505, and 701 of the Federal Food, Drug, and Cosmetic Acts (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: September 17, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–26454 Filed 10–3–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97C–0415]

Zauder Bros., Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Zauder Bros., Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of zinc sulfide as a color additive in externally applied cosmetics.

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 7C0251) has been filed by Zauder Bros., Inc., c/o Schiff & Co., 1129 Bloomfield Ave., West Caldwell, NJ 07006. The petition proposes to amend the color additive regulations to provide for the safe use of zinc sulfide as a color additive in externally applied cosmetics.

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 11, 1997.

Alan M. Rulis,

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

[FR Doc. 97–26354 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95F–0040]

Chemie Research and Manufacturing Co., Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition filed by Chemie Research and Manufacturing Co., Inc., proposing that the food additive regulations be amended to provide for the safe use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish.

FOR FURTHER INFORMATION CONTACT: Valerie M. Davis, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3181.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 16, 1995 (60 FR 14286), FDA announced that a food additive petition (FAP 2A4336) had been filed by Chemie Research and Manufacturing Co., Inc., 160 Concord Dr., P.O. Box 181279, Casselberry, FL 32718–1279. The petition proposed that the food additive regulations be amended to provide for the safe use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish.

By letter dated May 10, 1995, the agency notified the petitioner that consideration of the petitioned use for the glycerin extract of dried grapefruit seed and pulp would require the submission and evaluation of specific additional data. By letter of June 1, 1995, the petitioner provided a partial response to the agency's request for information and stated an intent to provide a complete response within 180 days. However, no further information was submitted within the 180-day time period.

By letter of July 24, 1996, FDA again requested that the necessary data be submitted within 30 days and stated that a failure to respond would be considered to be an agreement by the petitioner to withdraw the petition. Because FDA has received no response from the petitioner, and the required information has not been submitted, the petition is now withdrawn without prejudice to a future filing (21 CFR 171.7(b)). Future consideration of the use of a glycerin extract of dried grapefruit seeds and pulp as an antimicrobial agent in the processing of fresh or frozen poultry, fish, and shellfish will require submission of a new food additive petition.

Dated: September 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26413 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0412]

Mitsui Petrochemical Industries, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mitsui Petrochemical Industries, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13 at up to 30 percent of other regulated polymer blends.

DATES: Written comments on the petitioner's environmental assessment by November 5, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration,