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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 98S-1064]

Implementation of the Mutual Recognition Agreement Between the United States and the European Community; Pharmaceutical GMP's and Medical Devices; Establishment of a Public Docket and FDA Contact Points

AGENCY: Food and Drug Administration, HHS.

ACTION: Establishment of a public docket and FDA contact points.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for the submission and public availability of information concerning the implementation of the Mutual Recognition Agreement (MRA) between the United States and the European Community (EC) in the areas of pharmaceutical good manufacturing practices (GMP's) and medical devices. FDA is also establishing contact points for information covering particular subjects under the MRA implementation, and the agency is making appropriate information available on the FDA web site.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, **Rockville**, MD 20852. Documents concerning FDA's implementation of the MRA are available for public examination in the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT:

Pharmaceutical **GMP's:**

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For information regarding human drug GMP's: Brian J. Hasselbalch, Division of Manufacturing and Product Quality (HFD-325), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, **7520** Standish Pi., Rockville, MD 20855-2737, 301-827-7285, FAX: 301-594-2202, or E-mail: 'hasselbalchb@cder.fda.gov'.

For information regarding animal drug GMP's: Judith A. Gushee, Office of Surveillance and Compliance (HFV-232), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pi., **Rockville**, MD 20855-2773, 301-827-0150, FAX: 301-594-1807, or E-mail: 'jgushee@bangate.fda.gov'.

For information regarding human biologic GMP's: Jennifer A. Thomas, Office of Compliance and **Biologics** Quality (HFM-600), Center for **Biologics** Evaluation and Research, Food and Drug Administration, 1401 **Rockville** Pike, **Rockville**, MD 20852-1448, 301-827-6 190, FAX: 301-594-1944, or E-mail: 'thomasj@cber.fda.gov'.

Medical Devices:

For information regarding 510(k)'s: Eric J. Rechen, Office of Device Evaluation (HFZ-402), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., **Rockville**, MD 20850, 301-594-21 86, FAX: 301-594-2977, or E-mail: 'ejr@cdrh.fda.gov'.

For information regarding device quality systems and GMP's: Kimberly A. Trautman, Office of Compliance (HFZ-340), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., **Rockville**, MD 20850, 301-594-4646, FAX: 301-594-4672, or E-mail: 'kat@cdrh.fda.gov'.

For information regarding third-party program administrative matters and general MRA issues: John F. **Stigi**, Division of Small Manufacturers Assistance (HFZ-220), Office of Health and Industry Programs, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., **Rockville**, MD 20850, 301-443-7491, FAX: **301-443-**

8818, or E-mail: ‘jfs@cdrh.fda.gov’.

SUPPLEMENTARY INFORMATION: On November 6, 1998, FDA published a final rule in the **Federal Register (63 FR 60122)** that amended its regulations under an international agreement between the United States and the EC by adding part 26 (21 CFR part 26), subparts A through C entitled “Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community.” This rule became effective on December 7, 1998. Under the terms of subpart A of part 26, the importing country authority may normally endorse pharmaceutical GMP inspection reports provided by exporting authorities determined to be equivalent. Under the terms of subpart B of part 26, the importing country authority may endorse quality system audits performed according to the importing country authority’s requirements and procedures. In addition, certain medical device product evaluation reports performed by the exporting country’s conformity assessment bodies (CAB ‘s), according to the importing country authority’s requirements and procedures, may normally be endorsed.

In response to comments on FDA’s proposed rule published in the **Federal Register** of April 10, 1998 (63 FR 17744), FDA stated that it plans to make public summaries of key meetings held with its EC counterparts concerning implementation of the MRA and FDA’s regulation, and that it will make available to the public the administrative file that constitutes the basis for any of FDA’s equivalence determinations or listings, subject to exemptions from disclosure provided in the Freedom of Information Act, the Privacy Act, and FDA’s regulations (see comment 1 in section **II.C** at 60122 at 60127).

Through this notice, FDA is establishing a new docket (Docket No. 98 S–1064) in order to make available at a convenient location public information concerning the implementation of part 26.

Also, in the proposed rule (63 **FR** 17744), FDA requested (see also comment 1 in section **II.C** at 60122 at 60127) that all interested persons send to FDA information that is: (1) Generally

relevant to implementation of part 26, and (2) of particular relevance to equivalence criteria described in part 26, Appendix D of subpart A and their application to authorities listed in Appendix B of subpart A of part 26. The notice instructed persons to send their information to docket 98N-0185 (the **rulemaking** docket).

FDA is particularly interested in obtaining the following types of information from any interested persons:

- (a) Information relevant to determining the equivalence of EC Member State regulatory authorities that may provide pharmaceutical GMP inspection reports to FDA under the MRA, and
- (b) Information relevant to the assessment procedures of CAB's that may provide medical device quality system evaluation reports and certain medical device product evaluation reports to the FDA under the MRA.

Because FDA desires to separate the administrative record of the **rulemaking** for part 26 from the administrative records covering implementation of part 26, FDA hereby requests that all information relevant to the implementation of part 26 be sent to the docket established under this notice (Docket No. 98 S-1064). Furthermore, any information concerning implementation of part 26 and any information pertaining to the equivalence or listing criteria described previously that has already been sent to the **rulemaking** docket will be transferred to the new docket established for part 26 implementation.

FDA will also make appropriate information concerning the implementation of the MRA and part 26 available to the public on FDA's website at 'http://www.fda.gov' under the "International" section.

Dated: March 2, 1999.



William K. Hubbard
Acting Deputy Commissioner for Policy

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