

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1492]

JMB

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Certifier	Jan Wundral

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled "Implementation Plan for the Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building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 These draft guidance documents have been prepared jointly by FDA and the Commission for the European Communities (CEC's) and are intended to serve as guidance for all interested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 While these draft guidance documents reflect the latest European Union (EU) edits, they have not been accepted by FDA.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DATES: Submit written comments on these draft guidance documents to ensure their adequate consideration in preparation of the final document by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments concerning these draft guidance documents to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, ch0060

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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 If you do not have access to the Internet, submit written requests for single copies on a 3.5" diskette of the draft guidance documents listed above to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration,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

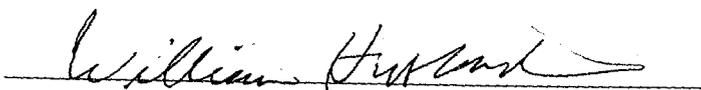
Persons interested in obtaining copies of these draft guidance documents may do so through the Internet at www.fda.gov/cdrh/mra.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these draft guidance documents by [*insert date 30 days after date of publication in the **Federal Register***]. 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

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