DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803 and 807

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and Registration

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations requiring medical device user facilities and manufacturers to report adverse events, related to medical devices, under a uniform reporting system. This regulation is mandated by the Safe Medical Devices Act of 1990 (SMDA) and prescribes the conditions under which reports must be submitted, the content and timing of the requisite reports, and how FDA will utilize the information in carrying out its public health protection responsibilities. This rule is intended to augment the agency's postmarket surveillance activities and public health protection responsibilities relating to medical devices.

In the future, FDA will propose to revoke the distributor adverse event reporting regulations that went into effect on May 28, 1992, by operation of law and replace them with provisions based on notice and comment. FDA will also propose to fully implement its authority under the Medical Device Amendments of 1992 (the 1992 amendments).

DATES: This final rule is effective April 11, 1996. Submit written comments, as requested elsewhere in this document by, January 10, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ-530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION: On November 26, 1991 (56 FR 60024), FDA published a tentative final rule implementing the user and distributor reporting provisions of the SMDA (hereinafter referred to as the November 1991 tentative final rule). The agency received over 300 comments in response to the tentative final rule, which are carefully evaluated and responded to in this final rule. The final rule also reflects the superseding reporting standard mandated by the Medical Device Amendments of 1992.

I. Highlights of the Final Rule

This final rule provides FDA with increased post-market surveillance information by requiring medical device user facilities and manufacturers to report adverse event information as follows:

(a) Medical device user facilities must submit a medical device report (MDR) to the device manufacturer within 10 days after becoming aware of a reportable death or serious injury (including serious illness). If the event involves a device-related death, or if the identity of the device manufacturer is not known, the report must be sent to FDA. User facilities must also submit a semiannual summary of reports to FDA.

(b) Device manufacturers must submit MDR reports to FDA within 30 days after becoming aware of a reportable death, serious injury, or malfunction.

(c) Device manufacturers must annually certify the number of MDR reports filed with FDA during the preceding year.

(d) Upon receiving information about an MDR reportable event, device manufacturers must submit a ''5-day report'' to FDA, within 5 work days of: (1) Becoming aware that a reportable event or events, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health; or (2) becoming aware of an MDR reportable event from which FDA has made a written request for the submission of a 5-day report.

(e) A device manufacturer is responsible for reporting MDR events related to its devices, whether or not the devices are still being marketed by the firm. If a manufacturer receives information about an event involving a device incorrectly identified as one marketed by that firm, the information received must still be forwarded to FDA, with an explanation that the device was misidentified.

In finalizing this regulation, FDA has worked to meet the significant challenges of devising an effective medical device adverse event reporting system while balancing industry concerns with public health needs and statutory imperatives. The agency has also taken steps to minimize the administrative costs and paperwork burdens that will inevitably result for FDA, the medical device industry, and the device user community. FDA is keenly aware of and sensitive to the impacts of these new regulatory requirements on the pace of technological advancement and economic well-being of the medical device industry. At the same time, the agency is cognizant of the usefulness of information about the clinical performance of medical devices in fulfilling its public health mandate.

In striving to achieve regulatory balance, the agency carefully analyzed over 300 public comments submitted in response to the November 1991 tentative final rule, and resolved policy and legal issues arising from the comments and internal deliberations. This review of comments, combined with an economic threshold analysis, and other agency studies and deliberations, resulted in a number of major modifications that will facilitate compliance with the final reporting requirements and substantially reduce the overall costs, by an estimated $31 million, borne by device user facilities, the device industry, and the agency. These modifications are as follows:

(a) The agency has eliminated certain criteria from the previously proposed manufacturer monthly reports including: An evaluation consisting of a narrative description of the results of statistical 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 any remedial actions taken.

FDA believes that the benefits of the proposed mandatory trend analyses were not commensurate with the attendant costs to industry. Upon further review, the agency has determined that it would incur the costs of data entry regardless of the industry's analysis, and operating a computer program for the analysis of the data would be a relatively low cost to the agency. The proposed requirements for other information that the final regulation is not adopting will still be made available to the agency under the existing current good manufacturing practice (CGMP) regulations (21 CFR part 820), and under proposed 21 CFR part 806, reports of removals and corrections (59 FR 13828, March 23, 1994).

(b) The final regulation's reporting timeframe is shorter than the timeframe proposed. Earlier access to adverse event information will help the agency better to protect the public health.

(c) The agency has eliminated the proposed training and educational requirements, which would have been particularly costly to user facilities,