Copies can also be obtained from an electronic docket maintained by the Division of Small Manufacturers Assistance. This system can also be accessed by dialing: 1–800–252–1366 or 301–594–2741. Persons wishing to obtain the guidance document via this system must have a video terminal or a personal computer with communication software (VT emulation) and a modem that can operate at a baud rate of 1200, 2400, 4800, or 9600. Persons wishing to transfer files from the electronic docket must use the KERMIT file transfer protocol.

66. One comment requested that the requirement for staff education be deleted.

The agency agrees and, as stated previously in this preamble, has removed this requirement from the final regulation.

67. One comment objected to the requirement for written procedures. Another comment objected to FDA having access to the firm's procedures.

The agency disagrees. Written procedures are essential to the development of a standard, institutional reporting program. FDA also needs access to such procedures so it can conduct an adequate audit of user facility and manufacturer compliance with MDR.

68. One comment requested clarification of the term ''information that facilitates a submission'' for which documentation and recordkeeping requirements were proposed.

''Information that facilitates the submission [of a semiannual report]'' refers to any information that was evaluated for the purpose of preparing a semiannual report or certification. The regulation has been revised in § 803.17 to clarify this point.

69. One comment stated that these provisions do not address the penalties for failure to comply.

FDA intends to enforce this regulation and will take appropriate action against any firm or facility that does not comply. Violations may result in criminal prosecutions and/or civil remedies such as seizure, injunction, recall, and civil penalties. FDA's enforcement mechanisms and penalties for noncompliance are detailed in the preamble to the November 1991 tentative final rule (56 FR 60024 at 60029 through 60030).

L. Files (§ 803.18)

70. Several comments complained that these requirements are overly broad, burdensome, and beyond the scope of the SMDA.

FDA does not agree. Sections 519 and 701 of the act provide FDA the authority to require user facilities and manufacturers to maintain records to ensure that devices are not adulterated or misbranded. The file requirements are necessary to enable FDA to: (1) Further investigate potentially adulterated or misbranded devices to determine the cause of adverse events; (2) verify information received; and (3) ensure compliance with the regulations. These filing requirements will also enable the reporting entity to more readily identify causes of problems associated with devices so they can take appropriate actions.

71. Several comments expressed concern about public access and a loss of confidentiality stating that these will lead to increased lawsuits and, therefore, decreased reporting. Some comments suggested that only events reportable to FDA be kept in FDA accessible files. Others suggested that confidential materials and irrelevant data be excluded from the files.

FDA has addressed issues related to confidentiality of reports it receives in section IV.C., comment 24 of this document. As stated therein, certain statutory and regulatory protections exist that prevent release of confidential information. FDA does not agree that only events that are ultimately determined to be reportable should be kept in MDR files. FDA must be able to audit files containing events that were determined not reportable to ensure such determinations were correct.

72. A few comments objected to FDA prescribing the method of record retention, preferring the use of individual systems.

The agency disagrees. Effective and uniform regulatory enforcement is better assured by a standardized method of record retention. The agency believes that the method of record retention prescribed in this regulation does not impose an undue burden on the entities required to maintain such records.

73. One comment suggested that separate files be kept for devices and patients.

FDA does not object to a reporting entity maintaining separate files for devices and patients provided that all required information is contained in the MDR files.

74. A few comments stated that a user facility should be required to keep files for a maximum of 2 years, rather than the expected life of the product, because some devices may have unusually long life expectancies.

The agency agrees and has modified this section accordingly. It should be noted that device manufacturers, however, are still required to retain their records for 2 years or a period of time equivalent to the expected life of the device, whichever is greater.

M. Who Must Register and Submit a Device List (Section 807.20)

75. One comment suggested that foreign manufacturers designate a U.S. agent to fulfill the registration and certification requirements. Another comment suggested that foreign manufacturers be permitted to register.

Under § 807.40 (21 CFR 807.40), foreign manufacturers are required to designate a U.S. agent to serve as an official correspondent, as well as to register and list their medical devices distributed in the United States, submit premarket notifications and ensure compliance with the MDR reporting requirements. In § 807.40(a), FDA has changed the time allowed for foreign manufacturers to inform the agency of their designated U.S. agents, or a change in such agents, from 30 days to 5 days. FDA believes this is sufficient time to comply with this requirement.

76. Under § 807.20 (21 CFR 807.20), an owner or operator is required to register its ''name, places of business, and all establishments.'' Under this regulation, FDA has required the registration of all locations that fit within the definition of ''establishment,'' which is defined under § 807.3(a) (21 CFR 807.3(a)) as a location where devices are ''manufactured, assembled, or otherwise processed.'' Although FDA has authority under § 807.20 to require the registration of ''places of business'' that are not ''establishments'' under initial registration and listing regulation that were issued in 1977, the agency previously has declined to exercise this authority.

Under this regulation, FDA will use registration numbers in its data bases to process all manufacturer adverse event reports. Thus FDA must receive reports that originate from locations that may not be ''establishments'' and, therefore, have previously not had registration numbers. Accordingly, FDA is notifying manufacturers that upon the effective date of this final regulation, the agency will exercise its authority under § 807.20, and require all locations that are MDR reporting sites to register because they are ''places of business'' under § 807.20, regardless of whether they fit under the definition of ''establishment.''

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,