Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–10312 Filed 4–21–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0157]

Japan Vilene Co., Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Japan Vilene Co., Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774–25–9) as a fluid absorbent material intended for use in contact with food.

DATES: Written comments on the petitioner's environmental assessment by May 22, 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: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

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 7B4537) has been filed by Japan Vilene Co., Ltd., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposes to amend the food additive regulations to provide for the safe use of 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774–25–9) as a fluid absorbent material intended for use in contact with food.

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 May 22, 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 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: April 1, 1997.

Alan M. Rulis,

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

[FR Doc. 97–10415 Filed 4–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94D–0422]

Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products'' prepared by FDA's Center for Drug Evaluation and Research (CDER). The guidance is intended to assist persons involved in the production of PET radiopharmaceutical drug products in achieving compliance with FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

DATES: Persons may submit written comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. An electronic version of this guidance is available via Internet using the World Wide Web (WWW). To connect to the CDER home page, type ''http://www.fda.gov/cder'' and go to the ''Regulatory Guidance'' section. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert K. Leedham, Center for Drug Evaluation and Research (HFD–343), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–1026.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products.'' PET is a medical imaging modality used to assess the body's biochemical processes. Radionuclides are manufactured into PET radiopharmaceutical drug products that are administered to patients for medical imaging. The images of the body's biochemical processes are then evaluated, generally for diagnostic purposes.

In the **Federal Register** of February 27, 1995 (60 FR 10593), FDA announced the availability of its ''Draft Guideline on the Manufacture of Positron Emission Tomographic (PET) Drug Products.'' The notice gave interested persons an opportunity to submit comments by May 30, 1995. FDA received comments from more than 20 persons. The final PET CGMP guidance