

and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

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 8B4619) has been filed by Dainippon Ink and Chemicals, Inc., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 20191. The petition proposes to amend the food additive regulations in § 177.1390 *Laminate structures for use at temperatures of 250 °F and above* (21 CFR 177.1390) to provide for the expanded safe use of a polyester-polyurethane resin-acid dianhydride adhesive in retortable pouches for use in contact with fatty food.

The agency has determined under 21 CFR 25.32(i) 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: August 17, 1998.

George H. Pauli,

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

[FR Doc. 98-23270 Filed 8-28-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 14, 1998, 10:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Martha T. O'Lone, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12520. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on the classification of unclassified washers and washer-disinfectors intended to process reusable medical devices.

Procedure: On September 14, 1998, from 11 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person before September 4, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. and between approximately 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those individuals desiring to make formal oral presentations should notify the contact person before September 4, 1998, 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 requested to make their presentation.

Closed Committee Deliberations: On September 14, 1998, from 10:30 a.m. to 11 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending issues and applications.

FDA regrets that it was unable to publish this notice 15 days prior to the September 14, 1998, General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 25, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-23305 Filed 8-28-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0646]

Global Harmonization Task Force: Draft Documents on Adverse Event and Vigilance Reporting of Medical Device Events; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of five draft documents entitled "Comparison of Device Adverse Report Systems" (SG2-N6), "Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices" (SG2-N8), "Global Medical Devices Vigilance Report (Form and Instructions)" (SG2-N9), "Pre cis" (Vigilance and Postmarket Surveillance) (SG2-N12), and "Adverse Event Reporting Guidelines for Manufacturers" (SG-N21). These documents have been prepared by members of the Global Harmonization Task Force (GHTF), study group 2 on Medical Devices Vigilance/Postmarket Surveillance Reporting Systems. The documents are intended to provide information only and represent a harmonized group of proposals. Elements of the approach set forth in these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Written comments by September 30, 1998. After the close of the comment period, written comments may be submitted at any time to Larry G. Kessler (address below).

ADDRESSES: Submit written comments on the draft documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web (WWW), submit written requests for single copies on a 3.5" diskette of the draft documents entitled "Draft Documents on Adverse Event and Vigilance Reporting of Medical Device