nor an environmental impact statement is required.

Dated: June 17, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–17547 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0195]

Agreement on Mutual Recognition Between the United States of America and the European Community; Third Party Review Program Under the Sectoral Annex on Medical Devices; Conformity Assessment Bodies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is identifying the process for designating Conformity Assessment Bodies (CAB's) under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA). The MRA was signed in London on May 18, 1998, but it has not entered into force. FDA has published a proposed rule on the parts of the MRA affecting FDA-regulated products. This notice announces the process for CAB's to become eligible for designation under the Sectoral Annex on Medical Devices (Medical Devices Annex). The availability of the draft guidance detailing the requirements for performing evaluations, training for CAB's, and content of evaluation reports by FDA is announced elsewhere in this issue of the **Federal Register**. Also announced elsewhere in this issue of the **Federal Register** is an emergency processing request for Office of Management and Budget review of the information collection provisions of this notice.

FOR FURTHER INFORMATION CONTACT:

Regarding the U.S./European Community MRA: John F. Stigi, Director, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, or FAX: 301–443–8818.

Regarding the process for being recognized to assess U.S. CAB's or for naming a recognized accreditor: Robert L. Gladhill, Conformity Assessment Systems Evaluation, National Institute of Standards and Technology, NN, 282 Gaithersburg, MD 20899, 301–975–4273, or FAX: 301–963–2871.

SUPPLEMENTARY INFORMATION:

I. Background

On June 20, 1997, the United States and the European Community (EC) completed negotiation of the MRA that covered a variety of product sectors, including telecommunication equipment, recreational craft, pharmaceuticals, and medical devices. The Medical Devices Annex applies only to medical devices manufactured for export to the United States or EC. The EC consists of the following member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. FDA issued a proposed rule on April 10, 1998 (63 FR 17744), to add a new section to its regulations setting out requirements through which FDA may normally endorse certain reports of conformity assessments. The Medical Device Annex applies to reports of quality system evaluations of all medical devices and premarket evaluations of selected medical devices provided by designated conformity assessment bodies.

Assuming the MRA enters into force and a final rule becomes effective, a 3-year transition period will start during which time both sides will engage in confidence building activities. After the 3-year transition period and the confidence building activities are successfully completed, the operational period will begin.

The MRA consists of a framework agreement and individual sectoral annexes (i.e., those product sectors covered by the MRA). The framework agreement covers the general aspects of the implementation of the agreement as well as the requirements governing the CAB's, such as designation, listing, suspension, and withdrawal.

Within the framework agreement there is a provision that FDA and EC Designating Authorities review the Medical Devices Annex. It is anticipated that aspects of the Medical Devices Annex will be modified by agreement of FDA and EC Designating Authority as laws and policies change. This provision was included because of FDA's concern during the negotiations that there could be a change in the status of the FDA Third Party Review Pilot Program for medical devices that would change the nature of the agreement.

Under the MRA, an EC CAB could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Similarly, a U.S. CAB could conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements. In addition, an alert system would be set up during the transition period and maintained thereafter by which FDA and regulatory authorities will notify each other when there is an immediate danger to public health. As part of that system, FDA and EC will notify each other of any confirmed problem reports, corrective actions, or recalls.

The MRA may: (1) Be an important means of facilitating movement of medical devices important to human health between the United States and EC, (2) enhance public health by allowing better use of scarce FDA resources, (3) enhance harmonization of U.S. and EC regulatory systems, and (4) permit FDA to better utilize its regulatory resources to focus on manufacturers located in other countries.

Under the MRA, both the United States and the EC may eventually be able to save resources by utilizing evaluations of manufacturers conducted by the other party, thereby saving overseas travel time and expense. However, CAB's will be required to participate in rigorous joint activities in order to demonstrate proficiency in conducting FDA and EC evaluations. Based on demonstrated proficiency during a 3-year transition period, both FDA and EC are expected to ''normally endorse'' evaluations conducted by the other party's CAB's, while reserving the final decision making to themselves and reserving the right to conduct their own evaluations should significant deficiencies be found in any reports.

II. Third Party Review Program

The Medical Devices Annex identifies legislation, regulations, and related procedures under which: (1) Products are regulated as medical devices by each party (i.e., FDA and the EC); (2) CAB's are designated and confirmed; and (3) evaluation reports are prepared. Assuming the MRA enters into force and a final rule becomes effective, FDA will be the Designating Authority for U.S. CAB's and the EC Regulatory Authorities will be the Designating Authority for EC CAB's. FDA intends to use the National Voluntary Conformity Assessment System Evaluation

(NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce to recognize one or more accreditation bodies that, in turn, will assess potential U.S. CAB's seeking to be designated under the MRA to assess medical devices produced for the EC market. FDA will consider the recommendations made by the recognized accreditation bodies from June 1, 1998, until October 1, 1998, review the list of recommended CAB's, and then designate U.S. CAB's that meet criteria for technical competence set forth in the Medical Devices Annex, assuming the MRA enters into force and a final rule on the MRA becomes effective. FDA intends to conduct training for EC CAB's from October 14 to 23, 1998.

Assessment of prospective U.S. CAB's for purposes of conducting quality system evaluations and product type-examination and verifications will be conducted under the NVCASE program under the procedures set forth in 15 CFR part 286. Prospective U.S. CAB's and accreditation bodies should contact NIST for additional information. Applications for designation should include sufficient information to address the qualifications for CAB's set forth in Article 1, Paragraph 1 of the Medical Devices Annex of the MRA. At a minimum, qualified U.S. CAB's should have knowledge of:

(1) Council Directive 90/385/EEC of June 20, 1990, on active implantable medical devices OJ No. L 189, 20.7.1990 (p. 17). Conformity assessment procedures: Annex 2 (with the exception of section 4), Annex 4, and Annex 5.

(2) Council Directive 93/42/EEC of June 14, 1993, on medical devices OJ No. L 169, 12.7.1993 (p. 1). Conformity assessment procedures: Annex 2 (with the exception of section 4), Annex 3, Annex 4, Annex 5, and Annex 6.

Assuming the MRA enters into force and a final rule becomes effective, designation of EC CAB's for the purpose of conducting quality system evaluations and premarket 510(k) evaluations will be conducted in accord with the Medical Devices Annex. At a minimum, qualified EC CAB's should have knowledge of:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*),

(2) The Public Health Service Act (42 U.S.C. 201 *et seq.*),

(3) Regulations of the United States Food and Drug Administration (21 CFR parts 800 to 1299); and

(4) The **Federal Register** document on the pilot program for third-party review of selected premarket notifications for medical devices that was published on April 3, 1996 (61 FR 14789 at 14796).

Prospective EC CAB's should contact their European Regulatory Authority, not FDA, for further information. Following designation, the EC CAB's can expect to be monitored through FDA surveillance audits at intervals determined by the agency.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(h) 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.

IV. Analysis of Impacts

FDA has examined the impacts of the U.S./EC MRA third party review program under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this voluntary program is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the program is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This regulation provides alternative review options for certain types of submissions. This is a voluntary program which imposes no additional requirements on regulated industry. Accordingly, the agency certifies that the program, if implemented, would not have a significant economic impact on small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Dated: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17597 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System 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). The meeting will be open to the public.

Name of Committee: Circulatory System 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 July 21 and 22, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 21, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a cardiac ablation device for ventricular tachycardia. On July 22, 1998, the committee is being asked to provide input to the agency regarding the design of clinical trials to support PMA's for cardiac ablation devices intended to treat atrial fibrillation and atrial flutter. Of particular concern are the following issues: (1) What are the appropriate controls to be used in such trials? (2) What are the appropriate safety and efficacy measures? and (3) When should assessments of these measures be made?

Procedure: 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 July 10, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. Near the end of