(discussed in section IV.F., comment 52 of this document) will facilitate information access and retrieval, and increase the agency's ability to evaluate the information.

41. Comments stated that the requirement for firms to compare events associated with the use of their devices, in order to perform trending studies, should be removed.

The agency agrees in part and has deleted MDR trending reporting requirements, as discussed in section IV.E, comment 39 of this document. Under the prior reporting regulation, FDA has faced difficulties in making an effective determination of the significance of many device failures, because the reports did not include the total number of similar devices in current use or similar failures. Such information, which is required in baseline reports, provides the agency with information regarding the rate of adverse events. An understanding of device failure rates is essential for the agency to determine the level of risk involved, and the appropriate regulatory or other public health response.

42. One comment suggested that instead of the manufacturer indicating to whom the information was reported in the monthly reporting form, it is more important to indicate by whom it was reported.

The agency agrees in part. As noted above, the monthly report requirement, as proposed, has been eliminated; however, information about the initial reporter is required on the individual adverse event MEDWATCH form (FDA Form 3500A or an FDA approved electronic equivalent).

43. One comment objected to the requirement to report problems found in the scientific literature. Another comment objected to reporting anything except problems found in the scientific literature or from research.

Any information which reasonably suggests that a reportable event occurred is important to evaluate the risks of a device, regardless of the source. Although reports in the scientific literature or research are usually not proximate in time to actual events, the information often represents the results of cumulative observations and experience, and provides important information to FDA about device safety and effectiveness.

44. One comment stated that the manufacturer reporting requirements are inappropriate for device sales made directly to the patient.

The agency disagrees. The act does not provide any restrictions or limitations with respect to how the device was marketed. FDA would lose a valuable source of information if manufacturers of devices sold directly to patients, such as many apnea monitors or home use glucose monitors, were excluded from this requirement. All information concerning device-related deaths, serious injuries or other reportable events is equally important, regardless of how the device is marketed.

45. One comment stated that there is no relationship between devices shipped by the manufacturer and those on the market, as the devices may have been altered; therefore, the manufacturer should not be responsible for reporting events involving such devices.

The agency disagrees. Devices in commercial distribution are presumed to be the same devices shipped by the manufacturer. If a manufacturer receives information about an MDR event involving a device that has been altered, the information must nevertheless be forwarded to FDA with an explanation that the device has been altered.

46. One comment suggested that a U.S.-designated agent should be responsible for reporting on behalf of foreign manufacturers.

FDA's November 1991 tentative final rule proposed that U.S.-designated agents should be required to report for foreign manufacturers. This requirement has been adopted in § 803.58.

47. One comment suggested that the manufacturer should disclose the results of event evaluations to distributors of the device.

FDA does not agree. Disclosure of evaluations would be burdensome and may result in release of information that is protected under other laws and regulations. FDA will inform the public, including distributors, of steps necessary to protect the public health if the agency determines such steps are necessary.

F. User Facility and Manufacturer Reporting Forms for Individual Adverse Events (§§ 803.32 and 803.52)

48. Several comments asserted that this section is costly, complicated, overly broad, unacceptably burdensome and not consistent with the SMDA as it requires the reporting of information not required or supported by the SMDA.

The agency disagrees. As stated earlier in the preamble, FDA has adopted the use of a single reporting form for most FDA-regulated products, in order to facilitate the cost-efficient submission of information required by or consistent with the provisions of the SMDA. The agency agrees that the data elements could be simplified and has modified the form after consideration of comments to the February 1993 notice submitted by medical device trade associations and other regulated or affected entities. FDA anticipates that the consolidated form will facilitate the submission, and improve the quality, of adverse event reports. During the initial period of its use, FDA will continue to closely monitor comments and suggestions received from interested parties regarding the reporting form, and will consider additional modifications to further improve the form as the need arises.

49. One comment stated that it will be difficult to find manufacturer reporting forms. Another comment stated that the report form, distributed as a draft to certain interested parties, is not compatible with the use of a word processor.

The MEDWATCH forms (FDA Forms 3500 and 3500A) are already in wide distribution and were published in the Federal Register on June 3, 1993. Information about the MEDWATCH form, and how to obtain it, is provided §§ 803.10 and 803.11.

Although a word processor would be able to fill the fields on FDA Form 3500A with great difficulty, the agency has made provisions for the submission of reports on alternative (electronic) media which would obviate the need for printing the form from a word processor.

50. Several comments were concerned with the adversarial and litigation issues which may be raised by reporting on the forms. In this regard, a few comments suggested deleting all items that require speculation and judgment in reporting, removing the signature block, or adding a disclaimer to the form.

As stated in section IV.C., comment 25 of this document, although FDA is aware that these reports may have some effect on liability, the required information is necessary to implement the agency's statutory responsibilities. Under the statute, user facilities and manufacturers must report adverse events when a device ''may'' have caused or contributed to the event. Accordingly, FDA does not have the discretion to require reporting only when a definitive causal relationship is established. Furthermore, adoption of such a standard would preclude FDA from receiving information that would help the agency assess the risks associated with devices.

FDA has removed the signature block on the form. FDA has provided a disclaimer statement on the reporting form, as discussed in section IV.C., comment 25 of this document.

51. Some comments suggested that the evaluation of events or reports be