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]

BILLING CODE 4163–18–P

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

contains revisions incorporating many of those comments.

The PET CGMP guidance discusses the requirements for manufacturing practices, procedures, and facilities used to prepare PET radiopharmaceuticals. The guidance addresses such matters as quality control units, personnel qualifications, staffing, buildings and facilities, equipment, components, containers, closures, production and process controls, packaging and labeling controls, holding and distribution, testing and release for distribution, stability testing and expiration dating, reserve samples, yields, second-person checks, reports, and records. The guidance focuses particular attention on CGMP requirements that are of special concern due to unique characteristics inherent in the production and control of PET radiopharmaceuticals.

PET radiopharmaceutical drug product manufacturing differs in a number of important ways from the manufacture of conventional drug products:

(1) Because of the short physical half-lives of PET radiopharmaceuticals, PET facilities generally manufacture the products in response to daily demand for a relatively small number of patients.

(2) Manufacturing may be limited and only a few lots produced each day.

(3) PET radiopharmaceuticals must be administered to patients within a short period of time after manufacturing because of the short half-lives of the products.

FDA recognized that, because of these differences, application of certain provisions of the CGMP regulations in part 211 (21 CFR part 211) to the manufacture of PET radiopharmaceuticals might result in unsafe handling or be otherwise inappropriate. Therefore, elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule authorizing manufacturers of PET radiopharmaceuticals to apply to the agency for exceptions or alternatives to provisions of the CGMP regulations. The PET CGMP guidance notes that while the CGMP regulations apply to the manufacture of PET radiopharmaceuticals, new § 211.1(d) permits manufacturers of such drugs to request an exception or alternative to any requirement in part 211.

This guidance represents the agency's current thinking on CGMP's for PET radiopharmaceuticals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. A regulated entity may adopt an alternative approach to CGMP's for PET drugs if such approach satisfies the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. If written comments demonstrate that changes to the final guidance are appropriate, FDA will revise the guidance accordingly. 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. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–10342 Filed 4–21–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. May 14, 1997, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 9, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will hear presentations and discuss data submitted regarding new drug application 20–766, Xenical™ (orlistat, tetrahydrolipstatin, Hoffman-LaRoche, Inc.) for long-term treatment of obesity.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized,