for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, Georgia 30305, Telephone (404) 842–6801, Email address: gcg4@cdc.gov.

Programmatic technical assistance may be obtained from Frederick Angulo, DVM, PhD, Medical Epidemiologist, National Centers for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop A–38, Atlanta, Georgia 30333, Telephone (404) 639–2840, Facsimile: (404) 639–2205, Email address: fja0@cdc.gov.

You may also obtain this announcement from one of two Internet sites on the actual publication date: CDC's homepage at http://www.cdc.gov or at the Government Printing Office homepage (including free on-line access to the **Federal Register** at http://www.access.gpo.gov).

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98–17592 Filed 7–1–98; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**Docket No. 98D–0375]**

### Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).'' Under the Sectoral Annex on Medical Devices (Medical Devices Annex), FDA has agreed to designate Conformity Assessment Bodies (CAB's). CAB's will be third parties (i.e., private individuals or organizations outside of FDA) authorized to perform premarket and quality system evaluations consistent with the Medical Devices Annex. Assuming the MRA enters into force and a final rule becomes effective, when finalized, this draft guidance will apply to CAB's seeking to be designated under the Medical Devices Annex, and it will assist those who are interested in participating in this program as CAB's or as applicants pursuing premarket and quality system evaluations consistent with the Medical Devices Annex.

**DATES:** Written comments by August 3, 1998.

**ADDRESSES:** Submit written comments on the guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. 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, submit written requests for single copies of the guidance document entitled ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)'' on 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 401–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** John F. Stigi, 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.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA has participated in negotiations on an international agreement on medical devices concluded in June 1997 between the United States and the European Community (EC). These negotiations resulted in the drafting of the MRA, which includes a special section pertaining to medical devices and is referred to as the Medical Devices Annex. After completion of a 3-year transition period, the Medical Devices Annex provides for normal endorsement of premarket and quality system evaluation reports of conformity assessment produced by equivalent third parties, the CAB's.

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 portions of the MRA affecting FDA-regulated products (63 FR 17744, April 10, 1998); the comment period closed on May 11, 1998.

In order to establish confidence in the conformity assessment process, CAB's will be required to participate in rigorous joint activities to demonstrate their proficiency to conduct evaluations. Upon implementation of this program, CAB evaluations will be exchanged and normally endorsed by both FDA and the EC for the marketing of medical devices.

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 Medical Devices Annex, to evaluate medical devices produced for the EC market. FDA will consider the recommendations made by the recognized accreditation bodies under NVCASE from June 1, 1998, to October 1, 1998, and then designate U.S. CAB's that meet criteria for technical competence established in the Medical Devices Annex. This draft guidance provides information regarding the process for CAB's to become eligible for designation under the Medical Devices Annex.

#### II. Significance of Guidance

This draft guidance document represents the agency's current thinking on guidance for staff, industry, third parties, and third party programs under the sectoral annex on medical devices to the Agreement on Mutual Recognition Between the United States of America and the European Community. 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. This guidance is not final nor is it in effect at this time.

The agency has adopted Good Guidance Practices (GGP's) that 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 is issued as a Level 1 guidance consistent with GGP's.

#### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so using the World Wide Web. CDRH maintains

an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH Home Page includes the ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA),'' device safety alerts, access to **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.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185. The terminal settings are 8/1/N. After the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA Home Page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

## IV. Comments

Interested persons may, on or before (*insert date 30 days after publication in the* **Federal Register**), submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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: June 24, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 98–17600 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0453]**

### Agency Emergency Processing Under OMB Review

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the submission of applications to recognized accreditation bodies that will assess potential U.S. Conformity Assessment Bodies (CAB's) seeking to be designated under the U.S./European Community (EC) Mutual Recognition Agreement (MRA) to assess medical devices produced for the EC market. This collection of information also concerns the submission of third-party evaluation reports by EC CAB's under the program. FDA is requesting OMB approval within 15 days of receipt of this submission.

**DATES:** Submit written comments on the collection of information by July 13, 1998.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

**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:**

## I. Background

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately in order for potential CAB's to be designated in time to participate in training for premarket and quality systems evaluations scheduled for October 14 through 23, 1998. The use of normal clearance procedures would be likely to result in the prevention or disruption of this collection of information and would delay the implementation of the confidence building activities authorized by the U.S./EC MRA.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The third-party program under the U.S./EC MRA is intended to implement that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. CAB. Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product-type examinations and verifications for selected devices based on EC requirements under the voluntary third-party program authorized by the MRA. Firms designated as EC CAB's could, in turn, conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EC CAB's to FDA. The EC CAB's would also be required to maintain copies of their evaluation reports.

FDA estimates the burden of this collection as follows: