

Diseases, Mailstop A-34, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, Telephone: (404) 639-4651, E-Mail: jsb6@cdc.gov

Dated: June 23, 1999.

John L. Williams,

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

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 98C-0431]

**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 ingested drugs.

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 June 22, 1998 (63 FR 33934), FDA announced that a color additive petition (CAP 8C0257) 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 to color ingested drugs at levels higher than the current limit and to provide for the safe use of mica to color ingested drugs.

The data in the petition indicated that the petitioner manufactured color additives, to color ingested drugs, 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. Titanium dioxide was already listed as a color additive for ingested drug use and the petition did

not propose to amend the existing regulation.

To more accurately describe the pigments that are the subjects of this petition, FDA is amending the filing notice of June 22, 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 ingested drugs.

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. 99-16527 Filed 6-28-99; 8:45 am]

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

**Biological Response Modifiers
Advisory Committee; Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 15, 1999, 8 a.m. to 5:45 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389.

Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 15, 1999, the committee will discuss the following issues: (1) An update of FDA's regulatory policy concerning the implications on biological product development of fast track and the recent pediatric rule, (2) a scientific discussion concerning immune reactions to therapeutic and diagnostic biological products, (3) the report of the June 3 through 4, 1999, meeting of the xenotransplantation subcommittee, and (4) an update of research programs in the Laboratory of Cytokine Research, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research.

Procedure: On July 15, 1999, from 8 a.m. to approximately 1 p.m., and from 1:30 p.m. to approximately 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 8, 1999. Oral presentations from the public will be scheduled between approximately 8:10 a.m. to 9:10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 8, 1999, 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 requested to make their presentation.

Closed Committee Deliberations: On July 15, 1999, from 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications. The meeting will also be closed from 5 p.m. to 5:45 p.m., to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 21, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99-16442 Filed 6-28-99; 8:45 am]

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