Dated: September 17, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25641 Filed 9–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0790]

EM Industries, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that EM Industries, Inc., has filed a petition proposing that the color additive regulations be amended 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.

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: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0262) has been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposes 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 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: September 4, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–25638 Filed 9–24–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0787]

Parke-Davis Pharmaceutical Research et al.; Withdrawal of Approval of 14 New Drug Applications and 13 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 14 new drug applications (NDA's) and 13 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: September 25, 1998.

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 3–402	Pitressin Tannate in Oil (Vasopressin Tannate), 5 Pressor Units, 1 milliliter	Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 6–212	Propylthiouracil Tablets	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 10–355	Quarzan (clindium bromide) Capsules	Hoffmann-LaRoche Inc., 340 Kingsland St., Nutley, NJ 07110–1199.
NDA 12–184	Norlutate (Norethindrone Acetate) 5-milligram (mg) Tablets	Parke-Davis Pharmaceuticals, 2800 Plymouth Rd., Ann Arbor, MI 48105.
NDA 12–470	Akrinol Cream	Schering-Plough Corp., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 13–294	Azo-Gantanol (sulfa-methoxazole and phenazo-pyridine hydro-chloride) Tablets	Hoffmann-La Roche Inc.
NDA 16–020	Symmetrel (amantadine hydro-chloride) Capsules, 100 mg	Endo Pharmaceuticals, Inc., 500 Endo Blvd., Garden City, NY 11530.
NDA 16–191	Sorbitrate (isosorbide dinitrate) Sublingual Tablets, 2.5 and 5 mg	Zeneca Pharmaceuticals, a business unit of Zeneca, Inc., 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850–5437.
NDA 17–117	Symmetrel (amantadine hydro-chloride) Capsules	Endo Pharmaceuticals, Inc.
NDA 17–552	Tylenol Acetminophen Extra Strength Tablets, 500 mg	McNeil Consumer Products Co., 7050 Camp Hill Rd., Fort Washington, PA 19034–2299.
NDA 18–179	Valrelease (diazepam) Capsules	Hoffman-LaRoche Inc.
NDA 50–345	Cordran N Ointment (flurandrenolide)	Lilly Research Laboratories.
NDA 50–346	Cordran N Cream (flurandrenolide)	Do.
NDA 50–379	Sterile Ophthalmic Solution Neo-Hydeltrasol (neomycin sul-fate-prednisolone sodium phosphate ophthalmic solution)	Merck & Co., Inc., P.O. Box 4, BLA–20, West Point, PA 19486.
ANDA 62–385	Neomycin Sulfate Powder, USP (for compounding oral prod-ucts)	Paddock Laboratories, Inc., 3940 Quebec Ave. North, Min-neapolis, MN 55427.