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Display Date	6/28/99
Publication Date	6/29/99
Certifier	J. J. [Signature]

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:

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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

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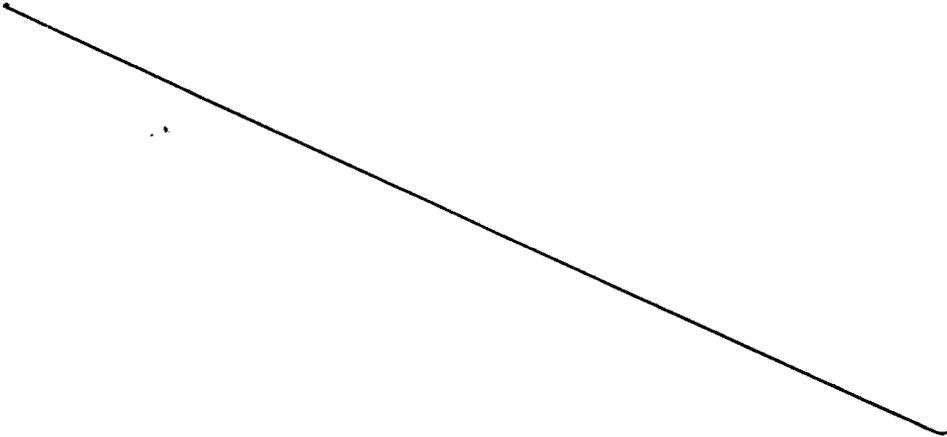
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ingested drugs at levels higher than the current limit and to provide for the safe use of mica to color ingested drugs.

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.

June 2, 1999

Alan M. Rulis

Alan M. Rulis
Director
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition

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Jen Wundson