Prevention (CDC), 1600 Clifton Road, NE, Mail Stop E–44, Atlanta, GA 30333, telephone (404) 639–1914 Email HTTP://WWW.RNK1.CDC.GOV
or
Jeff Efird, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mail Stop E–45, Atlanta, GA 30333 telephone (404) 639–6136, Email HTTP://WWW.JLE1@cdc.gov

Dated: June 15, 1999.

Henry S. Cassell III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–15632 Filed 6–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0790]

EM Industries, Inc.; Filing of Color Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a color additive petition filed by EM Industries, Inc., to clarify that the petitioner's request is to amend the color additive regulations to provide for the safe use of composite pigments made from synthetic iron oxide, titanium dioxide, and mica to color food.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1998 (63 FR 51359), FDA announced that a color additive petition (CAP 8C0262) had been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposed to amend the color additive regulations to provide for the safe use of synthetic iron oxide and mica to color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit.

The data in the petition indicated that the petitioner manufactured color additives, to color food, by combining synthetic iron oxide, mica, and titanium dioxide. Based on these data, at the time of the filing of the petition, FDA considered the color additive combinations the petitioner prepared from synthetic iron oxide, mica, and titanium dioxide to be color additive mixtures.

To more accurately describe the pigments that are the subjects of this petition, FDA is amending the filing notice of September 25, 1998, to indicate that the petition proposes to amend the color additive regulations to provide for the safe use of composite pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color food.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 2, 1999.

Alan M. Rulis,

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

[FR Doc. 99–15661 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1867]

Asahi Chemical Industry Co. and Japan Synthetic Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Asahi Chemical Industry Co. and Japan Synthetic Rubber Co. have filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,4-diphenyl-4-methyl-1-pentene (common name alpha-methylstyrene dimer) in the manufacture of coatings for food-contact paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4666) has been filed by Asahi Chemical Industry Co. and Japan Synthetic Rubber Co., c/o Environ International Corp., 4350 North Fairfax Dr., suite 300, Arlington, VA 22203. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of 2,4-diphenyl-4-methyl-1-pentene (common name alpha-methylstyrene dimer) in the manufacture of coatings for food-contact paper and paperboard.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 2, 1999.

Alan M. Rulis,

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

[FR Doc. 99–15662 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug 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) and 38 abbreviated new drug applications (ANDA's). SoloPak Laboratories, Inc., 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: July 21, 1999.

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: SoloPak Laboratories, Inc., 1845 Tonne Rd., Elk Grove Village, IL 60007–5125, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. SoloPak Laboratories, Inc.,

has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
NDA 19–961	Ganite (gallium nitrate)
ANDA 62–507	Gentamicin Sulfate Injection USP, 10 and 40 milligrams (mg)/milliliter (mL)
ANDA 62–605	Kanamycin Sulfate Injection USP, 500 mg/2 mL and 75 mg/2 mL and 1 gram/3 mL
ANDA 62–819	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 62–852	Clindamycin Phosphate Injection USP, 150 mg/mL
ANDA 70–046	Dopamine Hycrochloride Injection USP, 40 mg/mL
ANDA 70–047	Dopamine Hycrochloride Injection USP, 80 mg/mL
ANDA 70–078	Furosemide Injection USP, 10 mg/mL
ANDA 70–137	Propranolol Hydrochloride Injection USP, 1 mg/mL
ANDA 70–623	Metoclopramide Injection USP, 5 mg/mL
ANDA 70–633	Nitroglycerin Injection USP, 5 mg/mL
ANDA 70–696	Verapamil Hydrochloride Injection USP, 2.5 mg/mL
ANDA 70–801	Haloperidol Lactate Injection USP, 5 mg/mL
ANDA 70–841	Methyldopate Hydrochloride Injection USP, 50 mg/mL
ANDA 70–864	Haloperidol Injection USP, 5 mg/mL
ANDA 71–671	Naloxone Hydrochloride Injection USP, 0.02 mg/mL
ANDA 71–681	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
ANDA 71–682	Naloxone Hydrochloride Injection USP, 0.4 mg/mL
ANDA 71–754	Droperidol Injection USP, 2.5 mg/mL
ANDA 71–755	Droperidol Injection USP, 2.5 mg/mL
ANDA 87–591	Hydroxyzine Hydrochloride Injection USP, 25 mg/mL
ANDA 87–593	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 87–595	Hydroxyzine Hydrochloride Injection USP, 50 mg/mL
ANDA 88–239	Heparin Sodium Injection USP, 1,000 Units/mL
ANDA 88–457	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–458	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–459	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–460	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–517	Hydralazine Hydrochloride Injection USP, 20 mg/mL
ANDA 88–519	Phenytoin Sodium Injection USP, 50 mg/mL
ANDA 88–530	Procainamide Hydrochloride Injection USP, 100 mg/mL
ANDA 88–531	Procainamide Hydrochloride Injection USP, 500 mg/mL
ANDA 88–580	Heparin Lock Flush Solution USP, 10 Units/mL
ANDA 88–581	Heparin Lock Flush Solution USP, 100 Units/mL
ANDA 88–749	Aminophylline Injection USP, 25 mg/mL
ANDA 88–767	Fluorouracil Injection USP, 50 mg/mL
ANDA 88–960	Trimethobenzamide Hydrochloride Injection USP, 100 mg/mL
ANDA 89–251	Prochlorperazine Edisylate Injection USP, 5mg/mL
ANDA 89–434	Flourouracil Injection USP, 50 mg/mL

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 July 21, 1999.

Dated: June 7, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–15581 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1818]

Steris Laboratories, Inc.; Withdrawal of Approval of 55 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 55 abbreviated new drug applications (ANDA's). Steris Laboratories, Inc., 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: JULY 21, 1999.

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: Steris Laboratories, Inc., 620 North 51st Ave., Phoenix, AZ 85043–4705, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. Steris Laboratories, Inc., has also, by its request, waived its opportunity for a hearing.