With respect to manufacturers and distributors, FDA has attempted to provide protection from liability by clearly stating in § 803.16 of this final rule, and including a statement on FDA Form 3500A, that the submission of a report does not constitute an admission that the user facility, manufacturer/distributor, product, or medical personnel caused or contributed to the event. Moreover, in the Federal Register of April 3, 1995 (60 FR 16962), FDA issued a final rule that became effective on July 3, 1995, that protects the identity of voluntary reporters by preempting State laws or other requirements requiring or permitting disclosure.

26. Comments objected to providing FDA with proprietary information.

FDA may require the submission of certain proprietary information because it is necessary to fully evaluate the adverse event. Proprietary information will be kept confidential in accordance with § 803.9, which prohibits public disclosure of trade secret or confidential commercial information, and in accordance with the FOIA and FDA regulations in 21 CFR part 20.

D. Reports by Device User Facilities (Part 803, Subpart C)

27. Several comments stated that 10 days is too short a time period for user facilities to report adverse events properly. One comment suggested that the 10-day ''clock'' for reporting should commence when the facility completes its investigation and determines that an event is reportable.

FDA cannot agree because the 10-day time period is the maximum time allowed by the statute. (See section 519(b)(1)(A) of the act.) However, this comment raises the issue of when the reporting ''clock'' starts. In the preamble to the November 1991 tentative final rule, FDA proposed to consider a user facility to have ''become aware'' of reportable events only when it has sufficient information to make a determination that a report is required, and that this commences the 10-day reporting period. (See the notice of availability of the MEDWATCH adverse event reporting form (FDA Form 3500A) in the Federal Register of June 3, 1993 (58 FR 31596.))

FDA has reevaluated the issue of when a user facility should be considered to ''become aware'' of information that triggers the reporting requirements and has determined that user facilities should be considered to have ''become aware'' of information that triggers reporting requirements when they first receive a report. The agency does not believe that information-gathering required of user facilities is sufficiently burdensome or time consuming to justify triggering the 10-day timeframe any time after they receive a report of an adverse event. A user facility, unlike a manufacturer, is not required to provide any information that is not in its possession. For further discussion on when user facilities are considered to have ''become aware'' of an event, see section IV.A, comment 2 of this document.

28. Several comments suggested that the user/operator error reporting requirement be eliminated.

As stated in section IV.A., comment 3 of this document, the language of the SMDA as amended by the 1992 amendments requires reporting in all instances where the facility becomes aware of information that reasonably suggests that a device has or may have caused or contributed to certain device-related adverse events. FDA needs to be aware of events that are related to user error any time such error may have caused or contributed to a reportable event. By receiving information on device user problems, FDA can determine whether additional measures are necessary to resolve such problems, for example, relabeling or a redesign of the device.

29. One comment suggested that all reports be sent only to FDA.

FDA does not agree. This regulation merely implements section 519(b) of the act, which requires user facilities to submit deaths to FDA and the manufacturer, and serious injuries to the manufacturer or FDA, if the identity of the manufacturer is unknown.

30. Some comments suggested that an anonymous reporting path be provided for reporting directly to FDA.

FDA disagrees. It is important that both FDA and the manufacturer know the identity of the user facility in case followup information is needed. As discussed in section IV.C., comment 24 of this document, the act does provide some protection of the identity of user facilities.

31. Several comments requested clarification of the terms ''adverse events,'' ''formally affiliated,'' and ''user error.''

Adverse events are those events that may be related to an FDA-regulated product and which have a negative or harmful effect on the user or recipient of the product's use. The only adverse events required to be reported under this regulation, however, are ''MDR reportable events'' as defined in § 803.3(q) of the final rule.

The term ''formally affiliated'' means individuals who are employed by a user facility or medical personnel who have admitting, practicing, or equivalent privileges at a user facility. Reporting requirements for user facilities are triggered when medical personnel who are employed by or otherwise ''formally affiliated'' with the facility, receive information or become aware of information that reasonably suggests a reportable event has occurred.

The term ''user error'' means any error made by the person using the device. A user error may be the sole cause or merely contribute to a reportable adverse event.

32. One comment suggested that FDA provide user facilities with manufacturer and agency contacts. Another comment suggested that a hotline be established for reporting.

It would be very difficult for FDA to establish and maintain up-to-date manufacturer ''contact'' lists for device user facilities. The agency, however, will consider publicizing a list of firm contact names and telephone numbers. Although there is no requirement for telephone reporting in this regulation, emergency situations can be handled in accordance with § 803.12(c) of this final rule.

33. One comment asked how foreign user facilities will be affected by these provisions.

Only those user facilities located outside the United States which are operated by the U.S. Government are required to report under this regulation.

34. Comments suggested that the requirements for semiannual reports be deleted because they are redundant. Other comments suggested that no semiannual report be required if no reports had been submitted during that period.

Semiannual reports are required by section 519(b)(1)(C) of the act and therefore the requirement cannot be deleted. Under § 803.33(c), the user facility is not required to submit a semiannual report if no reportable events occurred during the reporting period.

E. Reports by Manufacturers (Part 803, Subpart E)

35. One comment suggested that manufacturer reporting of ''planned remedial actions'' be deleted. Another comment stated that remedial action often occurs after the reporting deadline, and therefore cannot be included in the report.

Remedial actions taken after a reporting deadline can be submitted to the agency via a supplemental report. The individual adverse event reports required under the final rule, with the exception of circumstances requiring 5-day reports, do not require information