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

withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

FDA regulations provide that any person may petition the agency for a determination as to whether a listed drug has been voluntarily withdrawn from sale for reasons of safety effectiveness (§ 314.161(b) (21 CFR 314.161(b))). Richard A. Hamer submitted a citizen petition dated May 24, 1996, under 21 CFR 10.25(a), 10.30, and 314.122(a), requesting that the agency determine whether chlorhexidine gluconate topical tincture 0.5% (Hibitane®) was withdrawn from sale for reasons of safety or effectiveness. Zeneca Pharmaceuticals (formerly Steuart Pharmaceuticals and ICI Americas) obtained approval of NDA 18–049 for chlorhexidine gluconate topical tincture 0.5% on December 18, 1978, as a patient preoperative skin preparation. The product was withdrawn from sale by the sponsor in early 1984. Because the sponsor discontinued marketing of the product, the agency currently lists chlorhexidine gluconate topical tincture 0.5% in the Orange Book's ''Discontinued Drug Product List.''

FDA has reviewed its records and, under §§ 314.161 and 314.162(a)(2), has determined that chlorhexidine gluconate topical tincture 0.5% was withdrawn from sale for reasons of safety. Specifically, the product was withdrawn because of the significant number of reports received concerning chemical and thermal burns associated with the use of the product. Therefore, chlorhexidine gluconate topical tincture 0.5% will be removed from the list of drug products with effective approvals published in FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' FDA will not accept ANDA's that refer to this drug product.

Dated: September 26, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26353 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0410]

Guidance for Industry on SUPAC–MR, Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes for Chemistry, Manufacturing, and Controls; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic applications (AADA's) who intend to change the components or composition, the manufacturing (process or equipment), the scale-up/scale-down of manufacture, and/or the site of manufacture of a modified release solid oral formulation during the postapproval period. This guidance document represents the agency's current thinking on scale-up and postapproval changes (SUPAC) for modified release solid oral dosage forms regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mehul U. Mehta, Center for Drug Evaluation and Research (HFD–860), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0501.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of NDA's, ANDA's, and AADA's who intend to change: (1) The components or composition; (2) the manufacturing (process or equipment); (3) the scale-up/scale-down of manufacture; and/or (4) the site of manufacture of a modified release solid oral formulation during the postapproval period. The guidance document defines the following: (1) Levels of change; (2) recommended chemistry, manufacturing, and controls (CMC) tests to support each level of change; (3) recommended in vitro dissolution release tests and/or in vivo bioequivalence tests to support each level of change; and (4) documentation to support the change.

For postapproval changes for modified release dosage forms that affect components and composition, manufacturing process or equipment changes, scale-up, and site change, this guidance supersedes the recommendations in section 4.G of the *Office of Generic Drugs Policy and Procedure Guide 22–90* (FDA, September 11, 1990). For all other dosage forms and changes, this guidance does not affect the recommendations in *Guide 22–90*.

This guidance document represents the agency's current thinking on SUPAC for modified release solid oral dosage forms regulated by CDER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance document to the Dockets Management Branch (address above). 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. A copy of the guidance