amendments reflects clear congressional intent to permit FDA to require, under the authority of section 519 of the act, manufacturers to report to FDA product defects and adverse effects of the firms' devices. (See H. Rept. 853, 94th Cong., 2d Sess. 23 (1976).)

Among other things, section 519 of the act states that any reporting requirement established under the authority of that section: (1) May not be unduly burdensome (considering the cost of compliance and the need for the requirement); (2) shall state the purpose for any required report or information and identify to the fullest extent practicable such report or information; (3) may not, except in certain circumstances, require the disclosure of a patient's identity; and (4) may not, except in certain circumstances, require the manufacturer of a class I device to maintain records or to submit information not in its possession, unless such report or information is necessary to determine whether a device is misbranded or adulterated. The House Report cautions, however, that these limitations ''should not be construed as limiting the Secretary's authority to obtain information needed to insure that the public is protected from potentially hazardous devices.'' (Id.) In its discussion of section 519 of the act, the House Report lists examples of reasonable reporting requirements, including reports of defects, adverse reactions and patient injuries. It is also clear from the legislative history that Congress intended FDA to use its authority under section 519 of the act to protect the public from potentially hazardous devices, as well as from devices with confirmed hazards. (Id.)

Since enactment of the 1976 amendments, Congress has focused considerable attention on FDA's implementation and enforcement of the act. Congress concluded that the 1976 amendments were not always adequate to protect the public health. (H. Rept. 808, 101st Cong., 2d Sess. 13–14 (1990); S. Rept. 513, 101st Cong., 2d Sess. 13–16 (1990).) To correct these problems, Congress passed and the President, on November 28, 1990, signed into law the SMDA, which amended the medical device provisions of the act.

The SMDA added section 519(b)(1) to the act to require that certain user facilities (e.g., hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities) report deaths related to medical devices to FDA, as well as to the manufacturer if the manufacturer's identity is known. Section 519(b)(5)(A) of the act also provides FDA with authority, which FDA has exercised in this final regulation, to include outpatient diagnostic facilities in this requirement. Serious illnesses and injuries are to be reported to the manufacturer, or to FDA if the manufacturer's identity is not known. Reports must be made as soon as practicable but no later than 10 working days after the user facility becomes aware of an event. The responsibility for reporting is limited to events involving patients and employees of the facility. Each device user facility is also required to submit to FDA, on a semiannual basis, a summary of reports it has submitted to both FDA and manufacturers.

Section 519(d) of the act, as added by the SMDA, also requires manufacturers to certify to FDA the number of reports submitted in the preceding 12-month period or, alternatively, certify that no such reports have been submitted to the agency during the same period. FDA believes that section 519 of the act, as amended by the SMDA and the 1992 amendments, provides clear authority to issue this regulation for manufacturers and user facility reporting.

Moreover, FDA does not believe that the provisions of this regulation are overly broad or unduly burdensome. FDA has reviewed and revised the regulation to clarify and limit the scope as appropriate. FDA believes that certain classes of persons, which might otherwise fit within the definition of manufacturer, should be exempt from the reporting requirements because reports from these persons are not necessary to ensure that the device is not adulterated or misbranded, and the device is otherwise safe and effective. Accordingly under § 803.19, dental laboratories and optical laboratories have been exempted from the reporting requirements. FDA believes that these entities are not likely to receive reports of device-related deaths, serious injuries, or reportable malfunctions. In addition, requiring negative annual certification reports from these entities would be burdensome and not provide significant benefit to the public health. Therefore, FDA is excluding such entities from the reporting requirements. Other specific revisions are discussed in detail throughout this document.

FDA believes this regulation carefully balances the interests of public health with industry burdens by limiting the required information to only that which is necessary to evaluate risks associated with medical devices and that it will enable the agency better to take appropriate regulatory measures to protect the public health. Furthermore, FDA does not believe that the burden on reporting entities will be significant. Based upon the number of reports FDA has received since the publication of the November 1991 tentative final rule, the agency anticipates that it will receive approximately 150,000 reports the first year of this reporting program (the agency currently receives over 100,000 reports annually).

2. Several comments pointed out that these provisions go beyond the scope of the SMDA in that the timeframes for reporting adverse events exceed the requirements of SMDA. Other comments argued that all employees of reporting entities should not be included under the reporting requirements of the SMDA, and that accordingly, the timeframes for reporting should not be triggered upon the knowledge of ''any employee'' of a reporting entity.

FDA does not agree that the regulation's 10-day reporting timeframes for user facilities and 5-day and 30-day reporting timeframes for manufacturers are beyond the scope of the SMDA. Section 519(b)(1)(A) of the act specifies that user facilities must report certain adverse events as soon as practicable, but not later than 10 work days after becoming aware of the information. This section further specifies that FDA has the discretion to prescribe, by regulation, a shorter reporting period. While the statute does not specify the time periods allowed to manufacturers, the timeframes are consistent with section 519 of the act, the legislative history and FDA's public health responsibility to require that the reports are forwarded to the agency in a timely manner. FDA believes the time periods prescribed in the final regulation allow sufficient time for reporting entities to gather information, and are sufficiently time sensitive to allow the agency to respond rapidly and appropriately to protect the public health.

FDA also does not agree that employees of reporting entities should not be subject to the reporting requirements and that timeframes for reporting should not be triggered when employees of the reporting entities become aware of events. The scope of the act does not exclude any responsible persons who are employees of these entities from complying with section 519 of the act.

Under the final regulation, the reporting periods are based upon the time at which the reporting entity becomes aware of the reportable event. FDA believes that the final regulation's definition of ''becomes aware'' in § 803.3(c) properly defines the types of user facility and manufacturer employees who must become aware of a reportable event in order to trigger the reporting requirement. FDA believes