because the projected costs substantially exceeded expected benefits. This change will provide a net estimated annual cost saving of $29.1 million.

(d) The proposed imminent hazard report deadline has been extended from 3 days to 5 days, and renamed a 5-day report. This extended reporting timeframe should provide a more realistic opportunity for the manufacturer to conduct a preliminary investigation regarding the event. Any information not available for submission on the 5-day report must be submitted in a supplemental report.

(e) The agency has developed reporting forms for baseline reports, semiannual reports, and annual certifications. This action will streamline the reporting procedure because industry will not be required to format its own reports. The standardized report forms and associated standardized electronic reporting formats will facilitate the input of information submitted into FDA's data base. This more efficient data processing will increase the agency's capacity to respond to critical device- related problems by permitting more rapid data analysis, leading to appropriate corrective measures.

(f) The agency has adapted its MDR systems and reporting requirements in order to use the MEDWATCH form for reporting individual adverse events. In so doing, FDA has eliminated a number of proposed reporting elements, including the ''degree of certainty'' associated with a reportable event, the ''medical status of patients'' involved in device-related incidents, product ''service and maintenance,'' etc. The adoption of the MEDWATCH reporting form streamlines the reporting process and reduces the amount of information reporters must submit to FDA.

(g) The agency has clarified that user facilities must report only information that is reasonably known to them, and are not required to investigate adverse events.

(h) The agency has devoted much time and effort to accommodate electronic reporting. The agency is in the process of developing formats, guidelines, and procedures for electronic reports which, when available, will obviate the need for written agency approval for the use of electronic submissions.

(i) In response to comments, the agency has clarified a number of the definitions included in the proposed rule and added new definitions to enhance clarity. The agency also substantially altered the organization and the paragraph designations of the final rule to provide information in the clearest and most usable form in part 803 (21 CFR part 803).

Revised part 803 has been subdivided into five subparts. Subpart A contains general provisions including sections for the scope, definitions, public availability of reports, and general reporting and record requirements.

Subpart B of revised part 803 contains generally applicable reporting requirements for individual adverse event reports. Specific requirements for individual adverse event reports, and other reports required by user facilities and manufacturers, are in subparts C and E, respectively. Each subpart divides the reporting requirements for each type of reporting entity into separate sections that are organized to improve readability. The agency believes that the new organization of the regulation provides clearer guidance to industry than the 1991 tentative final rule.

II. Background

Under the Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. 301–394) (the act), and the Medical Device Amendments of 1976 (Pub. L. 94–295) (the 1976 amendments), FDA issued medical device reporting regulations for manufacturers (49 FR 36326 at 36348, September 14, 1984). To correct weaknesses noted in the 1976 amendments, and to better protect the public health by increasing reports of device-related adverse events, Congress enacted the SMDA (Pub. L. 101–629), which required medical device user facilities, and distributors to report certain device-related adverse events. In response to a directive in the SMDA, FDA issued the November 1991 tentative final rule proposing to implement regulations concerning reporting of adverse events related to devices by user facilities and distributors. In the November 1991 tentative final rule, FDA also proposed to amend the existing manufacturer reporting regulations to conform to the proposed user facility and distributor reporting requirements.

A. User Facility, Manufacturer and Distributor Reporting Requirements Under the SMDA

The SMDA added section 519(b)(1) to the act (21 U.S.C. 360i(b)(1)) to require that certain user facilities (hospitals, nursing homes, ambulatory surgical facilities and outpatient treatment facilities) report certain adverse events. The SMDA also authorized FDA to require diagnostic outpatient facilities to submit reports. Under the SMDA, user facilities must report device-related deaths to FDA and to the manufacturer. They must also report serious illnesses and injuries to the manufacturer, or to FDA if the manufacturer's identity is unknown. Reports must be made as soon as practicable, but no later than 10 working days after the user facility becomes aware of a reportable event. In addition to individual adverse event reports, the SMDA requires each user facility to submit to FDA, on a semiannual basis, a summary of the reports it has submitted to FDA and to manufacturers. The provision in section 519(b) of the act that requires user facilities to report adverse events became effective by operation of law on November 28, 1991.

In addition to requiring reporting by user facilities, the SMDA added section 519(a)(6) (subsequently redesignated as 519(a)(9) by the 1992 amendments) to the act to require FDA to issue regulations regarding distributor reporting of adverse device events. The SMDA also added section 519(d) to the act to require both manufacturers and distributors to certify to FDA either the number of reports submitted in a year or that no such reports were submitted to the agency.

Distributor reporting requirements became effective on May 28, 1992, when the provisions relating to distributor reporting in the November 1991 tentative final rule became final by operation of law. In the Federal Register of September 1, 1993 (58 FR 46514), FDA published a notice announcing that the proposed distributor reporting regulations had become final by operation of law on May 28, 1992, and that these regulations had been amended by certain provisions of the 1992 amendments discussed below.

In the Federal Register of September 1, 1993, FDA also published a final rule, based on the November 1991 tentative final rule, requiring distributors to register and list their devices (58 FR 46514). Distributor registration and listing requirements became effective on October 1, 1993.

In a future rulemaking, FDA will propose in the Federal Register to revoke the distributor regulation that went into effect by operation of law and replace it with provisions based on notice and comment.

B. User Facility, Manufacturer and Distributor Reporting Requirements Under the Medical Device Amendments of 1992

Subsequent to FDA's issuance of the November 1991 tentative final rule to require adverse event reporting by user facilities, distributors, and manufacturers, on June 16, 1992, the President signed into law the 1992