panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

''The Packaging of This Product Contains Dry Natural Rubber.''

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.–

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term ''hypoallergenic'' on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with §10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

NOTE TO §801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses ''cold seal'' adhesives.

[62 FR 51029, Sept. 30, 1997, as amended at 63 FR 46175, Aug. 31, 1998]

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.
803.1 Scope.
803.3 Definitions.
803.9 Public availability of reports.
803.10 General description of reports required from user facilities, importers, and manufacturers.
803.11 Obtaining the forms.
803.12 Where to submit reports.
803.13 English reporting requirement.
803.14 Electronic reporting.
803.15 Requests for additional information.
803.16 Disclaimers.
803.17 Written MDR procedures.
803.18 Files and distributor records.
803.19 Exemptions, variances, and alternative reporting requirements.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

803.20 How to report.
803.21 Reporting codes.
803.22 When not to file.

Subpart C—User Facility Reporting Requirements

803.30 Individual adverse event reports; user facilities.
803.32 Individual adverse event report data elements.
803.33 Annual reports.

Subpart D— Importer Reporting Requirement

803.40 Individual adverse event reporting requirements; importers.
803.42 Individual adverse event report data elements.

Subpart E—Manufacturer Reporting Requirements

803.50 Individual adverse event reports; manufacturers.
803.52 Individual adverse event report data elements.
803.53 Five-day reports.
803.55 Baseline reports.
803.56 Supplemental reports.
803.58 Foreign manufacturers.

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 60 FR 63597, Dec. 11, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 803.1 Scope.

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. Medical device distributors, as defined in § 803.3, are also required to maintain records of incidents (files). Furthermore, manufacturers and importers are also required to report certain device malfunctions. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[60 FR 63597, Dec. 11, 1995, as amended at 62 FR 13306, Mar. 20, 1997; 65 FR 4118, Jan. 26, 2000]

§ 803.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred.

(1) Device user facilities are considered to have ''become aware'' when medical personnel, as defined in paragraph (s) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event.

(2) Manufacturers are considered to have become aware of an event when:

(i) Any employee becomes aware of a reportable event that is required to be reported within 30 days or that is required to be reported within 5 days under a written request from FDA under § 803.53(b); and

(ii) 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, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) Importers are considered to have become aware of an event when any employee becomes aware of a reportable event that is required to be reported by an importer within 30 days.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

(1) Failure;

(2) Malfunction;

(3) Improper or inadequate design;

(4) Manufacture;

(5) Labeling; or

(6) User error.

(e)(1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

(i) Basic design and performance characteristics related to device safety and effectiveness,

(ii) Intended use and function, and

(iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (b), (l), (t), (u), and (v), respectively, of this section, which is not a ''physician's office,'' as defined in paragraph (x) of this section. School nurse offices and employee health units are not device user facilities.

(g) *Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(h) [Reserved]

(i) *Expected life* of a device (required on the manufacturer's baseline report) means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified ''end of life'' (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, upgrades, etc., for an estimated period of time.

(j) *FDA* means the Food and Drug Administration.

(k) *Five-day report* means a medical device report that must be submitted by a manufacturer to FDA pursuant to §803.53, on FDA Form 3500A or electronic equivalent as approved under §803.14, within 5 work days.

(l) *Hospital* means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (medical, occupational, speech, physical, etc.), surgical and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(m) *Importer* means, for the purposes of this part, any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under paragraph (o) of this section.

(n) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in §801.4 of this chapter.

(o) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper or labeling of a

device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

(p) *Manufacturer or importer report number* means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of three parts as follows:

(1) The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. (If the manufacturing site or the importer does not have a registration number, FDA will assign a temporary MDR reporting number until the site is officially registered. The manufacturer or importer will be informed of the temporary number.);

(2) The four-digit calendar year in which the report is submitted; and

(3) The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear 1234567–1995–00001.)

(q) *MDR* means medical device report.

(r) *MDR reportable event* (or *reportable event*) means:

(1) An event about which user facilities become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(2) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury; or

(ii) Has malfunctioned and that the 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.

(s) *Medical personnel*, as used in this part, means an individual who:

(1) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;

(2) Has received a diploma or a degree in a professional or scientific discipline;

(3) Is an employee responsible for receiving medical complaints or adverse event reports; or

(4) Is a supervisor of such persons.

(t)(1) *Nursing home* means an independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

(i) Skilled nursing care and related services for persons who require medical or nursing care;

(ii) Hospice care to the terminally ill; or

(iii) Services for the rehabilitation of the injured, disabled, or sick.

(2) A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature, or location of the medical service provided by the nursing home.

(u)(1) *Outpatient diagnostic facility* means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients;

(ii) Does not assume ongoing responsibility for patient care; and

(iii) Provides its services for use by other medical personnel. (Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography and in-vitro testing).

(2) An outpatient diagnostic facility may be either independent (i.e., not a part of a provider of services or any

other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

(v)(1) *Outpatient treatment facility* means a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse.

(2) An outpatient treatment facility may be either independent (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

(w) *Patient of the facility* means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. For the purposes of this part, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

(x) *Physician's office* means a facility that operates as the office of a physician or other health care professional (e.g., dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

(y) [Reserved]

(z) *Remedial action* means, for the purposes of this subpart, any action other than routine maintenance or servicing, of a device where such action is necessary to prevent recurrence of a reportable event.

(aa) [Reserved]

(bb)(1) *Serious injury* means an injury or illness that:

(i) Is life-threatening;

(ii) Results in permanent impairment of a body function or permanent damage to body structure; or

(iii) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(2) *Permanent* means, for purposes of this subpart, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

(cc) *Shelf life*, as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

(dd) [Reserved]

(ee)(1) *User facility report number* means the number that uniquely identifies each report submitted by a user facility to manufacturers and FDA. This number consists of three parts as follows:

(i) The user facility's 10-digit Health Care Financing Administration (HCFA) number (if the HCFA number has fewer than 10 digits, fill the remaining spaces with zeros);

(ii) The four-digit calendar year in which the report is submitted; and

(iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000–1995–0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–1995–0001) and FDA will assign a number for future use. The number assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ff) *Work day* means Monday through Friday, excluding Federal holidays.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4118, Jan. 26, 2000; 66 FR 23156, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in § 803.3, paragraph (n)(4) was stayed indefinitely.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter;

(2) Any personal, medical, and similar information (including the serial number of implanted devices), which would constitute an invasion of personal privacy under § 20.63 of this chapter. FDA will disclose to a patient who requests a report, all the information in the report concerning that patient, as provided in § 20.61 of this chapter; and

(3) Any names and other identifying information of a third party voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which makes a report under this part except in connection with:

(1) An action brought to enforce section 301(q) of the act, including 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 required by a user facility under § 803.30; or

(3) A disclosure to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

(a) *Device user facilities.* User facilities must submit the following reports, which are described more fully in subpart C of this part.

(1) User facilities must submit MDR reports of individual adverse events within 10 days after the user facility becomes aware of an MDR reportable event as described in §§ 803.30 and 803.32.

(i) User facilities must submit reports of device-related deaths to FDA and to the manufacturer, if known.

(ii) User facilities must submit reports of device-related serious injuries to manufacturers, or to FDA, if the manufacturer is unknown.

(2) User facilities must submit annual reports as described in § 803.33.

(b) *Device importers.* Importers must submit the following reports, which are described more fully in subpart D of this part.

(1) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in §§ 803.40 and 803.42.

(i) Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer.

(ii) Importers must submit reports of malfunctions to the manufacturer.

(2) [Reserved]

(c) *Device manufacturers.* Manufacturers must submit the following reports as described more fully in subpart E of this part:

(1) MDR reports of individual adverse events within 30 days after the manufacturer becomes aware of a reportable death, serious injury, or malfunction as described in §§ 803.50 and 803.52.

(2) MDR reports of individual adverse events within 5 days of:

(i) Becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health or,

(ii) Becoming aware of an MDR reportable event for which FDA has made a written request, as described in § 803.53.

(3) Annual baseline reports as described in § 803.55.

(4) Supplemental reports if they obtain information that was not provided in an initial report as described in § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20875; from the Food and Drug Administration, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240; from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr. Rockville, MD 20850, FAX 301–443–8818; or from http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html on the Internet.

[65 FR 17136, Mar. 31, 2000]

§ 803.12 Where to submit reports.

(a) Any written report or additional information required under this part shall be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847–3002.

(b) Each report and its envelope shall be specifically identified, e.g., ''User Facility Report,'' ''Annual Report,'' ''Importer Report,'' ''Manufacturer Report,'' ''5–Day Report,'' ''Baseline Report,'' etc.

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Emergency Operations Branch (HFC–162), Office of Regional Operations, at 301–443–1240, and should be followed by the submission of a FAX report to 301–443–3757.

(d) A voluntary telephone report may be submitted to, or information regarding voluntary reporting may be obtained from, the MEDWATCH hotline at 800–FDA–1088.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.13 English reporting requirement.

(a) All reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

(b) All reports required in this part which are submitted on an electronic medium shall be submitted to FDA in a manner consistent with § 803.14.

§ 803.14 Electronic reporting.

(a) Any report required by this part may be submitted electronically with prior written consent from FDA. Such consent is revocable. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) Any electronic report meeting electronic reporting standards, guidance documents, or other procedures developed by the agency for MDR reporting will be deemed to have prior approval for use.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 56480, Sept. 19, 2000]

§ 803.15 Requests for additional information.

(a) FDA may determine that protection of the public health requires additional or clarifying information for medical device reports submitted to FDA under this part. In these instances, and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible, the agency will notify the reporting entity in writing of the additional information that is required.

(b) Any request under this section shall state the reason or purpose for which the information is being requested, specify the date that the information is to be submitted and clearly relate the request to a reported event. All verbal requests will be confirmed in writing by the agency.

§ 803.16 Disclaimers.

A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event.

§ 803.17 Written MDR procedures.

User facilities, importers, and manufacturers shall develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to medical device reporting requirements;

(2) A standardized review process/procedure for determining when an event meets the criteria for reporting under this part; and

(3) Timely transmission of complete medical device reports to FDA and/or manufacturers;

(b) Documentation and recordkeeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to FDA and manufacturers;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.18 Files and distributor records.

(a) User facilities, importers, and manufacturers shall establish and maintain MDR event files. All MDR event files shall be prominently identified as such and filed to facilitate timely access.

(b)(1) For purposes of this part, ''MDR event files'' are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information, e.g., medical records, patient files, engineering reports, etc., in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

(i) Information in the possession of the reporting entity or references to information related to the adverse event, including all documentation of the entity's deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part.

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that was submitted to FDA and other entities (*e.g.*, an importer, distributor, or manufacturer).

(2) User facilities, importers, and manufacturers shall permit any authorized FDA employee during all reasonable times to access, to copy, and to verify the records required by this part.

(c) User facilities shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. Manufacturers and

importers shall retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. MDR event files must be maintained for the time periods described in this paragraph even if the device is no longer distributed.

(d)(1) A device distributor shall establish and maintain device complaint records containing any incident information, including any written, electronic, or oral communication, either received by or generated by the firm, that alleges deficiencies related to the identity (*e.g.,* labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. Information regarding the evaluation of the allegations, if any, shall also be maintained in the incident record. Device incident records shall be prominently identified as such and shall be filed by device, and may be maintained in written or electronic form. Files maintained in electronic form must be backed up.

(2) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the record.

(3) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

(e) The manufacturer may maintain MDR event files as part of its complaint file, under § 820.198 of this chapter, provided that such records are prominently identified as MDR reportable events. A report submitted under this subpart A shall not be considered to comply with this part unless the event has been evaluated in accordance with the requirements of §§ 820.162 and 820.198 of this chapter. MDR files shall contain an explanation of why any information required by this part was not submitted or could not be obtained. The results of the evaluation of each event are to be documented and maintained in the manufacturer's MDR event file.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.19 Exemptions, variances, and alternative reporting requirements.

(a) The following persons are exempt from the reporting requirements under this part.

(1) An individual who is a licensed practitioner who prescribes or administers devices intended for use in humans and who manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a ''physician-patient'' relationship.

(2) An individual who manufactures devices intended for use in humans solely for such person's use in research or teaching and not for sale, including any person who is subject to alternative reporting requirements under the investigational device exemption regulations, part 812 of this chapter, which require reporting of all adverse device effects.

(3) Dental laboratories, or optical laboratories.

(b) Manufacturers, importers, or user facilities may request exemptions or variances from any or all of the reporting requirements in this part. The request shall be in writing and include information necessary to identify the firm and device, a complete statement of the request for exemption, variance, or alternative reporting, and an explanation why the request is justified.

(c) FDA may grant in writing, to a manufacturer, importer, or user facility, an exemption, variance, or alternative from, or to, any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time period. These modifications may be initiated by a request as specified in this section, or at

the discretion of FDA. When granting such modifications, FDA may impose other reporting requirements to ensure the protection of public health.

(d) FDA may revoke or modify in writing an exemption, variance, or alternative reporting requirements if FDA determines that protection of the public health justifies the modification or a return to the requirements as stated in this part.

(e) Firms granted a reporting modification by FDA shall provide any reports or information required by that approval. The conditions of the approval will replace and supersede the reporting requirement specified in this part until such time that FDA revokes or modifies the alternative reporting requirements in accordance with paragraph (d) of this section.

[60 FR 63597, Dec. 11, 1995, as amended at 61 FR 44615, Aug. 28, 1996; 65 FR 4119, Jan. 26, 2000; 65 FR 17136, Mar. 31, 2000; 66 FR 23157, May 8, 2001]

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How to report.

(a) *Description of form.* There are two versions of the MEDWATCH form for individual reports of adverse events. FDA Form 3500 is available for use by health professionals and consumers for the submission of voluntary reports regarding FDA-regulated products. FDA Form 3500A is the mandatory reporting form to be used for submitting reports by user facilities, importers, and manufacturers of FDA-regulated products. The form has some sections that must be completed by all reporters and other sections that must be completed only by the user facility, importer, or manufacturer.

(1) The front of FDA Form 3500A is to be filled out by all reporters. The front of the form requests information regarding the patient, the event, the device, and the ''initial reporter'' (*i.e.*, the first person or entity that submitted the information to the user facility, manufacturer, or importer).

(2) The back part of the form contains sections to be completed by user facilities, importers, and manufacturers. User facilities and importers must complete section F; device manufacturers must complete sections G and H. Manufacturers are not required to recopy information submitted to them on a Form 3500A unless the information is being copied onto an electronic medium. If the manufacturer corrects or supplies information missing from the other reporter's 3500A form, it should attach a copy of that form to the manufacturer's report form. If the information from the other reporter's 3500A form is complete and correct, the manufacturer can fill in the remaining information on the same form.

(b) *Reporting standards.* (1) User facilities are required to submit MDR reports to:

(i) The device manufacturer and to FDA within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer within 10 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. Such reports shall be submitted to FDA if the device manufacturer is not known.

(2) Importers are required to submit death and serious injury reports to FDA and the device manufacturer and submit malfunction reports to the manufacturer only:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

(ii) Within 30 days of receiving information that a device marketed by the importer has malfunctioned and that such a device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) Manufacturers are required to submit MDR reports to FDA:

(i) Within 30 days of becoming aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) Within 30 days of becoming aware of information that reasonably suggests a device has malfunctioned and

that device or a similar device marketed by the manufacturer would be likely to cause a death or serious injury if the malfunction were to recur; or

(iii) Within 5 days if required by § 803.53.

(c) *Information that reasonably suggests a reportable event occurred.* (1) Information that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event (i.e., death, serious injury, and, for manufacturers and importers, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur) includes 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 a reportable event.

(2) Entities required to report under this part do not have to report adverse events for which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Information which leads the qualified person to determine that a device-related event is or is not reportable must be contained in the MDR event files, as described in § 803.18.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000; 66 FR 23157, May 8, 2001]

§ 803.21 Reporting codes.

(a) FDA has developed a MEDWATCH Mandatory Reporting Form Coding Manual for use with medical device reports. This manual contains codes for hundreds of adverse events for use with FDA Form 3500A. The coding manual is available from the Division of Small Manufacturer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX 301–443–8818.

(b) FDA may use additional coding of information on the reporting forms or modify the existing codes on an ad hoc or generic basis. In such cases, FDA will ensure that the new coding information is available to all reporters.

§ 803.22 When not to file.

(a) Only one medical device report from the user facility, importer, or manufacturer is required under this part if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event.

(b) A medical device report that would otherwise be required under this section is not required if:

(1) The user facility, importer, or manufacturer determines that the information received is erroneous in that a device-related adverse event did not occur. Documentation of such reports shall be retained in MDR files for time periods specified in § 803.18.

(2) The manufacturer or importer determines that the device was manufactured or imported by another manufacturer or importer. Any reportable event information that is erroneously sent to a manufacturer or importer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured or imported by that firm.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart C—User Facility Reporting Requirements

§ 803.30 Individual adverse event reports; user facilities.

(a) *Reporting standard.* A user facility shall submit the following reports to the manufacturer or to FDA, or both, as specified below:

(1) *Reports of death.* Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall as soon as practicable, but not later than 10 work days after becoming aware of the information, report the information required by § 803.32 to FDA, on FDA Form 3500A, or an electronic equivalent as approved under § 803.14, and if the identity of the

manufacturer is known, to the device manufacturer.

(2) *Reports of serious injury*. Whenever a user facility receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility, the facility shall, as soon as practicable but not later than 10 work days after becoming aware of the information, report the information required by § 803.32, on FDA Form 3500A or electronic equivalent, as approved under § 803.14, to the manufacturer of the device. If the identity of the manufacturer is not known, the report shall be submitted to FDA.

(b) *Information that is reasonably known to user facilities*. User facilities must provide all information required in this subpart C that is reasonably known to them. Such information includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable followup within the facility. A user facility is not required to evaluate or investigate the event by obtaining or evaluating information that is not reasonably known to it.

§ 803.32 Individual adverse event report data elements.

User facility reports shall contain the following information, reasonably known to them as described in 803.30(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of event or problem, including a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests including dates and laboratory data; and

(7) Description of other relevant history including pre- existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number, or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether device was available for evaluation and whether device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and telephone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether initial reporter also sent a copy of the report to FDA, if known.

(e) User facility information (Block F) shall contain the following:

(1) Whether reporter is a user facility;

(2) User facility number;

(3) User facility address;

(4) Contact person;
(5) Contact person's telephone number;
(6) Date the user facility became aware of the event (month, day, year);
(7) Type of report (initial or followup (if followup, include report number of initial report));
(8) Date of the user facility report (month, day, year);
(9) Approximate age of device;
(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');
(11) Whether a report was sent to FDA and the date it was sent (month, day, year);
(12) Location, where event occurred;
(13) Whether report was sent to the manufacturer and the date it was sent (month, day, year); and
(14) Manufacturer name and address; if available.

§ 803.33 Annual reports.

(a) Each user facility shall submit to FDA an annual report on FDA Form 3419, or electronic equivalent as approved by FDA under § 803.14. Annual reports shall be submitted by January 1 of each year. The annual report and envelope shall be clearly identified and submitted to FDA with information that includes:
(1) User facility's HCFA provider number used for medical device reports, or number assigned by FDA for reporting purposes in accordance with § 803.3(ee);
(2) Reporting year;
(3) Facility's name and complete address;
(4) Total number of reports attached or summarized;
(5) Date of the annual report and the lowest and highest user facility report number of medical device reports submitted during the report period, e.g., 1234567890–1995–0001 through 1000;
(6) Name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA and whether that person is a new contact for that facility; and
(7) Information for each reportable event that occurred during the annual reporting period including:
(i) User facility report number;
(ii) Name and address of the device manufacturer;
(iii) Device brand name and common name;
(iv) Product model, catalog, serial and lot number;
(v) A brief description of the event reported to the manufacturer and/or FDA; and
(vi) Where the report was submitted, i.e., to FDA, manufacturer, distributor, importer, etc.
(b) In lieu of submitting the information in paragraph (a)(7) of this section, a user facility may submit a copy of FDA Form 3500A, or an electronic equivalent as approved under section 803.14, for each medical device report submitted to FDA and/or manufacturers by that facility during the reporting period.
(c) If no reports are submitted to either FDA or manufacturers during these time periods, no annual report is required.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4120, Jan. 26, 2000]

Subpart D—Importer Reporting Requirements

SOURCE: 65 FR 4120, Jan. 26, 2000, unless otherwise noted.

§ 803.40 Individual adverse event reporting requirements; importers.

(a) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 803.42 on FDA form 3500A as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.
(b) An importer shall submit to the manufacturer a report containing information required by § 803.42 on FDA form 3500A, as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or

through the importer's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

§ 803.42 Individual adverse event report data elements.

Individual medical device importer reports shall contain the following information, in so far as the information is known or should be known to the importer, as described in § 803.40, which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, that is:

(i) Death;

(ii) Life threatening injury or illness;

(iii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iv) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including preexisting medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or distributor;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) Importer information (Block F) shall contain the following:

(1) Whether reporter is an importer;

(2) Importer report number;

(3) Importer address;

(4) Contact person;

(5) Contact person's telephone number;

(6) Date the importer became aware of the event (month, day, year);

(7) Type of report (initial or followup (if followup, include report number of initial report));

(8) Date of the importer report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA ''Coding Manual For Form 3500A'');

(11) Whether a report was sent to FDA and the date it was sent (month, day, year);

(12) Location, where event occurred;

(13) Whether a report was sent to the manufacturer and the date it was sent (month, day, year); and

(14) Manufacturer name and address; if available.

Subpart E—Manufacturer Reporting Requirements

§ 803.50 Individual adverse event reports; manufacturers.

(a) *Reporting standards.* Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) *Information that is reasonably known to manufacturers.* (1) Manufacturers must provide all information required in this subpart E that is reasonably known to them. FDA considers the following information to be reasonably known to the manufacturer:

(i) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;

(ii) Any information in a manufacturer's possession; or

(iii) Any information that can be obtained by analysis, testing or other evaluation of the device.

(2) Manufacturers are responsible for obtaining and providing FDA with information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. Manufacturers are also responsible for conducting an investigation of each event and evaluating the cause of the event. If a manufacturer cannot provide complete information on an MDR report, it must provide a statement explaining why such information was incomplete and the steps taken to obtain the information. Any required information not available at the time of the report, which is obtained after the initial filing, must be provided by the manufacturer in a supplemental report under § 803.56.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

§ 803.52 Individual adverse event report data elements.

Individual medical device manufacturer reports shall contain the following information, known or reasonably known to them as described in § 803.50(b), which corresponds to the format of FDA Form 3500A:

(a) Patient information (Block A) shall contain the following:

(1) Patient name or other identifier;

(2) Patient age at the time of event, or date of birth;

(3) Patient gender; and

(4) Patient weight.

(b) Adverse event or product problem (Block B) shall contain the following:

(1) Adverse event or product problem;

(2) Outcomes attributed to the adverse event, e.g., death; or serious injury, that is:

(i) Life threatening injury or illness;

(ii) Disability resulting in permanent impairment of a body function or permanent damage to a body structure; or

(iii) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;

(3) Date of event;

(4) Date of report by the initial reporter;

(5) Description of the event or problem to include a discussion of how the device was involved, nature of the problem, patient followup or required treatment, and any environmental conditions that may have influenced the event;

(6) Description of relevant tests, including dates and laboratory data; and

(7) Other relevant patient history including pre-existing medical conditions.

(c) Device information (Block D) shall contain the following:

(1) Brand name;

(2) Type of device;

(3) Manufacturer name and address;

(4) Operator of the device (health professional, patient, lay user, other);

(5) Expiration date;

(6) Model number, catalog number, serial number, lot number or other identifying number;

(7) Date of device implantation (month, day, year);

(8) Date of device explantation (month, day, year);

(9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and

(10) Concomitant medical products and therapy dates. (Do not list products that were used to treat the event.)

(d) Initial reporter information (Block E) shall contain the following:

(1) Name, address, and phone number of the reporter who initially provided information to the user facility, manufacturer, or importer;

(2) Whether the initial reporter is a health professional;

(3) Occupation; and

(4) Whether the initial reporter also sent a copy of the report to FDA, if known.

(e) All manufacturers (Block G) shall contain the following:

(1) Contact office name and address and device manufacturing site;

(2) Telephone number;

(3) Report sources;

(4) Date received by manufacturer (month, day, year);

(5) Type of report being submitted (e.g., 5-day, initial, supplemental); and

(6) Manufacturer report number.

(f) Device manufacturers (Block H) shall contain the following:

(1) Type of reportable event (death, serious injury, malfunction, etc.);

(2) Type of followup report, if applicable (e.g., correction, response to FDA request, etc.);

(3) If the device was returned to the manufacturer and evaluated by the manufacturer, a summary of the evaluation. If no evaluation was performed, provide an explanation why no evaluation was performed;

(4) Device manufacture date (month, day, year);

(5) Was device labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA ''Coding Manual for Form 3500A'');

(7) Whether remedial action was taken and type;

(8) Whether use of device was initial, reuse, or unknown;

(9) Whether remedial action was reported as a removal or correction under section 519(f) of the act (list the correction/removal report number); and

(10) Additional manufacturer narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or importer report, including missing event codes, or information corrected on such forms after manufacturer verification;

(ii) For each event code provided by the user facility under § 803.32(e)(10) or the importer under § 803.42(e)(10), a statement of whether the type of event represented by the code is addressed in the device labeling; and

(iii) If any required information was not provided, an explanation of why such information was not provided and the steps taken to obtain such information.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

§ 803.53 Five-day reports.

A manufacturer shall submit a 5-day report to FDA, on Form 3500A or electronic equivalent as approved by FDA under § 803.14 within 5 workdays of:

(a) 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

(b) Becoming aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report. When such a request is made, the manufacturer shall submit, without further requests, a 5-day report for all subsequent 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.

§ 803.55 Baseline reports.

(a) A manufacturer shall submit a baseline report on FDA Form 3417, or electronic equivalent as approved by FDA under § 803.14 for a device when the device model is first reported under § 803.50.

(b) Each baseline report shall be updated annually, on the anniversary month of the initial submission, after the initial baseline report is submitted.

Changes to baseline information shall be reported in the manner described in § 803.56 (i.e., include only the new, changed, or corrected information in the appropriate portion(s) of the report form). Baseline reports shall contain the following:

(1) Name, complete address, and registration number of the manufacturer's reporting site. If the reporting site is not registered, FDA will assign a temporary registration number until the reporting site officially registers. The manufacturer will be informed of the temporary registration number;

(2) FDA registration number of each site where the device is manufactured;

(3) Name, complete address, and telephone number of the individual who has been designated by the manufacturer as its MDR contact and date of the report. For foreign manufacturers, a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a) is required;

(4) Product identification, including device family, brand name, generic name, model number, catalog number, product code and any other product identification number or designation;

(5) Identification of any device previously reported in a baseline report that is substantially similar (e.g., same device with a different model number, or same device except for cosmetic differences in color or shape) to the device being reported, including the identification of the previously reported device by model number, catalog number or other product identification, and the date of the baseline report for the previously reported device;

(6) Basis for marketing, including 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and, an estimate of the number of devices in current use; and

(10) Brief description of any methods used to estimate the number of devices distributed and the method used to estimate the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in § 803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§ 803.56 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H–2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and § 807.40 of this chapter, and shall

update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of §803.50;

(3) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(4) Maintain complaint files in accordance with §803.18; and

(5) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

[60 FR 63597, Dec. 11, 1995, as amended at 66 FR 23157, May 8, 2001]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.58 was stayed indefinitely.

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

Subpart A—General Provisions

Sec.
806.1 Scope.
806.2 Definitions.

Subpart B—Reports and Records

806.10 Reports of corrections and removals.
806.20 Records of corrections and removals not required to be reported.
806.30 FDA access to records.
806.40 Public availability of reports.

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 62 FR 27191, May 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food ... certa ... rections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

(2) Market withdrawals as defined in §806.2(h).

(3) Routine servicing as defined in §806.2(k).

(4) Stock recoveries as defined in §806.2(l).

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998]

§806.2 Definitions.

As used in this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Consignee* means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) *Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

(e) *Correction or removal report number* means the number that uniquely identifies each report submitted.

(f) *Importer* means, for the purposes of this part, any person who imports a device into the United States.

(g) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who ... ulti-