

表 4：報告に要する年間負担

CFR セクション	回答者数	回答者当たり の回答数	回答の 年間総数	回答あたりの 時間数	合計時間
803.19	100	1.0	100	3.0	300
803.30(a)	700	1.0	700	3.0	2,100
803.30(b)	20,000	1.5	30,000	3.0	90,000
803.33	2,000	1.0	2,000	1.0	2,000
803.50	1,250	40.0	50,000	0.5	25,000
803.53	100	1.0	100	0.5	50
803.55	1,000	20.0	20,000	1.1	22,000
803.56	500	20.0	10,000	1.0	10,000
803.57	12,000	1.0	12,000	1.0	12,000
803.58	5,000	1.0	5,000	1.0	5,000
合計					168,450

1.最初提出する報告書は大凡2時間要するが、その後の年次改訂は0.5時間で完成する。

よって、本表で示されているよう、回答に要する平均時間は1.1時間である。

表 5：記録に要する年間負担

CFR セクション	記録係の人数	記録係当たりの 時間数	合計時間
803.18(c).....	36,639	0.25	9,160
803.18(e)	625	16.00	10,000
合計			19,160

1991年11月26日の暫定的最終規則は60日間の意見提出期間(後に1992年1月24日の連邦官報57FR2861により90日間に延長)が設定され、本最終規則は寄せられた意見を加味しているものであるが、FDA書式3419(6ヶ月報告書)、FDA書式3417(基本報告書)およびFDA書式3381(年次証明)については今まで、検討のためOMBあるいは一般国民が入手することはできなかった。よって、1995年文書削減法のセクション3507(d)に基づき、FDAは情報収集要件の検討のため、最終規則をOMBに提出した。

また、FDA は (1) FDA が適切に機能するため、また収集される情報に現実的利用価値があるかを検討するため； (2) 情報収集に関わる負担についての計算に用いられた方法論と仮説の妥当性を含み、FDA の推定値が正確であるかを評価する； (3) 収集される情報の品質、有用性および明確性を向上させる；および (4) 情報収集を行うものにとっての負担を軽減するため、自動化技術、電子技術、機械あるいはその他の収集方法また情報技術を促進する（例えば、回答の電子的方法による提出を許可する）。

情報収集要件について、個人あるいは組織は FDA Dockets Management Branch（上記に住所記載）および Washington DC 17th St. NW 10235, 725 室、OMB 情報規制部 FDA 担当官当てに 1996 年 1 月 10 日までに意見を提出することができる。

現在有効な OMB 管理番号が示されていない場合、情報収集について回答する必要はない。この最終規則には OMB 第 0910-0059 号により許可され、1996 年 3 月 31 日に有効期限が切れる情報収集要件を含んでいる。当該情報収集要件を許可、訂正あるいは不許可とする OMB の決定について、FDA は本最終規則の発効日までに連邦官報に通知を記載する。

Monday
December 11, 1995

21 CFR Part 803

Part II

**Department of
Health and Human
Services**

Food and Drug Administration

21 CFR Part 803, et al.
Medical Device User Facility and
Manufacturer Reporting, Certification and
Registration; Delegations of Authority;
Medical Device Reporting Procedures;
Final Rules

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,

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

amendments (Pub. L. 102-300), amending certain provisions of section 519 of the act relating to reporting of adverse device events. In the future, FDA will publish a proposed rule to fully implement its authority under the 1992 amendments. A summary of these changes follows:

1. Adoption of a Single Reporting Standard

Section 5(a) of the 1992 amendments adopts a single standard to specify when injuries caused by devices must be reported to FDA. Manufacturers and importers are required to report a device-related adverse event to FDA whenever they receive or otherwise become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and that such device or a similar device marketed by them would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Similarly, section 5(a) of the 1992 amendments revises the reporting requirements to require a user facility to report whenever the facility receives or otherwise becomes aware of information that reasonably suggests that a device "has or may have caused or contributed" to the death, serious illness or serious injury of a patient of the facility.

2. Single Definition of Types of Injuries That Must Be Reported

Section 5(a) of the 1992 amendments also adopted a single definition for the types of injuries that user facilities, manufacturers, importers, and distributors must report. This definition requires reporting of an injury or illness that is: (1) Life-threatening; (2) results in permanent impairment of a body function or permanent damage to a body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. This definition differs from the previous statutory definition of "serious injury" or "serious illness" in the user facility provisions and the definition in the November 1991 tentative final regulation. The new definition deleted the requirement that an injury must require immediate intervention to preclude permanent impairment or damage in order to qualify as a reportable adverse event.

3. New Authority To Require Reporting of "Other Significant Adverse Device Experiences"

The 1992 amendments also authorized FDA to issue regulations requiring user facilities, manufacturers, importers, and distributors to report "significant adverse device experiences" that the agency determines are necessary to be reported, other than deaths, serious injuries or serious illnesses, that might otherwise not fall within the definitions of reportable deaths, serious injuries, or malfunctions.

III. Reporting Forms

A. Individual Adverse Event Reports by User Facilities and Manufacturers

Under §§ 803.30 and 803.50, user facilities and manufacturers are required to submit device-related reports of individual adverse events on FDA Form 3500A or an FDA approved electronic equivalent. In order to simplify and consolidate reporting of adverse events, FDA announced in the Federal Register of February 26, 1993 (58 FR 11768) the availability of a new single "MEDWATCH" form for reporting adverse events and product problems with devices, drugs, biologics, special nutritional products and other products regulated by the agency (hereinafter referred to as the February 1993 notice). In response to FDA's request for comments on the form in the Federal Register, 79 comments were submitted by medical device trade associations and other regulated or affected entities. On June 3, 1993 (58 FR 31596), after consideration of these comments, FDA published the final reporting form. (The form is described in § 803.10.)

B. Annual Certification by Manufacturers

Under § 803.57, manufacturers must also submit at the time of their annual registration a completed FDA Form 3381 or an FDA approved electronic equivalent, certifying: (1) That all reportable events were submitted; (2) the number of reports submitted; or (3) that no reports were submitted during the previous 12-month period.

C. Semiannual Summaries by User Facilities

Under § 803.33, user facilities are required to submit, on FDA Form 3419 or an FDA approved electronic equivalent, a semiannual summary of all events reported during the prior reporting period. Semiannual reports must include information regarding the user facility, device manufacturers,

products, and a brief description of the events.

D. Baseline Reports

Under § 803.55, manufacturers must submit baseline reports, on FDA Form 3417 or an FDA approved electronic equivalent, simultaneously with the submission of the first event report for each device. These reports, which are to be updated annually, must contain information on the manufacture and distribution of the relevant devices.

E. Effective Date of the Reports

Adverse event reports and other related reports required by this regulation must be submitted using the appropriate forms or approved electronic equivalents, after April 11, 1996.

IV. Summary and Analysis of Comments and FDA's Response

This final rule is based on FDA's analysis of the over 300 comments that the agency received in response to the November 1991 tentative final rule, and it conforms to certain statutory revisions in the 1992 amendments. This final rule reflects actions in two areas. First, it revises the manufacturer reporting regulations that have been in effect since 1984. Second, it implements the statutorily directed user facility reporting requirements that have been in effect since November 28, 1991.

Originally, FDA gave interested persons until January 27, 1992, to comment on the November 1991 tentative final rule. In the Federal Register of January 24, 1992 (57 FR 2861), FDA extended the comment period until February 26, 1992. A summary of the comments and FDA's responses follow:

A. Section 803.1—Scope

1. Several comments stated that the proposed regulation exceeds the SMDA and has no statutory authority. Many comments stated that the scope of the provisions was overly broad, and would increase the burdens, with unclear benefits, on all parties involved.

The agency disagrees. Section 519 of the act, as amended by the SMDA and the 1992 amendments, provides clear authority to issue this regulation. Section 519 of the 1976 amendments granted FDA the authority to issue regulations to require manufacturers to maintain such records, make such reports, and provide such information to FDA as may reasonably be necessary to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for human use. The legislative history of the 1976

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

that it will be feasible for user facilities and manufacturers to train the employees, described below, to be familiar enough with the obligation to report adverse events immediately to the appropriate person that the manufacturer or user facility designates as responsible for MDR reporting.

Under § 803.3(c), a device user facility is deemed to have "become aware" when medical personnel of a facility become aware of a reportable event. "Medical personnel" are defined in § 803.3(r) as individuals who are licensed, registered, or certified to administer health care; individuals with professional or scientific degrees; individuals who are responsible for receiving medical complaints or adverse event reports; or supervisors of such persons. FDA believes that a user facility can easily notify these types of employees about their obligation to immediately forward possible device-related adverse events to the appropriate person designated by the hospital to submit such reports.

FDA believes that manufacturers have a direct responsibility to inform all employees to immediately forward adverse event information to the appropriate person appointed by those entities to submit MDR reports. Accordingly, FDA generally considers that a manufacturer becomes aware of an adverse event whenever any employee becomes aware of an adverse event. The one exception is for 5-day reports under § 803.53(b), which requires manufacturers to submit a report when the manufacturer becomes aware of information that an adverse event or events necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

Under § 803.53, manufacturers must submit a 5-day report under two different circumstances. The first type of 5-day reporting obligation arises after a manufacturer has received a written request from FDA for 5-day reports for specific types of adverse events. Under this circumstance, a 5-day report must be submitted when any employee becomes aware of an adverse event. FDA believes that the awareness of any employee should trigger the reporting requirement when FDA has informed the manufacturer of the need for specific adverse events that require 5-day reports because the manufacturer could easily inform all of its employees of FDA's request.

The second type of 5-day report does not involve a direct request from FDA and is required only when the manufacturer becomes aware that an event or events necessitate remedial action to prevent an unreasonable risk

of substantial harm to the public health. Accordingly, this type of 5-day reporting requirement would only arise if remedial action were required, and the remedial action is necessary to prevent an unreasonable risk of substantial harm to the public health. If no remedial action is required, or the remedial action is taken but it is not necessary to prevent an unreasonable risk to the public health, reportable adverse events should be submitted as 30 day reports.

Because FDA does not believe certain employees, such as non-technical staff, would be able to recognize that an adverse event or events may require remedial action to prevent a substantial risk to the public health, the final regulation requires that these types of 5-day reports be submitted only when employees holding certain positions of responsibility become aware of adverse event information. Accordingly, the final regulation considers a manufacturer to be aware of this type of 5-day report only when an employee with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health. FDA believes that limiting the type of person who must be aware of the adverse event to these types of individuals is appropriate because persons in these positions should be able to recognize that the event or events may present significant risks to the public health.

3. Some comments suggested limiting the scope of these provisions so that reporting is required only when there is a death or serious injury. Other comments suggested that reports not be required if the device was only indirectly responsible for a death or serious injury, or was not a significant factor. Another comment suggested that reporting be limited to instances of malfunction.

Section 519 of the act provides FDA with authority to require reporting of adverse events other than deaths or serious injuries. FDA has exercised this authority since 1984 by requiring manufacturers to report certain malfunctions. Moreover, section 519(a)(1) of the act (as amended by section 5 of the 1992 amendments) specifically states FDA's adverse event reporting regulations must require manufacturers to report malfunctions if the recurrence of the malfunction would

be likely to cause a death or serious injury, regardless of whether an actual death or injury occurs. Because devices with such malfunctions pose significant risks, FDA needs to be informed of these incidents. The final regulation, therefore, requires manufacturers to report malfunctions when recurrence would be likely to cause a death or serious injury. User facilities are encouraged but not required to report malfunctions to manufacturers and distributors.

Section 519(b)(1)(B)(ii) of the act, as added by the 1992 amendments, also provides FDA with authority to require user facilities, distributors, and manufacturers to report other significant adverse device experiences that FDA determines necessary. Therefore, in a future issue of the Federal Register, FDA will propose to require that certain events be reported as significant adverse device experiences. Although some of these experiences may not have caused harm, FDA believes such events should be reported because of the potential risk to the public health if the event were to recur. Such information will enable the agency to take appropriate measures to prevent such recurrences.

FDA also disagrees with the comments stating that reporting should be required only when a device directly causes an adverse event or is a significant factor. Section 519(a)(1) and (b)(1)(A) of the act requires reporting of any adverse event when information reasonably suggests that a marketed device "may have caused or contributed" to a reportable event (emphasis added). Limiting reporting to adverse events directly or significantly caused by devices would narrow the statutory reporting standard which requires reporting of adverse events when a device "may have caused or contributed" to an adverse event (emphasis added).

FDA cannot agree with the comment that suggested reporting be limited to instances of malfunction. As stated above, section 519 of the act requires reporting of deaths and serious injuries, and authorizes FDA to require reporting of other significant adverse device experiences, as well as malfunctions.

FDA does not agree with the comments that reporting should not be required when events are anticipated or intrinsically caused by the device. The statute does not exempt events that were anticipated or intrinsically caused by the device. (See section 519(a)(1) and (b)(1)(B) of the act.) Moreover, merely knowing that adverse events are anticipated or intrinsically caused by a device does not obviate the need for information contained in event reports.

FDA needs to know the frequency and severity of adverse events in order to take appropriate action.

4. One comment objected to providing warranty information. Other comments stated that a manufacturer's responsibility to report should end at the expiration of the warranty.

The agency disagrees. Reporting requirements under section 519 of the act are not restricted or limited in any way by manufacturer warranties. Section 519 of the act requires manufacturers to report certain adverse events regardless of whether the warranty has expired. Warranties are private contracts between the purchaser and the manufacturer. In order to protect the public health and determine whether actions should be taken with respect to a device associated with an adverse event, FDA must receive information regarding all reportable events, including those that occur after a manufacturer's warranty has expired.

5. One comment stated that certain adverse events may result from the user not knowing how to properly use the device, and that this would lead to the reporting of events properly attributable not to the device, but to its incorrect use.

As with the 1984 manufacturer adverse event reporting regulation, this rule requires reports of certain adverse device events caused by user error. Device injuries attributed to user error may indicate that the device is misbranded within the meaning of section 502(f) of the act (21 U.S.C. 352(f)) in that the device fails to bear adequate directions for use or adequate warnings. In such cases, reports of adverse events that result from user error may alert FDA to the need for improved labeling to prevent future injuries.

6. One comment suggested that independent device service personnel be added to the list of people required to report because some manufacturers may not receive reports from their own service personnel.

Under section 519 of the act, only user facilities, manufacturers, and distributors are required to report adverse events to FDA. User facilities are considered to have "become aware" of such information whenever any medical personnel becomes aware of a reportable event. Manufacturers are considered to have "become aware" of events required to be reported in 30 days, or required to be reported in 5 days, pursuant to an FDA request, when any employee becomes aware of an adverse event. Manufacturers are considered to have become aware of significant risk 5-day reports, which are

more fully described in IV.A., comment 2, of this document, only when certain higher level employees become aware of adverse events requiring remedial action.

FDA believes that an employee of a manufacturer includes independent service personnel who are contracted by manufacturers to service their medical devices. It is the responsibility of manufacturers to ensure that their service personnel, whether staff employees or under contract, are informed of the requirement to report deaths, serious injuries, malfunctions, or other significant adverse device experiences that may be required by regulation in the future.

B. Section 803.3—Definitions

7. Many comments stated that the definition of "device family" (§ 803.3(e)) that is used to identify similar groups of devices on the manufacturer baseline report, is vague and overly broad. One comment suggested that each device be listed in the regulation; others suggested that the definition be deleted.

FDA does not agree that the definition should be deleted. The identification of the device family on the baseline reports for individual device models will help FDA and manufacturers group similar models for analysis. This will aid in identifying the causation and nature of device-related problems. FDA agrees, however, that the definition should be clarified and has revised it accordingly. Manufacturers may use their own methods of grouping devices if the groupings meet the definition of "device family," i.e., the devices have the same basic design and performance characteristics related to safety and effectiveness, intended use and function, and device classification and product code. FDA has the discretion to determine the appropriateness of a manufacturer's determination of the devices that comprise a device family. It would be impractical to list each device in the regulation.

8. Many comments stated that the definition of "device user facility" (§ 803.3(f)) is vague. Several of these comments requested clarification regarding what facilities are included in the definition. Several comments suggested that certain groups (i.e., blood banks, independent rescue squads, school clinics or nurse offices, employee health units, dental offices and free-standing care units operating as private physician offices) be specifically included or excluded from the definition.

FDA agrees in part. Under section 519(b)(5)(A) of the act, FDA has exercised its discretion to include

outpatient diagnostic facilities that are not physician offices in the definition of "device user facility." Under § 803.3(f), device user facility means "a hospital, ambulatory surgical facility, nursing home, or an outpatient diagnostic or treatment facility which is not a physician's office." To further clarify this definition, FDA has included definitions for the terms "physician's office" (§ 803.3(w)), "hospital" (§ 803.3(l)), "ambulatory surgical facility" (§ 803.3(b)), "nursing home" (§ 803.3(s)), "outpatient diagnostic facility" (§ 803.3(t)), and "outpatient treatment facility" (§ 803.3(u)).

Under section 519(b)(5)(A) of the act, physicians' offices are excluded from the definition of user facilities and are thereby excluded from adverse event reporting requirements. FDA believes that groups performing functions similar to physicians' offices such as dental offices and offices of other health care practitioners (e.g., chiropractors, optometrists, nurse practitioners, school nurse offices, employee health clinics, free-standing care units) fall within the definition of "physician's office" and therefore should be excluded from reporting. FDA invites further public comment on the definition of "physician's office" and may issue further guidance as necessary.

FDA has defined "outpatient treatment facility" as a distinct entity that operates for the primary purpose of providing non-surgical therapeutic care. FDA believes that ambulance or rescue squad services and independent home health care agencies fall within this definition. Given the critical risks posed by potential malfunctions of devices used by ambulance services and in home health care settings, FDA believes the inclusion of these services within the definition of "outpatient treatment facility" is appropriate.

Blood banks that operate in hospitals or as outpatient treatment or outpatient diagnostic centers fall within the definition of user facility. Accordingly, device-related adverse events that meet the definition of MDR reportable event, as defined in § 803.3(q), that occur in such blood banks must be reported. FDA invites further public comment on the definition of user facility and may issue further guidance as necessary.

9. Several comments stated that the definition of "imminent hazard" relating to types of adverse events that FDA proposed should have 3-day reporting timeframes (proposed § 803.3(g)) is unclear. A few comments suggested that the definition be deleted because it is too subjective, belongs in another regulation, or is beyond the scope of the SMDA. Some comments

stated that more than 3 days were needed for reporting.

FDA agrees. The agency is extending the time period to make such reports from 3 days to 5 days. FDA is also renaming "imminent hazard reports" as "5-day reports" (defined in § 803.3(k)), and has clarified this requirement in § 803.53.

The purpose of the 5-day report is to alert the agency rapidly to adverse events that may pose an unreasonable risk of substantial harm to the public health. Thus, the definition of "5-day report" has been revised to mean a report of an adverse event required by a manufacturer, submitted on FDA Form 3500A or an FDA approved electronic equivalent within 5 work days of: (1) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becoming aware that a reportable MDR 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) any employee becoming aware of an adverse event, if the manufacturer has received a written request from FDA for the submission of a 5-day report for those types of adverse events. When such a request is made, the manufacturer shall submit a 5-day report for all subsequent adverse events of the same nature that involve substantially similar devices for the time period specified in the written request. The time period stated in the original written request can be extended by FDA if it is in the interest of the public health.

FDA does not intend that a manufacturer delay or interrupt a remedial action in order to submit a 5-day report. The report must be made within 5 days of the manufacturer becoming aware that a reportable event or events necessitate remedial action to prevent unreasonable risk of substantial harm to the public health. Information that would reasonably suggest remedial action is necessary to prevent such risk may, for example, be from one MDR reportable event that makes the manufacturer aware of a serious design flaw that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public. On the other hand, information that would reasonably suggest remedial action is necessary may result from an internal trending analysis of several MDR reports that make the manufacturer aware that serious injuries or deaths occur at a

much higher frequency than expected. Further discussion relating to when a manufacturer is considered aware of a reportable event is in section IV.A., comment 2, of this document.

Manufacturers who submit 5-day reports are not required to submit reports of removals and corrections under section 519(f) of the act. Any information not available for reporting under the 5-day reporting timeframe may be submitted in a supplemental report.

FDA does not agree with comments asserting that 5-day reports are beyond the scope of the SMDA or belong in another regulation. Requiring 5-day reports is consistent with FDA's authority under section 519(a)(1) of the act to issue regulations requiring manufacturers to report information that reasonably suggests that one of their marketed devices "may have caused or contributed to a death or serious injury, or has malfunctioned and that such device * * * would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." For the protection of the public health, FDA may limit the time allowed to manufacturers for reporting events of which the agency should be quickly aware.

10. Many comments stated that the requirements relating to user facility incident files (proposed § 803.35(c)) that contain documents related to adverse events that a user facility must maintain are overly burdensome because the definition of "incident files" in proposed § 803.3(h) is overly broad. Many of these comments suggested that the definition of incident files be removed or changed in order to clarify or limit the scope of requirements relating to the files. Other comments suggested that FDA's access to the files be limited.

The agency agrees that the definition of these files (which have been renamed "MDR event files" in § 803.18 of the final regulation) could be narrowed. Accordingly, FDA has revised the definition of MDR event files to include MDR reports filed with FDA or other entities, and documents related to the adverse event, including documents relating to deliberations and decisionmaking processes used in the evaluation or determination of whether an event is an MDR reportable event. The final rule also allows the reporter to incorporate certain information by reference, such as medical records, patient files, and engineering reports, rather than include them in the MDR event file.

FDA does not agree that agency access to user facility files should be limited.

Under § 803.18(b), user facilities shall permit any authorized FDA employee during all reasonable times to have access to, and to copy and verify the records required under part 803. FDA has authority to inspect files under section 704(e) of the act (21 U.S.C. 374(e)). Section 704(e) of the act states that every person required to maintain records under section 519 of the act, and every person who is in charge or custody of such records, shall permit FDA at all reasonable times to have access to and to copy and verify such records. In issuing a regulation stating its authority under section 704(e) of the act to have access to user facility adverse event files, FDA is exercising its duty under the statute to protect the public health by ensuring that user facilities comply with reporting requirements issued under section 519 of the act.

11. Several comments stated that the definition of what kind of information triggers the reporting requirements, specifically, the definition of "information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury, or serious illness" (proposed § 803.3(i)), is unclear and requires further definition.

The agency agrees and has clarified this concept in § 803.20(c). As explained in section II.B.1 of this document, section 5 of the 1992 amendments revised section 519(a)(1) of the act, subsequent to FDA's November 1991 tentative final rule, to require the agency to issue regulations that require manufacturers and importers to report to FDA "whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." Similarly, section 5 of the 1992 amendments revised the reporting standard for user facilities under section 519(b)(1) (A) and (B) of the act to require a user facility to submit a report whenever it receives or otherwise becomes aware of information "that reasonably suggests that a device has or may have caused or contributed to a death * * * or serious illness of, or serious injury to, a patient of the facility * * *".

Under the revised 1992 amendments' statutory reporting standards, FDA has no discretion to change the reporting standards for manufacturers and user

facilities. Accordingly, FDA has revised the wording of the reporting standards in the final regulation for user facilities and manufacturers to reflect the exact wording in the 1992 amendments for these entities. Therefore, the final regulation requires user facilities and manufacturers to report certain adverse events whenever there is "information that reasonably suggests that a device may have caused or contributed to a death or serious injury."

The final rule describes, in § 803.20(c) "[i]nformation that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event" to be any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. Reports are not required when there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to an MDR reportable event. Information that leads to the conclusion that an event is not reportable must be retained in the MDR event files for the time periods specified in § 803.18.

The final rule further defines, in § 803.3(d), "caused or contributed" to mean that a death or serious injury was or may have been attributable to a medical device, or that a medical device was or may have been a factor in the adverse event including events occurring as the result of its failure, malfunction, improper or inadequate design, labeling, performance, manufacture, or user error. Devices may cause or contribute to MDR reportable events either directly or indirectly.

12. One comment stated that malfunctions of medical devices used for a nonmedical purpose should be exempted. Other comments stated that the term "malfunction," as defined in § 803.3(m), needed clarification, especially with regard to implanted devices. Another comment asked who is required to report implant malfunctions.

Under this final regulation in subpart E of part 803 manufacturers must report certain malfunctions, including implant malfunctions, that would be likely to cause or contribute to an MDR reportable event, regardless of how the device is used. Although user facilities are not required by statute or regulation to report malfunctions, FDA encourages user facilities to report malfunction information to manufacturers and distributors. Malfunction reports

provide important information to FDA concerning device safety.

Reporters do not need to assess the likelihood that a malfunction will recur. The fact that the malfunction occurred once leads to the presumption that the malfunction will recur. A malfunction is reportable if any one of the following is true: (1) The chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote; (2) the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury; (3) the malfunction results in the failure of the device to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences required by regulation (the essential function of a device refers, not only to the device's labeled use, but for any use widely prescribed within the practice of medicine); (4) the malfunction involves a long-term implant or a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life; or (5) the manufacturer takes or would be required to take an action under sections 518 or 519(f) of the act as a result of the malfunction of the device or other similar devices.

Malfunctions are not reportable if they are not likely to result in a death, serious injury or other significant adverse device experience, that FDA, in a future rulemaking, may require by regulation. A malfunction which is or can be corrected during routine service or device maintenance must be reported if the recurrence of the malfunction would be likely to cause or contribute to a death or serious injury, or other significant adverse device experiences required by a future regulation.

13. Several comments stated that the definition of a "manufacturer" (§ 803.3(n)), who is subject to adverse event reporting requirements, is overly broad with regard to custom devices and devices modified by users. One comment suggested that the definition be modified to include manufacture for commercial distribution only.

FDA believes that for protection of the public health, the definition should be broad enough to provide for reporting by all persons engaged in the manufacture, preparation, propagation, compounding, assembly or processing of medical devices, who may receive information about adverse events related to medical devices, except those manufacturers exempted under section 519(c) of the act and § 803.19. Under

section 519(c) of the act and § 803.19, a practitioner licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of that individual's professional practice is exempt from reporting. Manufacturers of devices not being commercially distributed but which are being used under an investigational device exemption are required to report adverse events under parts 812 and 813 (21 CFR parts 812 and 813) and are not required to submit reports under part 803. Parts 812 and 813, however, require reporting of all adverse device effects.

14. Many comments stated that the definition of "MDR reportable event" (§ 803.3(q)) is unclear, beyond the scope of SMDA, or otherwise in need of revision.

The definition of "MDR reportable event" has been modified to conform to revisions made to section 519 of the act by section 5 of the 1992 amendments. As defined in § 803.3(q), the revised definition of "MDR reportable event" mirrors the language of section 519(a)(1) and (b)(1) of the act, as amended by section 5 of the 1992 amendments.

FDA has further clarified terms contained in the definition of an "MDR reportable event" throughout this document. These include: "caused or contributed," as defined in § 803.3(d) and discussed in section IV.B., comment 11 of this document; "information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury" as defined in § 803.20(c) and discussed in section IV.B., comment 11 of this document; "malfunction" as defined in § 803.3(m) and discussed in section IV.B., comment 12 of this document; "become aware" as defined in § 803.3(c) and discussed in sections IV.A., comments 2 and 6, and IV.D., comment 27 of this document; and "serious injury," as defined in § 803.3(aa) and discussed in section IV.B., comment 21 of this document. The terms "necessitated medical or surgical intervention" and "permanent," which are now included in the definition of "serious injury," are also clarified in this document. "Necessitated medical or surgical intervention" is discussed in section IV.B., comment 16 of this document. FDA believes that these added definitions and discussion of these terms this document provides adequate clarification of the term "MDR reportable event."

15: A few comments stated that the definition of "manufacturer report number" (§ 803.3(o)), should be changed to allow flexibility and permit

manufacturers to use their own numbers.

The agency disagrees. A uniform numbering system is essential for FDA evaluation of reports, recordkeeping, filing and analyses. Because the manufacturer report number is based on the manufacturer registration number and all manufacturing sites are required to have a registration number, there is no additional burden on the manufacturer to comply with this requirement. If the manufacturer reporting site does not have a registration number, FDA will assign a temporary registration until the site is officially registered.

16. Several comments stated that the definition of "necessitated immediate medical or surgical intervention" (proposed § 803.3(o)), included as an element of the "serious injury" definition in § 803.3(aa), which is unclear, overly broad, and unduly burdensome. Some of these comments suggested that the terms "timely" and "intervention" be further defined or a standard for "immediate intervention" be set (e.g., within 6 hours). Other comments suggested that the event be reported only if significant intervention actually occurred.

In light of the 1992 amendments, most of the comments relating to the "immediate medical or surgical intervention" definition are no longer relevant. Section 5(a)(2) of the 1992 amendments revised and broadened the scope of reportable events that fall within the definition of "serious injury" by deleting the immediacy requirement from the definition. Under the 1992 amendments' revisions, FDA must require that injuries be reported that necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, that have or may have been caused by a device, regardless of the immediacy of the surgical or medical intervention.

FDA agrees with comments suggesting that an event be reported if significant intervention actually occurred. FDA believes, however, that any intervention is per se "significant" if it is necessary to preclude permanent impairment of a body function or permanent damage to a body structure.

17. Many comments stated that the definition of "patient of the facility" whose serious injuries and deaths user facilities must report (§ 803.3(v)) is too broad. Several comments objected to including individuals being diagnosed, treated, or receiving care "under the auspices of" the facility under this definition. Other comments objected to including employees of the facility who

suffer death or serious injury from a device used at or by the facility as a "patient of the facility." They further asserted that FDA does not have clear jurisdiction over these types of employee events and that MDR reports would duplicate reports required by other regulations (e.g., Occupational Safety and Health Administration (OSHA) regulations). A few comments suggested that the term "patient" be further defined.

The agency agrees that including any individuals treated or diagnosed "under the auspices" of a facility could be read very broadly to include certain individuals that are not intended to be covered by this regulation. Accordingly, FDA has revised this definition to include only individuals that are "being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility."

FDA does not agree, however, that employees of the facility who are injured and/or receive medical care arising from a device-related event at the facility should be excluded from the definition of "patient of the facility," and that information provided to other agencies for work-related injuries is duplicative of information required in an MDR report. FDA believes that facility employees who suffer injury or death in a device-related event reasonably fall within the meaning of the requirement under section 519(b)(1)(A) of the act to report such events that involve a "patient of the facility." To ensure the safety and efficacy of devices, FDA needs information required in the MDR reports for all device-related adverse events regardless of the individual's employment relationship to the facility. MDR reports are required to provide information that is specifically tailored to help FDA determine the risks posed by a certain device and whether further action may be necessary. Reports required by other agencies relating to work injuries, such as OSHA, do not provide the MDR report information that is necessary for FDA to make these determinations. Accordingly, there is no unnecessary duplication involved in reporting.

18. A few comments stated that injuries must be reported because they are "permanent." (proposed § 803.3(q)), should exclude "trivial" or "cosmetic" irreversible damage.

FDA agrees in part. To improve clarity, the agency has included the definition of "permanent" with the "serious injury" definition (§ 803.3(aa)). The agency has also modified the definition of "serious injury" to exclude trivial irreversible damage. While most

cosmetic damage will be trivial, not all cosmetic damage would be considered trivial. Therefore, FDA is not excluding all cosmetic damage from this definition.

19. A few comments recommended that the definition of "probability, probable, or probably" in the reporting standard be clarified and suggested using a "greater than 50 percent" standard.

As discussed earlier in this document, the 1992 amendments deleted the term "probability" from the reporting standard and revised the standard for manufacturers and user facilities. Therefore, this definition has been removed from the final rule.

20. A few comments stated that the definition of a "remedial action," (§ 803.3(y)), which is required to be reported under §§ 803.53(a) and 803.52(f)(7), is unclear. One comment suggested that the definition be deleted; another suggested that it be removed from the user reporting form.

The agency does not agree that this definition should be deleted. The agency should be aware of remedial actions taken in response to reportable events in order to thoroughly evaluate the event. However, the definition has been reworded for clarity. Also, the request for remedial action information has been removed from the user facility section of the final reporting form (FDA Form 3500A) because user facilities do not ordinarily undertake remedial actions. The revised definition of "remedial action" appears in § 803.3(y).

21. Several comments stated that the definition of a reportable "serious injury or serious illness" (§ 803.3(aa)) is overly broad and needs to be better defined. Another comment suggested that these terms be deleted from the manufacturer and distributor report forms altogether. One comment suggested that "temporary damage" be excluded from the definition.

The agency disagrees with comments that requirements to report serious injuries or illnesses should be deleted from the manufacturer and distributor reporting form. Section 519(a)(1)(a) of the act requires manufacturers to report serious injuries. Nor does FDA agree that the definitions of these terms are overly broad. The regulatory definition in § 803.3(aa) of the terms "serious illness" and "serious injury" are derived directly from the statutory definitions provided in section 519(a)(2) and (b)(5)(B) of the act, as amended by the 1992 amendments.

The SMDA added section 519(b)(5)(B) to require that user facilities report "serious illnesses" as well as "serious injuries." The 1992 amendments

amended section 519(a)(2) to require that manufacturers report only "serious injuries." The statutory definitions of the terms "serious injury" and "serious illness," however, are identical. (See section 519(a)(2) and (b)(5)(B) of the act.) The legislative history of the 1992 amendments indicates that "the term 'injury' probably covers any illness that could be caused by a device * * *." (138 Congressional Record H 3884 (1992).)

In accordance with the statutory definition, FDA has defined "serious injury" to mean an injury or illness that is: (1) Life-threatening; (2) results in permanent impairment of a body function or permanent damage to body structure; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

As stated in response to comments described in section IV.B., comment 18 of this document, FDA has further clarified the definition of serious injury by clarifying the term "permanent" within the definition in § 803.3(aa). Because section 519(a)(2) and (b)(5)(B), as amended by the 1992 amendments, identically defines the terms "serious injury" and "serious illness" FDA has revised the definition of the term "serious injury" to include "serious illness."

FDA does not agree with the comment stating that temporary damage should not fall within the definition of "serious injury." Section 519(a)(2)(A) and (b)(5)(B) define serious injury to include any event that is "life-threatening." Because life-threatening events may include temporary damage, FDA believes that life-threatening events that may have been caused by a device must be reported, regardless of whether the damage was "temporary."

22. One comment stated that the definition of "user facility report number" (§ 803.3(dd)) needs to be more specific, especially regarding leading zeroes in the number.

The agency agrees and has modified the definition for clarity. The revised definition appears in § 803.3(dd).

23. Several comments requested that the terms: "become aware," "expected life," and "shelf life" be defined.

FDA agrees. These definitions have been included in the final rule and appear in § 803.3(c), (i), and (bb) respectively. For further discussion of the term "become aware," see sections IV.A., comments 2, 6, and IV.D., comment 27 of this document.

C. Section 803.9—Public Availability of Reports

24. Many comments expressed concern over confidentiality of the reports.

The agency is aware of confidentiality concerns and will protect the confidentiality of information to the fullest extent allowed under the law. FDA is generally required, under the Freedom of Information Act (FOIA) (5 U.S.C. 552), to make publicly available reports received under this final rule. Public availability of such reports is governed by FOIA and part 20 (21 CFR part 20). Before a report is made publicly available, FDA, in accordance with FOIA and part 20 as promulgated in 1984, will delete from the report information whose disclosure would constitute an invasion of personal privacy (see 5 U.S.C. 552(b)(6); § 20.63) or information that constitutes trade secret, confidential commercial or financial information (see 5 U.S.C. 552(b)(4); § 20.61). Persons who are subjects of the reports, however, can receive all information in the report concerning themselves, except for trade secret, confidential commercial or financial information.

FDA has modified § 803.9 in this final rule to clarify that the identity of a third party who submits a voluntary adverse event report, such as a physician or other health care professional, will be protected. This revision does not add any new protection for voluntary third-party reporters. It merely clarifies that the existing protection afforded to voluntary reporters under § 20.111 is applicable to MDR reports.

Revised § 803.9 incorporates the confidentiality provisions relating to user facility reporting in section 519(b)(2) of the act, as added by the SMDA. Specifically, § 803.9(c) states that FDA may not disclose the identity of a device user facility except in connection with: (1) An action brought to enforce section 301(q) of the act (21 U.S.C. 331(q)), which includes the failure or refusal to furnish material or information required by section 519 of the act; (2) a communication to a manufacturer of a device which is the subject of a report of a death, serious injury or other significant adverse device experience required by a user facility under § 803.30; (3) a disclosure relating to a manufacturer or distributor report which is required under section 519(a) of the act; and (4) a disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to duly authorized committees and subcommittees of the Congress.

As stated above, § 803.9, which is derived from the statutory language in section 519(b)(2)(C) of the act, allows disclosure of the user facility's identity when disclosure is required under provisions requiring manufacturer and distributor reporting. The legislative history of section 519(b)(2)(C) of the act states that this section is not intended to affect public access to information contained in MDR reports to FDA, and that the full requirements of reporting under section 519(a) of the act (the manufacturer and distributor reporting provisions), will apply. If a manufacturer chooses to forward a user report to FDA, that will then constitute a report described in section 519(a) of the act, not a report described in section 519(b) of the act, for purposes of public access to the contents of the report. (H. Rept. 101-808, 101st Cong., 2d sess., pp. 21-22). Accordingly, if information in a required user facility report is submitted as part of a distributor or manufacturer report, the information relating to the identity of the user facility would be disclosable because the report would be submitted under section 519(a) of the act. FDA notes that, in accordance with part 20 and section 519(b) of the act, the agency will not disclose the identity of the user facility physicians, persons designated by the user facility to submit reports, or other user facility employees, although the identity of the user facility may be disclosed.

25. Many comments expressed concern that the regulation will increase liability and that the availability of reports will lead to civil litigation.

Although FDA is aware that litigants in civil suits may attempt to use information in adverse event reports as evidence in product liability suits, FDA does not have any information as to whether the information from reports will actually lead to the initiation or increase of civil litigation. Section 519 of the act requires user facilities and manufacturers to submit reports of adverse events. While these reports may have some effect on a reporter's liability, these regulations are required to implement statutory requirements. They are also necessary to make FDA aware of unsafe devices and better enable the agency to take appropriate action to safeguard the public health. With respect to user facilities, section 519(b)(3) of the act provides some protection against liability in that it prohibits the admissibility of device user facility adverse event reports into evidence for civil actions involving private parties, except where the party making the report had knowledge that information in the report is false.

With respect to manufacturers and distributors, FDA has attempted to provide protection from liability by clearly stating in § 803.16 of this final rule, and including a statement on FDA Form 3500A, that the submission of a report does not constitute an admission that the user facility, manufacturer/distributor, product, or medical personnel caused or contributed to the event. Moreover, in the Federal Register of April 3, 1995 (60 FR 16962), FDA issued a final rule that became effective on July 3, 1995, that protects the identity of voluntary reporters by preempting State laws or other requirements requiring or permitting disclosure.

26. Comments objected to providing FDA with proprietary information.

FDA may require the submission of certain proprietary information because it is necessary to fully evaluate the adverse event. Proprietary information will be kept confidential in accordance with § 803.9, which prohibits public disclosure of trade secret or confidential commercial information, and in accordance with the FOIA and FDA regulations in 21 CFR part 20.

D. Reports by Device User Facilities (Part 803, Subpart C)

27. Several comments stated that 10 days is too short a time period for user facilities to report adverse events properly. One comment suggested that the 10-day "clock" for reporting should commence when the facility completes its investigation and determines that an event is reportable.

FDA cannot agree because the 10-day time period is the maximum time allowed by the statute. (See section 519(b)(1)(A) of the act.) However, this comment raises the issue of when the reporting "clock" starts. In the preamble to the November 1991 tentative final rule, FDA proposed to consider a user facility to have "become aware" of reportable events only when it has sufficient information to make a determination that a report is required, and that this commences the 10-day reporting period. (See the notice of availability of the MEDWATCH adverse event reporting form (FDA Form 3500A) in the Federal Register of June 3, 1993 (58 FR 31596.))

FDA has reevaluated the issue of when a user facility should be considered to "become aware" of information that triggers the reporting requirements and has determined that user facilities should be considered to have "become aware" of information that triggers reporting requirements when they first receive a report. The agency does not believe that

information-gathering required of user facilities is sufficiently burdensome or time consuming to justify triggering the 10-day timeframe any time after they receive a report of an adverse event. A user facility, unlike a manufacturer, is not required to provide any information that is not in its possession. For further discussion on when user facilities are considered to have "become aware" of an event, see section IV.A., comment 2 of this document.

28. Several comments suggested that the user/operator error reporting requirement be eliminated.

As stated in section IV.A., comment 3 of this document, the language of the SMDA as amended by the 1992 amendments requires reporting in all instances where the facility becomes aware of information that reasonably suggests that a device has or may have caused or contributed to certain device-related adverse events. FDA needs to be aware of events that are related to user error any time such error may have caused or contributed to a reportable event. By receiving information on device user problems, FDA can determine whether additional measures are necessary to resolve such problems, for example, relabeling or a redesign of the device.

29. One comment suggested that all reports be sent only to FDA.

FDA does not agree. This regulation merely implements section 519(b) of the act, which requires user facilities to submit deaths to FDA and the manufacturer, and serious injuries to the manufacturer or FDA, if the identity of the manufacturer is unknown.

30. Some comments suggested that an anonymous reporting path be provided for reporting directly to FDA.

FDA disagrees. It is important that both FDA and the manufacturer know the identity of the user facility in case followup information is needed. As discussed in section IV.C., comment 24 of this document, the act does provide some protection of the identity of user facilities.

31. Several comments requested clarification of the terms "adverse events," "formally affiliated," and "user error."

Adverse events are those events that may be related to an FDA-regulated product and which have a negative or harmful effect on the user or recipient of the product's use. The only adverse events required to be reported under this regulation, however, are "MDR reportable events" as defined in § 803.3(q) of the final rule.

The term "formally affiliated" means individuals who are employed by a user facility or medical personnel who have

admitting, practicing, or equivalent privileges at a user facility. Reporting requirements for user facilities are triggered when medical personnel who are employed by or otherwise "formally affiliated" with the facility, receive information or become aware of information that reasonably suggests a reportable event has occurred.

The term "user error" means any error made by the person using the device. A user error may be the sole cause or merely contribute to a reportable adverse event.

32. One comment suggested that FDA provide user facilities with manufacturer and agency contacts. Another comment suggested that a hotline be established for reporting.

It would be very difficult for FDA to establish and maintain up-to-date manufacturer "contact" lists for device user facilities. The agency, however, will consider publicizing a list of firm contact names and telephone numbers. Although there is no requirement for telephone reporting in this regulation, emergency situations can be handled in accordance with § 803.12(c) of this final rule.

33. One comment asked how foreign user facilities will be affected by these provisions.

Only those user facilities located outside the United States which are operated by the U.S. Government are required to report under this regulation.

34. Comments suggested that the requirements for semiannual reports be deleted because they are redundant. Other comments suggested that no semiannual report be required if no reports had been submitted during that period.

Semiannual reports are required by section 519(b)(1)(C) of the act and therefore the requirement cannot be deleted. Under § 803.33(c), the user facility is not required to submit a semiannual report if no reportable events occurred during the reporting period.

E. Reports by Manufacturers (Part 803, Subpart E)

35. One comment suggested that manufacturer reporting of "planned remedial actions" be deleted. Another comment stated that remedial action often occurs after the reporting deadline, and therefore cannot be included in the report.

Remedial actions taken after a reporting deadline can be submitted to the agency via a supplemental report. The individual adverse event reports required under the final rule, with the exception of circumstances requiring 5-day reports, do not require information

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.

(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

left to FDA, the manufacturer or another third party. Other comments suggested that the manufacturer should not be required to verify data or provide data about which it has no knowledge. Other comments suggested that user facilities do not have the appropriate expertise to analyze events or make determinations concerning the reportability of events.

FDA agrees that user facilities should not be required to conduct in-depth analyses of events and has deleted certain requirements regarding information relating to evaluation and testing. User facilities serve principally as conduits of information and thus are required only to fill out information that is known to them. However, the statute and regulations still require user facilities to make an initial determination as to whether an event should be reported under the regulation's criteria. Accordingly, FDA has retained elements that relate to this determination. In § 803.30, FDA explains user facilities' obligations to obtain information about adverse events.

FDA believes that the manufacturer who is responsible for placing a device into interstate commerce is the appropriate entity to initially investigate and evaluate whether, and why, the device may have caused or contributed to a reportable event or malfunctioned and that such malfunction is a reportable event. In order for FDA to determine whether the risk posed by a device necessitates action to protect the public health, the manufacturer is also required to verify data and provide missing information after investigating the event. If after an investigation the information cannot be determined, a manufacturer must explain in the MDR report why the information cannot be obtained.

The agency agrees that an analysis of reports for patterns and trends may be more appropriately conducted by the manufacturer or FDA. FDA will conduct statistical analyses of report information submitted. The agency expects that manufacturers will conduct trend analyses as part of their CGMP.

52. Several comments suggested that numerical event and evaluation codes should not be used on the adverse event reporting form. Other comments stated that the codes lacked accuracy or were insufficient.

The agency disagrees. It is the manufacturer's responsibility to evaluate reports to determine causation. It is reasonable that an evaluation will result in the assignment or identification of failure modes and that these can be communicated to FDA in the form of a structured vocabulary or

"coded" data. In developing these codes, the agency has used the experience gained from reviewing nearly 400,000 reports submitted since 1984. The use of these codes is essential to the rapid evaluation of device risks and processing of reports by computer. Regardless of whether the codes are specific enough to describe a particular event, the event must be fully described in the narrative section of the reporting form.

The list of codes for use with the final form (FDA Form 3500A or FDA approved electronic equivalent) has been expanded for completeness and modified to improve accuracy. The agency will continue to improve the accuracy of its codes as needed.

53. Various comments suggested that the following elements be removed from the form: Degree of certainty, labelled usage, result of analysis, list of other devices, purchase date, service and maintenance items, event description, and medical status of the patient.

FDA has deleted requirements for user facilities and manufacturers to report service and maintenance information and to state the degree of certainty concerning whether the device caused or contributed to an adverse event. FDA believes the burden of requiring this information would usually outweigh the benefit of assessing the cause of an adverse event. FDA, however, has retained the requirements for manufacturers to report use indications specified in the labeling and device analyses because this information is valuable in determining causation of the event. FDA has deleted the requirements to report these elements for user facilities because the agency believes the manufacturer is the most appropriate source for this information. All user facilities and manufacturers will still be required to provide information regarding concomitant product use, age of the device, event description and certain patient information. FDA believes this information is important to assess adverse events and should be available to user facilities as well as manufacturers.

G. Manufacturer Annual Certification Report (§ 803.57)

54. A few comments stated that this section is redundant, overly broad and burdensome, exceeds the scope of the SMDA and should be deleted. Another comment suggested that certification be limited to events involving class III devices.

The agency cannot agree. Section 519(d) of the act states that each manufacturer required to make reports

under section 519(a) of the act must submit annual statements certifying the number of reports filed or that no reports were filed during the previous 12-month period. The provisions of this regulation pertaining to the statutory certification requirement merely explain what information should be contained in the submission. Furthermore, FDA does not agree that certification should be limited to reports about adverse events involving class III devices. Any device, regardless of its classification, can pose serious risks that need to be reported to FDA:

55. Some comments suggested that the certification be limited to the number of reports actually filed, and that liability should attach only in instances of known reporting violations.

The agency disagrees. The purpose of this provision is to ensure reporter compliance with MDR requirements by certifying that all reportable events have been submitted. Such purpose would be thwarted and the certification requirement rendered meaningless if it were limited to simply certifying the number of reports submitted instead of all reportable events known to the certifying entity. The legislative history of section 519(d) of the act references a U.S. General Accounting Office recommendation that the certification state that the reporter "filed a specific number of reports * * * and that the firm received or became aware of information concerning only these events." (H. Rept. 808, 101st Cong., 2d sess. 23 (1990)).

Accordingly, consistent with Congress' intent, FDA is requiring certification that all known reportable events were reported. This requirement does not impose liability for adverse events that are unknown to the reporter because the reporting requirements are triggered only when the reporting entity "becomes aware" of a reportable event.

56. Several comments stated that the purpose of certification should be to verify reports, not to certify with absoluteness; therefore the standard should be changed to "reasonably certain" and a disclaimer should be added.

The agency disagrees. Section 519(d) of the act specifically states that firms shall certify, not verify their reports. As discussed in the previous paragraph, the purpose of this provision is to ensure that the reporter complies with the law by certifying that it has submitted all the reports it was required to submit. This purpose would not be accomplished by verifying the report.

57. One comment asked for clarification about who is required to certify. Another comment suggested that

the signature block be for the certifier and contractor as well.

The agency agrees with the need for clarification regarding who must certify and has incorporated language in the final rule to address this suggestion. Under the final rule, the president, chief executive officer, executive officer, U.S.-designated agent of a foreign manufacturer or other official most directly responsible for the firm's operations shall certify reports submitted under section 519 of the act.

58. Two comments requested that decentralized certification be allowed for multisite firms. Another comment suggested that centralized reports be used in this situation.

Manufacturers have the option of certifying centrally or on a decentralized basis. Firms deciding to certify centrally must identify the sites covered by the certificate by name and registration number or FDA-assigned identification number.

H. Additional Requirements (§ 803.15)

59. A few comments asserted that these provisions are vague and inappropriate in the absence of a device failure complaint.

The agency disagrees. This provision refers to submission of additional information after an adverse event report has been filed. Accordingly, FDA would not be requesting information in the absence of a device failure or complaint.

60. A few comments objected to the idea of giving FDA unlimited access to data. One comment wanted to restrict FDA's right to copy data and another wanted an appeal process.

FDA does not agree with comments proposing to restrict or limit the agency's access to additional information about adverse events. Under section 704(e) of the act, every person who is required to maintain records under section 519 of the act and every person who is in charge or custody of such records must permit FDA at all reasonable times to have access to and to copy and verify such records. Failure to provide such information may be a violation of section 301 of the act and may subject a person to civil or criminal penalties. Section 704(e) of the act does not limit in any way the types of device records maintained under section 519 of the act that FDA may inspect.

FDA does not agree that the agency should be required to provide an appeal process with respect to requests for additional information. As described above, FDA has statutory authority to require additional information concerning adverse events. Moreover,

such information needs to be provided as quickly as possible to enable FDA to take appropriate action.

61. Several comments suggested the regulation be modified to remove the requirement that each reportable event be investigated because in some instances an investigation is unnecessary.

The agency disagrees. All reportable events must be investigated by the manufacturer. The scope of an investigation may vary according to the circumstances; however, an investigation must be able to adequately assess the cause of the event. Sections 820.162 and 820.198 of FDA's CGMP regulations require manufacturers to review, evaluate and investigate any complaint involving the failure of a device to meet its performance specifications or involving injury, death, or any hazard to safety. FDA considers any event that must be reported under this part to be a death, injury, or hazard to safety.

I. Exemptions, Variances, and Alternative Reporting Requirements (§ 803.19)

62. One comment asked that alternative reporting requirements under the current MDR system be incorporated into this regulation. One comment stated that the criteria for alternative reporting should be clarified.

FDA has incorporated the alternative reporting options from the MDR regulation issued in 1984 and expanded the options available in this regulation. Under the final regulation, FDA may grant a written exemption, variance, or alternative to some or all of the requirements when it determines compliance with all MDR requirements is not necessary to protect the public health. Examples of situations include: (1) Devices for which FDA is already aware of a type of malfunction and appropriate action has been taken to protect the public health, such as a recall, removal, or other correction; (2) adverse events that are known and well documented, are occurring at a normal rate, and do not justify the initiation of remedial action; and (3) device events occurring on an infrequent basis or where a longer period for investigation or followup is appropriate and necessary.

In these cases, FDA may impose conditions on its approval of an exemption, variance, or alternative reporting mechanism, including the requirement to report on a less frequent basis than otherwise required or to provide summary data rather than individual reports. The final regulation, upon its effective date, will supersede

all previously granted exemptions and variances from the 1984 reporting requirements. The agency intends to review all current exemptions and variances and notify relevant parties about the status of their exemptions and variances and the additional steps that may be necessary to conform to the new requirements effected by this regulation.

63. A few comments stated the criteria for exemption are unclear, especially with respect to investigational device exemptions, and thus create a loophole.

The criteria for exemptions (§ 803.19) are based upon interpretations of the act as to the types of entities Congress intended should be subject to reporting. FDA believes these exemptions are reasonably clear. The exemptions specifically granted under this final regulation are the same as those in the MDR regulation issued in 1984. Devices subject to investigational device exemptions are subject to reporting under the regulations governing that process (parts 812 and 813). The exception to this are devices with investigational device exemptions that are approved for export. These devices are considered to be in commercial distribution and, therefore, subject to MDR.

J. Where To Submit a Report (§ 803.12)

64. There were only two comments on this section. One suggested that "MDR" be added to the mailing address. The other recommended the use of electronic reporting.

The agency agrees with these comments. "MDR" has been added to the mailing address. In addition, the agency, with prior approval, will accept required reports submitted electronically or on reporting media such as magnetic disc or tape in accordance with § 803.14(a). The agency is in the process of developing standards, guidelines, or procedures for the format to be used with electronic reports. Once available, any electronic reporting system meeting such criteria will be deemed to have prior FDA approval.

K. Written MDR Procedures (§ 803.17)

65. A few comments requested additional guidance on written MDR procedures.

FDA agrees and has developed guidance concerning MDR procedures. Requests for this guidance should be directed to:

Division of Small Manufacturers Assistance (HFZ-220), Office of Health and Industry Programs, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850.

Copies can also be obtained from an electronic docket maintained by the Division of Small Manufacturers Assistance. This system can also be accessed by dialing: 1-800-252-1366 or 301-594-2741. Persons wishing to obtain the guidance document via this system must have a video terminal or a personal computer with communication software (VT emulation) and a modem that can operate at a baud rate of 1200, 2400, 4800, or 9600. Persons wishing to transfer files from the electronic docket must use the KERMIT file transfer protocol.

66. One comment requested that the requirement for staff education be deleted.

The agency agrees and, as stated previously in this preamble, has removed this requirement from the final regulation.

67. One comment objected to the requirement for written procedures. Another comment objected to FDA having access to the firm's procedures.

The agency disagrees. Written procedures are essential to the development of a standard, institutional reporting program. FDA also needs access to such procedures so it can conduct an adequate audit of user facility and manufacturer compliance with MDR.

68. One comment requested clarification of the term "information that facilitates a submission" for which documentation and recordkeeping requirements were proposed.

"Information that facilitates the submission [of a semiannual report]" refers to any information that was evaluated for the purpose of preparing a semiannual report or certification. The regulation has been revised in § 803.17 to clarify this point.

69. One comment stated that these provisions do not address the penalties for failure to comply.

FDA intends to enforce this regulation and will take appropriate action against any firm or facility that does not comply. Violations may result in criminal prosecutions and/or civil remedies such as seizure, injunction, recall, and civil penalties. FDA's enforcement mechanisms and penalties for noncompliance are detailed in the preamble to the November 1991 tentative final rule (56 FR 60024 at 60029 through 60030).

L. Files (§ 803.18)

70. Several comments complained that these requirements are overly broad, burdensome, and beyond the scope of the SMDA.

FDA does not agree. Sections 519 and 701 of the act provide FDA the authority

to require user facilities and manufacturers to maintain records to ensure that devices are not adulterated or misbranded. The file requirements are necessary to enable FDA to: (1) Further investigate potentially adulterated or misbranded devices to determine the cause of adverse events; (2) verify information received; and (3) ensure compliance with the regulations. These filing requirements will also enable the reporting entity to more readily identify causes of problems associated with devices so they can take appropriate actions.

71. Several comments expressed concern about public access and a loss of confidentiality stating that these will lead to increased lawsuits and, therefore, decreased reporting. Some comments suggested that only events reportable to FDA be kept in FDA accessible files. Others suggested that confidential materials and irrelevant data be excluded from the files.

FDA has addressed issues related to confidentiality of reports it receives in section IV.C., comment 24 of this document. As stated therein, certain statutory and regulatory protections exist that prevent release of confidential information. FDA does not agree that only events that are ultimately determined to be reportable should be kept in MDR files. FDA must be able to audit files containing events that were determined not reportable to ensure such determinations were correct.

72. A few comments objected to FDA prescribing the method of record retention, preferring the use of individual systems.

The agency disagrees. Effective and uniform regulatory enforcement is better assured by a standardized method of record retention. The agency believes that the method of record retention prescribed in this regulation does not impose an undue burden on the entities required to maintain such records.

73. One comment suggested that separate files be kept for devices and patients.

FDA does not object to a reporting entity maintaining separate files for devices and patients provided that all required information is contained in the MDR files.

74. A few comments stated that a user facility should be required to keep files for a maximum of 2 years, rather than the expected life of the product, because some devices may have unusually long life expectancies.

The agency agrees and has modified this section accordingly. It should be noted that device manufacturers, however, are still required to retain their records for 2 years or a period of time

equivalent to the expected life of the device, whichever is greater.

M. Who Must Register and Submit a Device List (Section 807.20)

75. One comment suggested that foreign manufacturers designate a U.S. agent to fulfill the registration and certification requirements. Another comment suggested that foreign manufacturers be permitted to register.

Under § 807.40 (21 CFR 807.40), foreign manufacturers are required to designate a U.S. agent to serve as an official correspondent, as well as to register and list their medical devices distributed in the United States, submit premarket notifications and ensure compliance with the MDR reporting requirements. In § 807.40(a), FDA has changed the time allowed for foreign manufacturers to inform the agency of their designated U.S. agents, or a change in such agents, from 30 days to 5 days. FDA believes this is sufficient time to comply with this requirement.

76. Under § 807.20 (21 CFR 807.20), an owner or operator is required to register its "name, places of business, and all establishments." Under this regulation, FDA has required the registration of all locations that fit within the definition of "establishment," which is defined under § 807.3(a) (21 CFR 807.3(a)) as a location where devices are "manufactured, assembled, or otherwise processed." Although FDA has authority under § 807.20 to require the registration of "places of business" that are not "establishments" under initial registration and listing regulation that were issued in 1977, the agency previously has declined to exercise this authority.

Under this regulation, FDA will use registration numbers in its data bases to process all manufacturer adverse event reports. Thus FDA must receive reports that originate from locations that may not be "establishments" and, therefore, have previously not had registration numbers. Accordingly, FDA is notifying manufacturers that upon the effective date of this final regulation, the agency will exercise its authority under § 807.20, and require all locations that are MDR reporting sites to register because they are "places of business" under § 807.20, regardless of whether they fit under the definition of "establishment."

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

VI. Intergovernmental Partnership

The agency has analyzed this rulemaking in accordance with the principles and criteria set forth in the Unfunded Mandate Reform Act (Pub. L. 104-4) and Executive Order 12875. Executive Order 12875 states that no agency or executive department shall promulgate any regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government unless the Federal government supplies funds necessary to comply with the mandate, or the agency provides the Office of Management and Budget (OMB) a description of the agency's consultations with affected State, local, and tribal governments, the nature of their concerns, any written communications submitted to the agency by such units of government, and the agency's position supporting the need to issue the regulation containing the mandate. Executive Order 12875 does not apply to this final rule because the regulatory requirements that are applicable to government facilities are required by the provisions of the SMDA, as amended by the 1992 amendments. Moreover, many of the comments the agency received in response to the November 26, 1991, tentative final rule were from Federal, State, or local government facilities or from organizations representing these facilities. The agency believes this final rule is responsive to those comments.

The agency has also examined the consistency of this final rule with the Unfunded Mandate Reform Act. The Unfunded Mandate Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation). The Unfunded Mandate Reform Act does not apply to this final rule because it will not result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million.

VII. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the principles set out in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order.

Many comments stated that the provisions of the rule, as proposed, are overly burdensome, that the costs outweigh the benefits, and that the economic impact was underestimated and misleading. Several comments stated that the provisions constitute too great a burden for FDA, as well as for user facilities, distributors, and manufacturers.

The agency does not agree. For the reasons stated in the preamble, including section IV.A., comment 1 of this document, FDA believes this regulation carefully balances the interests of public health with industry requirements. The agency also does not agree that the economic impact assessment was misleading. The cost projections contained in the proposed rule were based upon the information available to the agency at the time.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The full economic impact assessment is on file at the Dockets Management Branch (address above). This rule is designed to: (1) Implement provisions of the SMDA regarding user facility reporting to FDA of deaths and serious injuries and illnesses related to medical devices and (2) amend the MDR regulations that require manufacturers to report deaths, serious injuries and malfunctions related to medical devices to FDA.

A. Benefits

The legislative history of the SMDA documents reports that device problems that occur in hospitals are rarely reported, despite full scale implementation of the current medical device reporting regulation. A 1986 Government Accounting Office report showed that less than 1 percent of device problems occurring in hospitals were reported directly to FDA. As a result, neither patients nor medical providers would have access to relevant safety information. This final rule requires user facilities to report device-related deaths and serious injuries promptly, and thus it expands the

information base of FDA and the manufacturer for early detection of problems associated with medical devices. In addition to manufacturers, those required to report to FDA include device distributors, hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment and diagnostic facilities. As a result of this rule, FDA, patients, and medical providers will have access to relevant safety information not previously available. MDR reports alert FDA to life-threatening and other serious problems with medical devices that are on the market, and FDA then can address these problems through the appropriate mechanisms. Further, when the final rule is in place, FDA will begin to receive denominator, or baseline data, such as the number of a particular device manufactured, distributed, and in use in the previous year. This information will enable FDA to better perform trend analyses and determine the significance of a report or group of reports.

Unfortunately, there are insufficient data available to quantify the benefits of the rule. The primary benefit of this rule is that it provides an early warning of device problems which is then evaluated together with other information and, if appropriate, followed by a corrective action such as the issuance of an FDA Safety Alert, recall, or other action. The agency believes the actions taken as a result of the information provided by MDR reports will provide benefits such as injuries prevented, lives saved, avoidance of hospitalization and outpatient treatment costs, and other possible benefits. Any quantification of benefits would require an estimation of both the number and seriousness of adverse events prevented by actions taken as the result of the evaluation of MDR reports. Thus the agency does not believe benefits can be quantified with any reliable accuracy.

B. Nature of the Economic Impact

This regulation will require certain device user facilities to develop, maintain, and implement procedures for reporting deaths and serious injuries related to medical devices. Some current MDR requirements for manufacturers are being eliminated or reduced, but manufacturers will now be required to develop and maintain written MDR procedures and implement new reporting requirements, including the submission of baseline reports and annual updates and annual certification. In addition, foreign manufacturers will be required to designate an agent in the United States that will be responsible