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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:

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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

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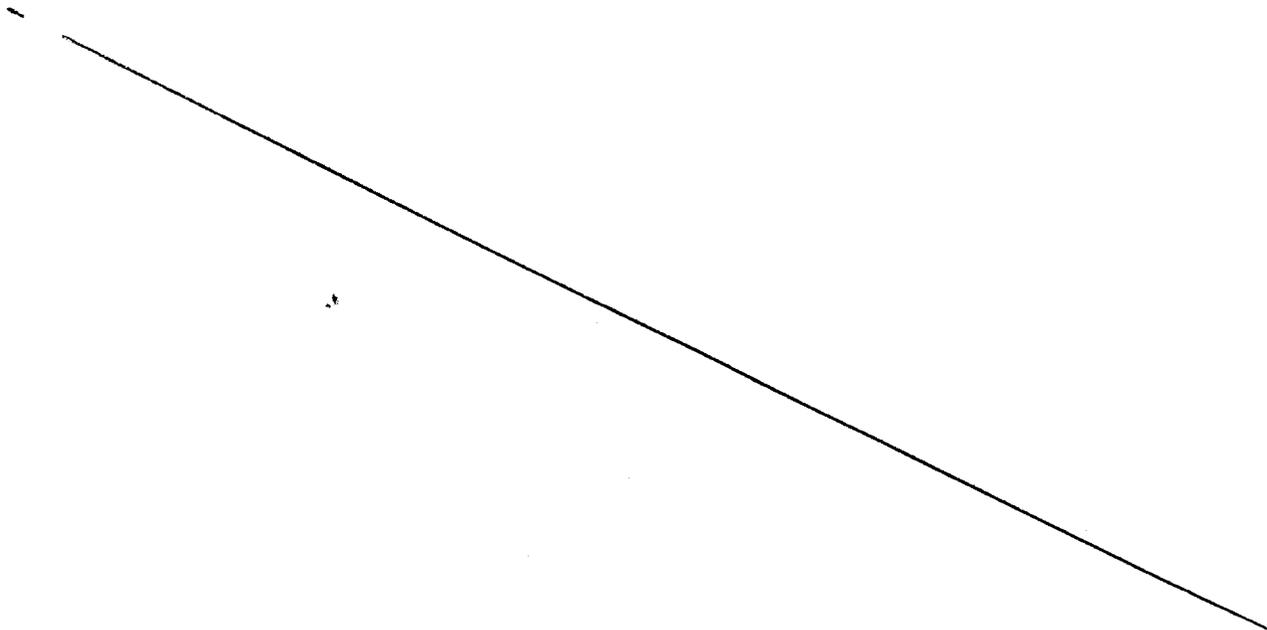
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color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit.

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.

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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