

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]

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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]

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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

Events" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these draft documents.

FOR FURTHER INFORMATION CONTACT:

Larry G. Kessler, Office of Surveillance and Biometrics (HFZ-500), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2812.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements, as described in an FDA notice on these activities published in the **Federal Register** of October 11, 1995 (60 FR 53078). As part of this effort, FDA has been actively involved since 1992 with GHTF. GHTF has formed four study groups, each tasked with assignments to draft documents and carry on other activities, designed to facilitate global harmonization. The purpose of this notice is to seek public comments on draft documents that have been prepared by one of the GHTF study groups.

Study group 2 was formed by GHTF in February 1996 and tasked with the responsibility to examine the requirements for the reporting of adverse incidents involving medical devices; consider postmarket surveillance and other forms of vigilance; and recommend ways of harmonizing these requirements. Study group 2 was also requested to promote the dissemination of relevant information concerning these matters. Study group 2 helps to improve protection of the health and safety to patients, users, and others; evaluate reports and disseminate information which may reduce the likelihood of or prevent repetitions of adverse events, or alleviate consequences of such repetitions; and define postmarket medical device reporting and surveillance requirements and guidelines on an international basis.

Reporting of adverse events involving medical devices is an important element in any good postmarketing surveillance system and can be achieved only through mutual confidence among all

parties concerned. The obligation to report adverse events differs widely among countries. Some systems are voluntary, while others are mandatory. The common thread that could tie all of the worldwide reporting systems together is the obligation for the manufacturer to report adverse events or incidents of which they are aware that involve medical devices.

It is the premise of the work of GHTF study group 2 that an international system for reporting adverse events can be developed to handle information provided by the manufacturer to the authorities.

1. In the draft document entitled "Comparison of the Device Adverse Report Systems" (SG2-N6), study group 2 compares 11 aspects of the regulatory systems of each of these countries with respect to the purpose of the device adverse event report systems, applicability, report timing, reporting criteria, not reportable incidents/events, procedures to report, applicable forms, content of the forms, role of the authority, definitions, and responsible entity for the investigation of the adverse event.

2. In the draft document entitled "Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices" (SG2-N8), information and guidance is provided that represents a harmonized proposal. This document contains information on communication between National Competent Authorities on events related to medical devices; when and how to inform publicly about adverse events; concerns with releasing information nationally; a list of criteria on how to disseminate information on adverse events, nationally; and recommendations on when an authority decides to disseminate information to the public.

3. In the draft document entitled "Global Medical Devices Vigilance Report (Form and Instructions)" (SG2-N9), information and guidance is provided about relevant measurers and/or recommendations relating to the prevention of adverse incidents concerning medical devices.

4. In the draft document entitled "Pre'cis" (SG2-N12R6), an overview and focus is provided of the mission, scope, and activities of the GHTF-SG-2.

5. In the draft document entitled "Adverse Event Reporting Guideline for Decisions for Manufacturers" (SG2-N21), a "Decision Tree" matrix is presented for manufacturers and their

representatives to decide when an adverse event should be reported.

It should be noted that these GHTF draft documents represent the current thinking and directions for harmonized postmarket surveillance, adverse event, and vigilance reporting aspects worldwide. These draft documents are presented for review and comment so that industry and other members of the public may express their views regarding global harmonization of medical device adverse event reporting.

II. Electronic Access

Persons interested in obtaining a copy of these draft documents may also do so using the WWW. CDRH maintains an entry on the WWW for easy access to the Web. Updated on a regular basis, the CDRH Home Page includes "Draft Documents on Adverse Event and Vigilance Reporting of Medical Device Events," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video-oriented conferencing and electronic submissions, mammography matters, and other device oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

III. Comments

Interested persons may on or before September 30, 1998, submit to the Dockets Management Branch (address above) written comments regarding the draft documents. 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 and with the full title of these documents. The draft documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After September 30, 1998, written comments regarding the draft documents may be submitted at any time to the contact person (address above).

Dated: August 19, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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