concerning ''planned remedial action'' because supplemental reports and reports of Removals and Corrections will provide the agency with the same information. Remedial actions that are necessary to prevent an unreasonable risk to the public health should be reported as 5-day reports under to § 803.53.

36. Several comments requested that manufacturers be exempt from the requirement of submitting supplemental reports because they are vague and burdensome.

FDA does not agree. The supplemental report does not impose any significant additional burden under § 803.56 because it requires information that a manufacturer was required to submit on its initial report, but did not do so because such information was unknown or unavailable at the time of the report. This information may include, for example, the results of a firm's investigations that may not have been completed at the time of the initial report, or any other required information that the manufacturer becomes aware of after filing a report. The information required is not vague and is clearly specified in §§ 803.52 and 803.56. Both initial and supplemental reports are to be submitted on FDA Form 3500A or electronic equivalent.

Under § 803.15, FDA may also require supplemental information (termed ''request for additional information'' in the final rule) in addition to that required on other reports specified in this part. FDA believes these reports are not unduly burdensome given that they will be required only in instances when the agency determines that the protection of the public health requires such information. In such cases, FDA will specify the type of information needed.

37. One comment stated that the quality of information will decrease if manufacturers are denied access to products.

FDA agrees that manufacturers should evaluate a device problem if they have access to the device. FDA has no authority to require that a device be returned to the manufacturer, but the agency encourages device users, when possible, to permit access or return the device to the manufacturer for evaluation.

38. One comment suggested that manufacturer reports should be sent to user facilities, as well as to FDA.

FDA does not agree. FDA believes that user facilities do not have the appropriate resources or personnel to properly evaluate the public health significance of manufacturers' reports. FDA is the proper entity to evaluate MDR information to determine whether further action, including notification to user facilities or others of device risks, is appropriate.

39. A few comments suggested that the 1984 requirements for manufacturer reporting should be retained to avoid possible confusion caused by the creation of a new standard. Other comments called for the elimination of the monthly reporting requirement.

As discussed earlier in the preamble, subsequent to the issuance of the November 1991 tentative final rule, the 1992 amendments modified the language for reporting standards that apply to user facilities, manufacturers, and importers. The language used in the November 1991 tentative final rule no longer reflected the statutory language, as modified. In this final regulation, FDA has revised the reporting standard to reflect the statutory language added by the 1992 amendments. This statutory reporting standard is substantially similar to the manufacturer reporting standard in the 1984 regulations.

Although the final regulation retains the reporting standard language from the 1984 regulation referenced above, it incorporates many changes from that regulation that are intended to enhance the quality of the reports received and increase the efficiency of FDA's report processing. FDA believes the benefits of changes implemented by the new regulation far outweigh the limited costs for manufacturers to familiarize themselves with the new requirements.

Under the final rule, manufacturers have 30 days after they become aware of an MDR event (with the exception of 5-day reports required by § 803.53) to report the event to FDA. FDA, however, has eliminated the portions of monthly reporting requirements, as proposed, that would have required manufacturers to submit, in addition to individual adverse event report information, an evaluation of adverse events consisting of the results of a statistically-based trend analyses conducted by the manufacturer, a discussion of the underlying methodologies used, a description of any unusual or unexpected events, and a description of remedial action taken.

As proposed, the greatest benefit of the evaluation portions of the monthly report would have been the overview of adverse experience trends it would provide. However, FDA has reevaluated the benefits of these monthly reports, and determined that the agency would incur the costs of data entry regardless of the industry's analysis, and that a computer program for the analysis of the data may be used at a relatively low cost to the agency. Furthermore, the agency anticipates that internal trending analysis will be conducted as part of a manufacturer's CGMP. Any remedial actions presenting an unreasonable risk of substantial harm that are undertaken based upon internal trend analyses are reportable in a 5-day report. Other essential information under the proposed monthly report will also be made available to the agency under the CGMP regulations, and would be made available to FDA under the proposed reports of removals and corrections regulation.

The final regulation will also allow FDA to receive information about reports sooner than the monthly reports as previously proposed. The proposed regulation allowed the manufacturer up to 2 months from the date of an adverse event to submit the monthly report. For example, under the proposed regulation, information received by the manufacturer on January 1 would have been due in a monthly report in March. Under the final regulation, the manufacturer will submit all reports of adverse events within 30 days of the event. Accordingly, under the final rule, information about a reportable event the manufacturer received on January 1, would have to be reported within 30 days.

FDA believes that the timeframes under the final regulation allow sufficient time for completing individual reports because the manufacturer would no longer be required to compile the trend analysis and other evaluations as previously proposed for the monthly reports. FDA also believes that the monthly reporting of individual adverse events in the final rule will achieve FDA's goal of obtaining better quality initial reports from manufacturers by allowing more time to complete the reports than allowed under the 1984 regulation. Nonetheless, the public health will benefit under the final rule because FDA will receive reports of individual events sooner than under the proposed rule.

40. One comment objected to the use of identification (ID) numbers on the reporting form, claiming they are unnecessary.

The agency disagrees. Report ID numbers are essential to FDA's ability to efficiently audit, process, analyze and evaluate MDR data. One of the major deficiencies of the current system is its inability to consistently identify similar devices and other data elements that facilitate the comparison of adverse events. The use of device ID numbers (§§ 803.32(c)(6) and 803.52(c)(6)), user facility and manufacturer report numbers (§§ 803.3(dd) and (o), respectively)), and event codes