDA 87–077	Heparin Sodium Injection USP, 5,000 units/mL (syringe).	Do.
ANDA 87–101	Isoetharine Inhalation Solution, USP 1%	Alpharma, U.S. Pharmaceuticals Div.

Application No.	Drug	Applicant
ANDA 87–107	Heparin Sodium Injection USP, 10,000 units/mL (syringe).	SoloPak Laboratories
ANDA 87–109	Nitroglycerin Extended-Release Capsules, 9 mg	KV Pharmaceutical Co.
ANDA 87–310	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL.	SoloPak Laboratories
ANDA 87–344	Isosorbide Dinitrate Extended-release Capsules, 40 mg.	Inwood Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–363	Heparin Sodium Injection USP, 10,000 units/0.5 mL (syringe).	SoloPak Laboratories
ANDA 87–395	Heparin Sodium Injection USP, 5,000 units/0.5 mL (syringe).	Do.
ANDA 87–551	Cyanocobalamin Injection USP, 1,000 micrograms/mL (syringe).	Do.
ANDA 87–596	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL and 100 mg/mL.	Do.
ANDA 87–903	Heparin Lock Flush Solution USP, 10 units/mL (syringe).	Do.
ANDA 87–905	Heparin Lock Flush Solution USP, 100 units/mL (syringe).	Do.
ANDA 88–120	Hydroxyzine Hydrochloride Tablets USP, 10 mg	Purepac Pharmaceutical Co.
ANDA 88–121	Hydroxyzine Hydrochloride Tablets USP, 25 mg	Do.
ANDA 88–122	Hydroxyzine Hydrochloride Tablets USP, 50 mg	Do.
ANDA 88–139	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 88–177	Hydralazine Hydrochloride Tablets, 25 mg	Do.
ANDA 88–520	Phenytoin Sodium Injection USP, 50 mg/mL (syringe).	SoloPak Laboratories
ANDA 88–532	Procainamide Hydrochloride Injection USP, 500 mg/mL (syringe).	Do.
ANDA 89–094	Trimethobenzamide Hydrochloride Injection USP, 100 mg/mL (syringe).	Do.

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 listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective December 29, 1997.

Dated: November 17, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–31214 Filed 11–26–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0451]

Microbial Safety of Produce; Grassroots and International Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing six grassroots meetings and one international meeting to discuss generally the President's recently announced initiative to ensure the safety of imported and domestic fruits and vegetables and other foods, and specifically the microbial safety of produce. The meetings are intended to give an overview of, and obtain input on the general draft guide entitled ''Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables.''

DATES AND TIME: For the domestic meetings see Table 1 in the ''**SUPPLEMENTARY INFORMATION**'' section of this document. For the international meeting see Table 2. Submit written comments by December 19, 1997. All the meetings will be held from 9 a.m. to 4 p.m.

ADDRESSES: For the domestic meetings see Table 1 in the ''**SUPPLEMENTARY INFORMATION**'' section of this document. For the international meeting see Table 2. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the ''Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruit and Vegetables'' may be obtained from Joan E. Duy, Center for Food Safety and Applied Nutrition (HFS–335), Food and Drug Administration, 200 C St. SW., rm. 3812, Washington, DC 20204, 202–260–8920, FAX 202–205–4422, e-mail jduy@bangate.fda.gov.

FOR FURTHER INFORMATION CONTACT: *For general information on this document*: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., rm. 3169, Washington, DC, 202–260–8920, FAX 202–205–4422, e-mail ceb@cfsan.fda.gov. Send registration information (including name, title, firm name, mailing address, telephone number and fax number if appropriate) to the contact person listed for the city in which you will attend.

SUPPLEMENTARY INFORMATION: On October 2, 1997, the President announced an initiative to ensure the safety of imported and domestic produce and other foods. This initiative is geared to optimize the microbial safety of domestic and imported fresh fruits and vegetables. As part of this initiative, the President directed the Secretary of the Department of Health and Human Services (DHHS), in partnership with the Secretary of the Department of Agriculture (USDA), and in cooperation with the agricultural community, to issue advice on good agricultural practices and good manufacturing practices for fresh fruits and vegetables. FDA will coordinate the effort for DHHS. As part of this effort, FDA plans to publish for public