

provided by States, Federal agencies contacted, and an indication of the type(s) of information returned, will be stored on a history tape and in hard copy for five years and then destroyed.

Records of information provided by financial institutions for the purpose of facilitating matches will be maintained only long enough to communicate the information to the appropriate State agent. Thereafter, the information provided will be destroyed. However, records pertaining to the disclosures, which include information provided by States, Federal agencies contacted, and an indication of the type(s) of information returned, will be stored on a history tape and in hard copy for five years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Program Operations, Office of Child Support Enforcement Administration for Children and Families, 370 L'Enfant Promenade, SW, 4th Floor East, Washington, DC 20447.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager at the address listed above. The request must indicate whether the information concerns the requestor or someone else. It must also be notarized and contain the individual's full name and address. Additional information, such as Social Security Number, date of birth or mother's maiden name, may be requested by the system manager in order to distinguish between individuals having the same or similar names.

RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records. Requesters should provide a detailed description of the records contents they are seeking.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under system manager above, and identify the record and specify the information to be contested and corrective action sought with supporting justification to show how the record is inaccurate, incomplete, untimely or irrelevant.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State and from multistate financial institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0453]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices: Third-Party Review Program Under the U.S./EC MRA

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 Review Program Under the U.S./EC MRA" 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 December 14, 1998 (63 FR 68773), 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 February 28, 2002. A copy of the supporting statement for this information collection is available on the Internet at "<http://www.fda.gov/ohrms/dockets>".

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0645]

Medical Device Warning Letter Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is initiating a pilot program involving the medical device industry that is a continuation of the "medical device industry initiatives." This pilot concerns the issuance of warning letters for quality system, premarket notification submission (510(k)), and labeling violations. This pilot is intended to optimize resource utilization, enhance communication between industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The pilot includes eligibility criteria and procedures for the issuance of warning letters.

EFFECTIVE DATES: Initiation date March 29, 1999. Termination date September 8, 2000.

ADDRESSES: Submit written comments on the pilot to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the pilot.

FOR FURTHER INFORMATION CONTACT:

Device quality system warning letter pilot: Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411, FAX 301-827-0482. Premarket notification (510(k)) and labeling warning letter pilot: Chester T. Reynolds, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4618, FAX 301-594-4610.

SUPPLEMENTARY INFORMATION:

I. Background

During FDA/medical device industry grassroots forums, several issues were discussed concerning FDA's interaction with the medical device industry. After considering these issues, the agency is initiating a pilot program that will last