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]

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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

notify the other party of any confirmed problem reports, corrective actions, or recalls.

These 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'' provide guidance on how to implement confidence building activities under the Medical Device Annex of the MRA for quality system evaluations and product evaluations. Guidance on implementing an alert system will be issued separately at another time.

II. Significance of Guidance

These draft guidance documents are intended to provide guidance. The draft guidance documents were developed by FDA and the European Commission (EC) to further implementation of the MRA. This current draft represents the EC's latest edits. FDA will be providing comments to the EC and proposing certain changes that are described in the ''FDA Concerns'' section of the guidance document. These draft guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of 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). These guidance documents are issued as a draft Level 1 guidance consistent with GGP's.

III. Electronic Access

Persons interested in obtaining copies of these draft guidance documents may do so through the Internet at www.fda.gov/cdrh/mra.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these draft guidance documents by November 2, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. To expedite receipt and review, FDA requests, if possible, that a copy of your comments be sent to the contact person (address above) or by e-mail to mcn@cdrh.fda.gov.

Dated: September 22, 2000.

William K. Hubbard,

Senior Associate, Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–25351 Filed 10–2–00; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4563–N–16]

Notice of Proposed Information Collection for Public Comment; Contract and Subcontract Activity

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 4, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Contract and Subcontract Activity.

OMB Control Number: 2577–0088.

Description of the need for the information and proposed use: The information provided to HUD by Housing Agencies/Grantees will be used to prepare an annual report on Minority Business Enterprise (MBE) participation in Public and Indian Housing Programs. The report will be submitted to the Department of Commerce pursuant to Executive Order 12432. HUD will also use the information to monitor and evaluate Housing Agency performance. HUD plans to collect this information electronically over the Internet.

Agency form number: HUD–2516.

Members of affected public: State, Local or Tribal Government, Small Businesses or Organizations.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 3,400 respondents annually, one hour per response, 3,400 total burden hours.

Status of the proposed information collection: Extension, without change.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: September 27, 2000.

Milan Ozdinec,

General Deputy Assistant, Secretary for Public and Indian Housing.

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