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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 D-0375]

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 guidance entitled “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 (Annex), FDA has agreed to designate conformity assessment bodies (CAB’s) as third parties (i.e., organizations outside of FDA) authorized to perform premarket and quality system evaluations consistent with the Annex. This guidance 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 Annex.

DATES: Written comments may be submitted at any time.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. If you do not have access to the World Wide Web, submit written requests for single copies of the guidance entitled “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 301-443-8818. Written comments concerning this guidance may be submitted at any time to the contact person listed below.

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

The United States and the European Community (EC) exchanged letters on October 30, 1998, which brought the MRA into force on December 7, 1998. FDA published a final rule on the MRA on November 6, 1998 (63 FR 60122),

In the MRA negotiations, FDA led the negotiations on the Annex to the MRA between the United States and the EC. These negotiations resulted in the drafting of the MRA, which includes a special section pertaining to medical devices that is referred to as the Annex. The Annex provides for a 3-year transition period. After the transition period FDA and the EC may normally endorse premarket and quality system evaluation reports provided by equivalent third parties, the CAB 's.

In order to establish confidence in the conformity assessment process, CAB's will be required to participate in rigorous joint exercises 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 is using 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 accredit potential U.S. CAB's seeking to be designated under the Annex to evaluate medical devices produced for the EC market. FDA has considered the recommendations made by the NIST under NVCASE

and has designated the U.S. CAB's that meet criteria for technical competence established in the Annex, for possible participation in transition activities.

In the **Federal Register** of July 2, 1998 (63 FR 36247), FDA published information regarding the process for CAB's to become eligible for designation under the Annex. On the same date, the agency announced the availability of a draft guidance on the third party program (63 FR 3621). The agency received three comments on the draft guidance. FDA has reviewed these comments and has made no significant revisions in the guidance in response to these comments. The agency has, however, included additional information regarding conflicts of interest, including additional examples of situations that would indicate a potential conflict of interest.

II. Significance of Guidance

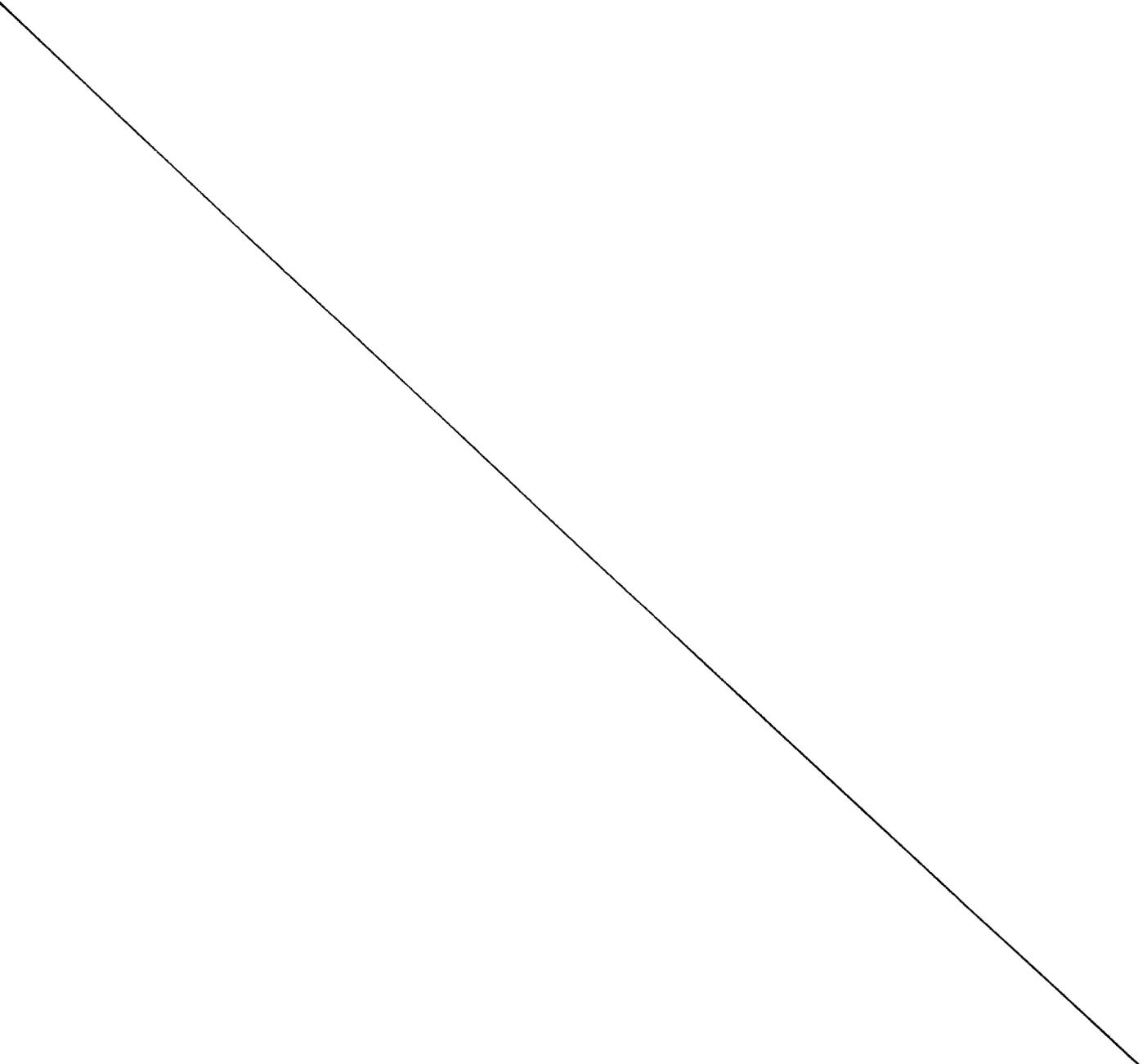
This guidance represents the agency's current thinking on "Guidance for Staff, Industry, and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community." It does not create or confer 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) 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 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 "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](http://www.fda.gov/cdrh)”.



IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the contact person listed above. Such comments will be considered when determining whether to amend the current guidance.

Dated: 1-19-99
January 19, 1999

D.B. Burlington

D.B. Burlington
Director
Center for Devices and Radiological Health

LOC [FR Dec. 9)⁹3-???? Filed ??-??-9⁹\$, 8:45 am]

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