• The availability of data and/or, any information on product utilization, cost, the incidence, prevalence, and/or severity of the particular disease, health condition, adverse event or medical error relevant to the topic being nominated.

• Include, if relevant, the significance to Federal Health Programs or underserved populations; or an indication of how the research results or Center activities might be used within the professional or organizational setting.

AHCPR will not reply to individual responses, but will consider all responses in developing the CERTS program and selecting topics for study. AHCPR will review the submissions and supporting information before making final determinations, seeking additional information as appropriate.

Dated: October 26, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–29335 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research and Subcommittee for Community Affairs: Meetings

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 committee meetings.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Times and Dates: 8:30 a.m.–5:15 p.m., November 19, 1998; 8:30 a.m.–12 noon, November 20, 1998.

Place: Radisson Plaza Hotel at Mark Center, 5000 Seminary Road, Alexandria, Virginia 22311, telephone 703/845–1010, fax 703/845–2610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies.

Matters to be Discussed: Agenda items will include update presentations from the National Institute for Occupational Safety and Health (NIOSH) and ATSDR on the progress of current studies; an update by the National Center for Environmental Health (NCEH) on coordination of activities with the National Cancer Institute (NCI); a presentation by NCI on Chernobyl, Radio Epi Tables and Ethel Gilbert's Research; a discussion by a panel of risk communications professionals on recommendations made by the National Academy of Sciences/Institutes of Medicine on the NCI report; and a discussion of committee recommendations and public involvement activities.

Agenda items are subject to change as priorities dictate.

Name: ACERER Subcommittee for Community Affairs.

Times and Dates: 1 p.m.–5 p.m., November 20, 1998; 8:30 a.m.–5 p.m., November 21, 1998.

Place: Radisson Plaza Hotel at Mark Center, 5000 Seminary Road, Alexandria, Virginia 22311, telephone 703/845–1010, fax 703/845–2610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This subcommittee will advise ACERER on matters related to community needs and will report back to the Agency through the full committee.

Matters to be Discussed: Agenda items will include update presentations from NCEH, NIOSH, and ATSDR on the progress of current studies; a discussion of the September 24, 1998, ACERER meeting and the resolution resulting from that meeting; a discussion of a special report presented by the Tennessean newspaper on health problems in the vicinity of nuclear facilities; and a discussion of committee recommendations and public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michael J. Sage, Deputy Chief, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE., m/s F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, fax 770/488–7044.

Dated: October 28, 1998.

Carolyn J. Russell,

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

[FR Doc. 98–29380 Filed 11–2–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0515]

Agency Information Collection Activities; Announcement of OMB Approval; Amendments to Humanitarian Use Device (HUD) Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Amendments to Humanitarian Use Device (HUD) Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 7, 1998 (63 FR 42404), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0384. The approval expires on October 31, 2001.

Dated: October 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29392 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0672]

Guidance on Criteria and Approaches for Postmarket Surveillance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance.'' This guidance document provides examples of the agency's criteria and approaches for determining which products may be subject to postmarket surveillance (PS) under the Food and Drug Administration Modernization Act of 1997 (FDAMA). In developing this guidance document, the agency considered comments received from consumer, clinical, and industry representatives at a public meeting on changes in medical device tracking and PS authority on January 15, 1998, in Gaithersburg, MD. To facilitate conformance with the requirements under FDAMA, this guidance document is immediately in effect.

DATES: Written comments concerning the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' must be received by February 1, 1999. After February 1, 1999, you may submit written comments on the guidance document to the contact person listed below.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' on a 3.5'' diskette 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 request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit written comments regarding this guidance 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.

FOR FURTHER INFORMATION CONTACT: Anita M. Rayner, Center for Devices and Radiological Health (HFZ–543), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0639.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 amended the Federal Food, Drug, and Cosmetic Act (the act), among other things, to add section 522 (21 U.S.C. 360l) to require PS for certain medical devices. Section 522 of the act was further amended by FDAMA (Pub. L. 105–115). As amended, section 522 of the act revises the criteria for determining which devices are subject to PS and revises the procedures for implementing PS. The revised provisions of section 522 of the act became effective on February 19, 1998. FDA is making this guidance document available at this time in order to facilitate the initial implementation of the revised PS provisions.

This guidance document represents the agency's current thinking on criteria and approaches for PS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's. This document is for immediate implementation to facilitate conformance with PS changes in section 522 of the act under FDAMA.

II. Electronic Access

In order to receive the guidance document entitled ''Guidance on Criteria and Approaches for Postmarket Surveillance'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (009) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance on Criteria and Approaches for Postmarket Surveillance,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video 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 February 1, 1999, submit to Dockets Management Branch (address above) written comments regarding the guidance document. After February 1, 1999, submit to the contact person (address above) written comments regarding the guidance document. Such comments will be considered when determining whether to amend the current guidance 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. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29390 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0108]

SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols.'' This guidance is for industry and FDA staff. This document indicates the agency's intent to terminate or continue postmarket surveillance (PS) orders for existing products and describes the criteria used to reach these determinations.

DATES: Written comments may be submitted at anytime.

ADDRESSES: Submit written comments on ''SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols'' to the contact person. Submit written