issues set forth above and to provide a basis for any subsequent regulatory, adjudicatory or injunctive action by the Commission.

It is further ordered, That the Investigative Officer shall be Commissioner D.J.H. Won of the Commission. The Investigative Officer shall be assisted by staff members as may be assigned by the Commission's Managing Director and shall have full authority to hold public or non-public sessions, to resort to all compulsory process authorized by law (including the issuance of subpoenas ad testificandum and duces tecum), to administer oaths, to require reports, and to perform such other duties as may be necessary in accordance with the laws of the United States and the regulations of the Commission;

It is further ordered, That the Investigative Officer shall issue a report of findings and recommendations no later than 90 days after publication of this Order in the **Federal Register**, and interim reports if it appears that more immediate Commission action is necessary, such reports to remain confidential unless and until the Commission provides otherwise;

It is further ordered, That this proceeding shall be discontinued upon acceptance of the final report of findings and recommendations by the Commission, unless otherwise ordered by the Commission; and

It is further ordered, That notice of this Order be published in the **Federal Register**.

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 98–25636 Filed 9–24–98; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Safety and Occupational Health Study Section; NIOSH Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5:30 p.m., October 29, 1998; 8 a.m.–5:30 p.m., October 30, 1998.

Place: Holiday Inn, 5520 Wisconsin Ave., Washington, DC 20815.

Status: Open 8 a.m.–8:30 a.m. October 29, 1998; Closed 8:30 a.m.–5:30 p.m. October 29, 1998; Closed 8 a.m.–5:30 p.m. October 30, 1998.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas. The Study Section will also consider grant applications received in response to the Institute's numbered solicitations as follows:

Request for Application Number 98030 entitled, ''Occupational Radiation and Energy-Related Health Research Grants,'' which pertains to the following endeavors: (a) research to identify and investigate the relationships between health outcomes and occupational exposure to radiation and other hazardous agents; (b) epidemiological methods research relevant to energy-related occupational health research; and (c) research related to assessing occupational exposures. The focus of the proposed research should reflect the following topical areas, emphasizing field research: (1) retrospective exposure assessment; (2) radiation measurement issues; (3) non-cancer morbidity and mortality outcomes; (4) meta-analysis and combined analysis methodologies; (5) uncertainty analysis; (6) effects of measurement error on risk estimates; (7) studies of current workers; and (8) risk communication and worker outreach.

Request for Application Number 98056 entitled, ''Mining Occupational Safety and Health Research Grants,'' which pertains to the following endeavors: (a) research to develop knowledge that can be used to prevent occupational diseases and injuries to miners; (b) hypothesis-testing research to identify and quantify occupational health and safety hazards to miners; (c) methods and technology development to measure and control mining related safety hazards; and (d) strategies to translate research findings so that they might be applied to solve health and safety problems in mines. The focus of the proposed grants should emphasize research in the following topical areas, which are in priority order: (1) hearing loss prevention; (2) mining injury prevention; (3) dust and toxic substance control; (4) social and economic consequences of mining illness and injury; and (5) surveillance.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as tO support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene in open session from 8–8:30 a.m. on October 29, 1998, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the Safety and Occupational Health Study Section to consider safety and occupational health related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in section 552(c)(4) and (6) title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: September 18, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–25670 Filed 9–24–98; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0335]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Good Laboratory Practices (GLP) Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by October 26, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the

PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Good Laboratory Practices (GLP) Regulations for Nonclinical Studies, 21 CFR Part 58—(OMB Control Number 0910–0119—Extension)

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOP's), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOP's; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under the GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts on-site audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

In the **Federal Register** of June 10, 1998 (63 FR 31786), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
58.35(b)(7)	400	60.25	24,100	1	24,100
58.185	400	60.25	24,100	27.65	666,400
Total burden hours					690,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
58.29(b)	400	20	8,000	.21	1,700
58.35(b)(1) to (b)(6) and (c)	400	270.76	108,400	3.36	363,900
58.63(b) and (c)	400	60	24,000	.09	2,200
58.81(a) to (c)	400	301.8	120,000	.14	16,800
58.90(c) and (g)	400	62.7	25,000	.13	3,200
58.105(a) and (b)	400	5	2,000	11.8	23,600
58.107(d)	400	1	400	4.25	1,700
58.113(a)	400	15.33	6,132	6.8	41,700
58.120	400	15.38	6,160	32.7	201,200
58.195	400	251.5	100,000	3.9	392,400
Total					1,048,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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]

BILLING CODE 4160–01–F

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 hydrochloride) 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 sulfate-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 products)	Paddock Laboratories, Inc., 3940 Quebec Ave. North, Minneapolis, MN 55427.