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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0402]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 14, 2002 (67 FR 1770), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0378. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: 3-22-02

March 22, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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