3. Continued accessibility of RTECS® to the international scientific community. The Licensee must make RTECS® continuously available world-wide and market the Database in a variety of formats including, but not limited to on-line, CD–ROM, and the Internet.

4. Multiple point and free access to NIOSH of all RTECS® products. The Licensee will provide NIOSH research and information staff with multiple point and free access to RTECS® to accommodate NIOSH users at six NIOSH sites, maximum usage not to exceed 25 users.

5. NIOSH representation on editorial or policy board or committee. A NIOSH representative will be designated to serve on any editorial or policy board established for the Database to ensure that the interests of the Institute are considered. This representative will serve in a consultative capacity without decision-making authority.

General Terms

1. Ownership of the RTECS® trademark will be retained by NIOSH.

2. The licensing agreement can be terminated by either party.

3. Ownership of data files, microfiche, and other files. NIOSH will retain ownership of the last RTECS® Master File produced with NIOSH funds. The Licensee will retain ownership of all new data generated and indexed under this agreement. NIOSH will also retain ownership of the microfiche collection of the bibliographical references. The full hard copy collection of the same references will be delivered to the Licensee, along with the annual microfiche editions produced after 1987. In the event of a termination of the Licensing Agreement, the hard copy collection and annual microfiche additions will be returned to NIOSH.

4. Duration of agreement will be negotiated in the license.

5. In submitted proposals, each requirement shall be addressed individually.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 00–25429 Filed 10–02–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

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

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., October 18, 2000; 8:30 a.m.–12 p.m., October 19, 2000.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: Agenda items include issues pertaining to the IOM Report on TB Elimination in the U.S. and other TB related topics.

Contact Person for More Information: Paulette Ford, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 27, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–25322 Filed 10–2–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1224]

Agency Information Collection Activities; Announcement of OMB Approval; Submitting and Reviewing Complete Responses to Clinical Holds; Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submitting and Reviewing Complete Responses to Clinical Holds; Guidance for Industry'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April, 13, 2000 (65 FR 19910), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0445. The approval expires on September 12, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: September 26, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25283 Filed 10–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs 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.

Name of Committee: Cardiovascular and Renal Drugs 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 October 19, 2000, from 9 a.m. to 5 p.m., and on October 20, 2000, from 8:30 a.m. to 4 p.m.

Location: National Institutes of Health, 9000 Rockville Pike, Bldg. 10, Clinical Center, Jack Masur Auditorium, Bethesda, MD.

Contact Person: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419–259–6211, or John M. Treacy, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 19, 2000, the committee will meet in closed session. On October 20, 2000, the committee will discuss dose response using data from approved antihypertensive drugs.

Procedure: On October 20, 2000, from 8:30 a.m. to 4 p.m., the meeting will be 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 October 12, 2000. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. on October 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 12, 2000, 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 October 19, 2000, from 9 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information regarding pending investigational new drug applications and new drug applications (5 U.S.C. 552b(c)(4)).

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

Dated: September 22, 2000.

Bernard A. Schwetz,

Acting Deputy Commissioner.

[FR Doc. 00–25284 Filed 10–2–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1492]

Mutual Recognition Agreement, Medical Device Annex; Confidence Building Activities: Availability of Draft Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled ''Implementation Plan for the Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview'' and ''Implementation Plan for the Mutual Recognition Agreement Between the European Union and the United States of America: Procedures for Joint Confidence Building.'' These draft guidance documents have been prepared jointly by FDA and the Commission for the European Communities (CEC's) and are intended to serve as guidance for all interested parties participating in confidence building activities under the medical device annex to the Mutual Recognition Agreement (MRA). While these draft guidance documents reflect the latest European Union (EU) edits, they have not been accepted by FDA. FDA is requesting comments on these documents. FDA plans to provide its comments on these documents and any stakeholder comments the agency receives to the CEC's.

DATES: Submit written comments on these draft guidance documents to ensure their adequate consideration in preparation of the final document by November 2, 2000.

ADDRESSES: Submit written comments concerning these draft guidance 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. To expedite the review process, if possible, FDA requests that you send a copy of your comments to the contact person, Christine Nelson (address below) or by e-mail to mcn@cdrh.fda.gov. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these documents. If you do not have access to the Internet, submit written requests for single copies on a 3.5″ diskette of the draft guidance documents listed above 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.

FOR FURTHER INFORMATION CONTACT: Christine Nelson, Office of Health and Industry Programs (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, ext. 128, FAX 301–443–8818, or e-mail mcn@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 27, 1997, the United States and the EU signed an MRA that covers a variety of product sectors including telecommunication, electrical safety, recreational crafts, pharmaceuticals, and medical devices. The Medical Device Annex to the MRA became effective December 7, 1998, and initiated a 3-year transition period during which both sides will engage in confidence building activities. Article 7 of the Medical Device Annex provides that FDA and the CEC's will establish a joint confidence building program to provide sufficient evidence of the capabilities of the nominated Conformity Assessment Bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties. After the 3-year period, the Medical Device Annex would become operational if the confidence building activities are successfully completed.

The Medical Devices Annex covers the exchange of quality systems evaluation/inspection reports for all medical devices and premarket evaluations for selected low to medium risk devices. A European CAB can conduct inspections for all classes of devices and 510(k) evaluations for selected devices based on FDA requirements for European device manufacturers who wish to market their devices in the United States. Similarly, a U.S. CAB can conduct quality system or type-testing evaluations based on EU requirements for U.S. device manufacturers who wish to market their devices in the EU. In addition, an alert system would be set up during the transition period and maintained thereafter, by which the parties will notify each other when there is an immediate danger to public health. As part of that system, each party will