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]

BILLING CODE 4160–01–F

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,

200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4549) has been filed by Mitsui Petrochemical Industries, Ltd., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) 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.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before November 5, 1997 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: September 17, 1997.

Alan M. Rulis

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

[FR Doc. 97–26452 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–0414]

Stilbene Whitening Agent Task Force; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Stilbene Whitening Agent Task Force has filed a petition proposing that the food additive regulations be amended to provide for the safe use of benzenesulfonic acid,2′2′-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl-amino]-6-[(4-sulfophenyl)amino]-1,3,5-triazin-2-yl]amino]-,tetrasodium salt as an optical brightener in paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4554) has been filed by Stilbene Whitening Agent Task Force, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of benzenesulfonic acid,2′2′-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl)-amino]-6-[(4-sulfophenyl)amino]-1,3,5-triazin-2-yl]amino]-, tetrasodium salt as an optical brightener in paper and paperboard intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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 17, 1997.

Alan M. Rulis,

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

[FR Doc. 97–26453 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96P–0181]

Determination that Chlorhexidine Gluconate Topical Tincture 0.5% Was Withdrawn From Sale for Reasons of Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that chlorhexidine gluconate topical tincture 0.5% (Hibitane®) was withdrawn from sale for reasons of safety. The agency will not accept abbreviated new drug applications (ANDA's) for chlorhexidine gluconate topical tincture 0.5%.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was