DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency For Toxic Substances and Disease Registry

[ATSDR–133]

Availability of the Interagency Workgroup Document, a Draft Report on Multiple Chemical Sensitivity (MCS); Correction

A notice announcing the Availability of the Interagency Workgroup Document, A Draft Report on Multiple Chemical Sensitivity (MCS) was published in the **Federal Register** on August 31, 1998, (63 FR 46225). This notice is corrected as follows:

On page 46225, in the first column under **DATES**, the public comment period should be changed from October 30, 1998 to December 15, 1998.

On page 46225, in the first column under **ADDRESSES**, second paragraph, please add the MCS report is also available on the Environmental Health Policy Committee's website: http://web.health.gov/environment.

All other information and requirements of the August 31, 1998, notice remain the same.

Dated: October 21, 1998.

Donna Garland,

Acting Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 98–28800 Filed 10–27–98; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

Name: Ethics Subcommittee of the Advisory Committee to the Director, CDC.

Time and Date: 9 a.m.–3 p.m., November 23, 1998.

Place: CDC, Building 16, Room 5126, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 25 people.

PURPOSE: This subcommittee will anticipate, identify, and propose solutions to strategic and broad ethical issues facing CDC.

Matters To Be Discussed: Agenda items will include an update from the Associate Director for Science, Dixie E. Snider, M.D., M.P.H.; a discussion on CDC's pandemic influenza plan; and ethical consultation on blinded HIV serosurveys.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Linda Kay McGowan, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333. Telephone 404/639–7080, fax 404/639–7181, e-mail lkm3@cdc.gov.

Dated: October 22, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–28820 Filed 10–27–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Immunology 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: Immunology 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 November 9, 1998, 9:45 a.m. to 5:30 p.m.

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

Contact Person: Louise E. Magruder, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a fluorescence *in situ* hybridization assay used in the detection of amplification of the HER–2/neu gene from subjects with node positive, stage II breast cancer to aid in the assessment of response to adjuvant therapy.

Procedure: On November 9, 1998, from 10:15 a.m. to 5:30 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 by November 2, 1998. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 2, 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 November 9, 1998, from 9:45 a.m. to 10:15 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future device submissions.

FDA regrets that it was unable to publish this notice 15 days prior to the November 9, 1998, Immunology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Immunology 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: October 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–28900 Filed 10–23–98; 3:31 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0878]

Global Harmonization Task Force: Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft'' (draft document). This draft document has been prepared by members of the Global Harmonization Task Force (GHTF), study group 1 on product approval issues and requirements. The draft document is intended to provide information only and represents a harmonized proposal. Elements of the approach set forth in this document may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on this draft document.

DATES: Written comments by January 26, 1999. After the close of the comment period, written comments may be submitted at any time to Kimber C. Richter (address below).

ADDRESSES: Submit written comments on the draft document 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 document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft'' 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 this draft document.

FOR FURTHER INFORMATION CONTACT: Kimber C. Richter, Office of Device Evaluation (HFZ–400), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

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 to draft documents and carry on other activities designed to facilitate global harmonization. The purpose of this notice is to seek public comments on a draft document that has been prepared by one of the GHTF study groups.

Study group 1 was formed in January 1993 and was originally tasked with identifying divergence between various regulatory systems. In 1995, the group was asked to propose areas of premarket device regulation and possible guidances or other documents that could lead to harmonization of requirements. As a result of their efforts, this group has developed a draft document entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft,'' which suggests a minimum harmonized set of expectations that medical devices worldwide should meet. It is not intended to exclude country-specific requirements or higher standards that already exist. It may be used by governments developing new systems for premarket regulation of devices. This draft document also provides harmonized language for study group 1 to build on as they develop further guidance documents, and may ultimately be adapted in place of country or region-specific language in existing systems.

The draft document is presented for review and comment so that industry and other members of the public may express their views regarding global harmonization of premarket regulation of medical devices.

II. Electronic Access

Persons interested in obtaining a copy of the draft document 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 ''Essential Principles for Safety and Performance of Medical Devices on a Global Basis; Final Working Draft,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' 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 January 26, 1999, submit to the Dockets Management Branch (address above) written comments regarding the draft document. 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 the document. The draft document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After January 26, 1999, written comments regarding the draft document may be submitted at any time to the contact person (address above).

Dated: October 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–28833 Filed 10–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0416]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated