DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. 2004N–0527]

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Certifier R. LEDESMA

Medical Devices; Medical Device Reporting; Companion to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend its regulation governing reporting of deaths, serious injuries, and certain malfunctions related to medical devices. We are revising the regulation into plain language to make the regulation easier to understand, and we are making technical corrections. Elsewhere in this issue of the **Federal Register**, we are publishing a direct final rule that is identical to this proposed rule. This proposed rule will provide a procedural framework to finalize the rule in the event we receive any significant adverse comment and withdraw the direct final rule.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the* **Federal Register**].

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0527, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

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- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0527 in the subject line of your e-mail message.

- FAX: 301–827–6870.

- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Howard Press, Center for Devices and Radiological Health (HFZ–531), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2983.

SUPPLEMENTARY INFORMATION: This proposed rule is a companion to the direct final rule regarding adverse event reporting requirements for medical devices that is published in the final rules section of this issue of the **Federal Register**. The direct final rule and this companion proposed rule are identical. We are publishing the direct final rule because we believe the rule contains noncontroversial changes, and we anticipate that it will receive no significant

adverse comment. A detailed discussion of the rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on [*insert date 135 days after date of publication in the* **Federal Register**]. You can find additional information about FDA's direct final rulemaking procedures in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not

be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

I. What Is the Background of This Rule?

FDA's regulations governing device adverse event reporting, codified at part 803 (21 CFR part 803), implement section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i). That statutory provision has undergone several changes since its enactment as part of the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295). As a result, FDA's regulations at part 803 have also undergone multiple revisions.

In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA first issued final medical device reporting (MDR) regulations (part 803) for manufacturers and importers under the section 519 of the act, requiring reports of deaths, serious injuries, and certain malfunctions involving devices.

To address shortcomings in the 1976 amendments, and to better protect the public health by ensuring reporting of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (Public Law 101–629), which amended the statute to add requirements for medical device user facilities and distributors to report certain device-related adverse events. Reporting regulations for user facilities and for distributors became effective by operation of law on May 28, 1992, following the November 26, 1991 (56 FR 60024), publication of those requirements in a tentative final rule. This regulation required user facilities to report deaths to FDA and to manufacturers, and to report serious illnesses and injuries to manufacturers,

or to FDA if the manufacturer was unknown. Distributors were required to report deaths and serious illnesses or injuries to FDA and to manufacturers, and to report certain malfunctions to manufacturers. Existing reporting requirements for manufacturer and importers under the 1984 regulation remained in effect.

In the **Federal Register** of September 1, 1993 (58 FR 46514), we published a notice confirming that the distributor reporting regulation had become final and was codified in part 804 (21 CFR part 804). On June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (the 1992 amendments) (Public Law 102–112) further amending certain provisions of section 519 of the act relating to reporting of adverse device events. Among other things, the 1992 amendments amended section 519 of the act to modify the requirements for manufacturer and importer reporting. Consequently, under the regulation issued September 1, 1993, importers were required to report as manufacturers if they were engaged in manufacturing activities or to report as distributors if they were engaged solely in distribution activities.

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115) into law. FDAMA made several changes regarding the reporting of adverse experiences related to devices. In the **Federal Register** of May 12, 1998, FDA published a direct final rule (63 FR 26069) and a companion proposed rule (63 FR 26129) to implement new amendments to the MDR provisions. We received significant adverse comments on the 1998 direct final rule and the 1998 companion proposed rule; therefore, we withdrew the 1998 direct final rule and issued a revised final rule on January 26, 2000 (65 FR 4112). Under the act as amended by FDAMA, distributors are no longer required to report adverse

events but are required to keep records. Importers are still required to report adverse events related to medical devices. Because of FDAMA's changes, we revised part 803 and rescinded part 804.

In summary, the present version of part 803, as it is codified in the Code of Federal Regulations, imposes the following general reporting and recordkeeping requirements:

Device user facilities must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit annual reports. Manufacturers and importers must report deaths and serious injuries that a device has or may have caused or contributed to, must report certain device malfunctions, and must establish and maintain adverse event files. Manufacturers also must submit specified followup and baseline reports. Distributors must maintain records of incidents but are not required to report these incidents.

II. What Does This Proposed Rule Do?

This proposed rule does not change the substantive regulatory requirements described previously in this document. FDA is revising part 803 solely to ensure that despite the many revisions that have been made, part 803 is clear and easy to understand. To achieve this goal, we have rewritten part 803 into plain language, in accordance with the Presidential Memorandum on Plain Language, issued on June 1, 1998. That memorandum directed the agency to ensure that all of its documents are clear and easy to read. Part of achieving that goal involves having readers of a regulation feel that it is speaking directly to them. Therefore, we have attempted to incorporate plain language in this rule as much as possible. We have tried to make each section of the proposed rule easy to understand by using clear and simple language

rather than jargon, by keeping sentences short, and by using active voice rather than passive voice whenever possible. We have also made changes to improve the consistency of the format and language used throughout parallel regulations governing user facilities, importers, and manufacturers that were added or amended at different times. We would like your comments on the following topics: (1) How effectively we have used plain language, (2) the organization and format of the proposed rule, and (3) whether these changes have made the document clear and easy to read. In addition, in this proposed rule, as in the direct final rule, we have made technical corrections to several provisions.

A detailed description of specific changes in the rule is contained in the preamble to the direct final rule, published elsewhere in this issue of the **Federal Register**.

We note that §§ 803.55(b)(9) and (b)(10) and 803.58 were stayed indefinitely, under notices published in the **Federal Registers** of July 31, 1996 (61 FR 39868 at 39869) and July 23, 1996 (61 FR 38346 at 38347). This proposed rule does not propose any changes to those provisions, which remain stayed indefinitely, but for the sake of completeness, we include as follows, the current text of those provisions.

III. What Is the Legal Authority for This Proposed Rule?

This proposed rule, like the existing medical device adverse event reporting regulations to which it makes nonsubstantive changes, is authorized by sections 502, 510, 519, 520, 701, and 704 of the act (21 U.S.C. 352, 360, 360i, 360j, 371, and 374).

IV. What Is the Environmental Impact of This Proposed Rule?

We have determined under 21 CFR 25.30(h) and (i) that this action does not have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. What Is the Economic Impact of This Proposed Rule?

We have examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule will not change any existing requirements or impose any new requirements, we certify that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after

adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the rule have been approved by OMB in accordance with the PRA under the regulations governing medical device reporting (part 803, OMB control number 0910–0437).

VII. What Are the Federalism Impacts of This Proposed Rule?

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of

this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 803 be amended as follows:

1. Part 803 is revised to read as follows:

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

803.1 What does this part cover?

803.3 How does FDA define the terms used in this part?

803.9 What information from the reports do we disclose to the public?

803.10 Generally, what are the reporting requirements that apply to me?

803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

803.12 Where and how do I submit reports and additional information?

803.13 Do I need to submit reports in English?

803.14 How do I submit a report electronically?

803.15 How will I know if you require more information about my medical device report?

803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

803.20 How do I complete and submit an individual adverse event report?

803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

803.22 What are the circumstances in which I am not required to file a report?

Subpart C—User Facility Reporting Requirements

803.30 If I am a user facility, what reporting requirements apply to me?

803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

803.33 If I am a user facility, what must I include when I submit an annual report?

Subpart D—Importer Reporting Requirements

803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?

803.42 If I am an importer, what information must I submit in my individual adverse event reports?

Subpart E—Manufacturer Reporting Requirements

803.50 If I am a manufacturer, what reporting requirements apply to me?

803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

803.55 I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?

803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

803.58 Foreign manufacturers.

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

Subpart A—General Provisions

§ 803.1 What does this part cover?

(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup and baseline reports. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.

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

§ 803.3 How does FDA define the terms used in this part?

Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:

Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, as amended.

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.

Become aware means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

(1) If you are a device user facility, you are considered to have "become aware" when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.

(2) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event

that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 calendar days.

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.

Device family. (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) You may consider devices that differ only in minor ways not related to safety or effectiveness to be in the same device family. When grouping products in device families, you may consider 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).

Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician's office, as defined in this section. School nurse offices and employee health units are not device user facilities.

Distributor means 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. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

Expected life of a device 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 activities such as maintenance, repairs, or upgrades, for an estimated period of time.

FDA, we, or us means the Food and Drug Administration.

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

Hospital means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, physical), 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.

Importer means 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. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

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.

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 either:

(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 that 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.

Manufacturer or importer report number. 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 the following three parts:

(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 an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting 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 as follows: 1234567–1995–00001.)

MDR means medical device report.

MDR reportable event (or reportable event) means:

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

(2) An event that manufacturers or importers become aware of 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.

Medical personnel 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 these persons.

Nursing home means:

(1) 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.

Outpatient diagnostic facility. (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.

(2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. 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.

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 in a 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 the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. 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.

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. This includes 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.

Physician's office means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination,

evaluation, and treatment or referral of patients. Examples of physician offices include dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

Remedial action means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

Serious injury means an injury or illness that:

(1) Is 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.

Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Shelf life 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.

User facility report number means the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:

(1) The user facility's 10-digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has fewer than 10 digits, fill the remaining spaces with zeros);

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

(3) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000–2004–0001. If a user facility has more than one CMS number, it must select one that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–2004–0001). We will assign a number for future use and send that number to the user facility. This number is used in our record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.)

Work day means Monday through Friday, except Federal holidays.

§ 803.9 What information from the reports do we disclose to the public?

(a) We may disclose to the public any report, including any FDA record of a telephone report, submitted under this part. Our disclosures are governed by part 20 of this chapter.

(b) Before we disclose a report to the public, we will delete the following:

(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. However, if a patient requests a report, we will disclose to that patient 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 that voluntarily submitted an adverse event report.

(c) We may not disclose the identity of a device user facility that 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 that is the subject of a report required to be submitted 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.

§ 803.10 Generally, what are the reporting requirements that apply to me?

(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:

(1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or

(ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.

(2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:

(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or

(ii) Submit reports of device-related malfunctions to the manufacturer.

(2) [Reserved]

(c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:

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

(ii) A reportable event for which we made a written request.

(3) Submit annual baseline reports.

(4) Submit supplemental reports if you obtain information that you did not submit in an initial report.

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

If you are a user facility, importer, or manufacturer, you must submit all reports of individual adverse events on FDA MEDWATCH Form 3500A or in an electronic equivalent as approved under § 803.14. You may obtain this form and all other forms referenced in this section from any of the following:

(1) The Consolidated Forms and Publications Office, Beltsville Service Center, 6351 Ammendale Rd., Landover, MD 20705;

(2) Food and Drug Administration, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240;

(3) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ–220), 1350 Piccard

Dr., Rockville, MD 20850, by e-mail: *DSMICA@CDRH.FDA.GOV*, or FAX: 301–443–8818; or

(4) On the Internet at *http://www.fda.gov/cdrh/mdr/mdr-forms.html.*

§ 803.12 Where and how do I submit reports and additional information?

(a) You must submit any written report or additional information required under this part to Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847–3002.

(b) You must specifically identify each report (e.g., "User Facility Report," "Annual Report," "Importer Report," "Manufacturer Report," "10-Day Report").

(c) If you have a public health emergency, you can alert the FDA Emergency Operations Branch (HFC–162), Office of Regional Operations, at 301–443–1240. After contacting us, you should submit a FAX report to 301–443–3757.

(d) You may submit a voluntary telephone report to the MEDWATCH office at 800–FDA–1088. You may also obtain information regarding voluntary reporting from the MEDWATCH office at 800–FDA–1088. You may also find the voluntary MEDWATCH 3500 form and instructions to complete it at *http://www.fda.gov/medwatch/getforms.htm.*

§ 803.13 Do I need to submit reports in English?

(a) Yes. You must submit all written or electronic equivalent reports required by this part in English.

(b) If you submit any reports required by this part in an electronic medium, that submission must be done in accordance with § 803.14.

§ 803.14 How do I submit a report electronically?

(a) You may electronically submit any report required by this part if you have our prior written consent. We may revoke this consent at anytime. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) If your electronic report meets electronic reporting standards, guidance documents, or other MDR reporting procedures that we have developed, you may submit the report electronically without receiving our prior written consent.

§ 803.15 How will I know if you require more information about my medical device report?

(a) We will notify you in writing if we require additional information and will tell you what information we need. We will require additional information if we determine that protection of the public health requires additional or clarifying information for medical device reports submitted to us and in cases when the additional information is beyond the scope of FDA reporting forms or is not readily accessible to us.

(b) In any request under this section, we will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. If we verbally request additional information, we will confirm the request in writing.

§ 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do

not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

§ 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?

If you are a user facility, importer, or manufacturer, you must 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 MDR requirements;

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

(3) Timely transmission of complete medical device reports to manufacturers or to us, or to both if required.

(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 manufacturers and/or us;

(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 us.

§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them 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), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

(i) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decisionmaking processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this part; and

(ii) Copies of all MDR forms, as required by this part, and other information related to the event that you submitted to us and other entities such as an importer, distributor, or manufacturer.

(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(c) If you are a user facility, you must retain an MDR event file relating to an adverse event for a period of 2 years from the date of the event. If you are a manufacturer or importer, you must 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. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this paragraph.

(d)(1) If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity

(e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.

(2) You must retain copies of the required device incident records 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. You must maintain copies of these records for this period even if you no longer distribute the device.

(3) You must maintain the device complaint files established under this section at your principal business establishment. If you are also a manufacturer, you may maintain the file at the same location as you maintain your complaint file under part 820 of this chapter. You must permit any authorized FDA employee, at all reasonable times, to access, to copy, and to verify the records required by this part.

(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

(a) We exempt the following persons from the adverse event reporting requirements in this part:

(1) A licensed practitioner who prescribes or administers devices intended for use in humans and 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 this person's use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations (described in part 812 of this chapter), which require reporting of all adverse device effects; and

(3) Dental laboratories or optical laboratories.

(b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part. You must submit the request to us in writing. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified.

(c) If you are a manufacturer, importer, or user facility, we may grant in writing an exemption or variance from, or alternative 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. We may grant these modifications in response to your request, as described in paragraph (b) of this section, or at our discretion. When we grant modifications

to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.

(d) We may revoke or modify in writing an exemption, variance, or alternative reporting requirement if we determine that revocation or modification is necessary to protect the public health.

(e) If we grant your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that we revoke or modify the alternative reporting requirements in accordance with paragraph (d) of this section.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

§ 803.20 How do I complete and submit an individual adverse event report?

(a) What form must I complete and submit? There are two versions of the MEDWATCH form for individual reports of adverse events. If you are a health professional or consumer, you may use the FDA Form 3500 to submit voluntary reports regarding FDA-regulated products. If you are a user facility, importer, or manufacturer, you must use the FDA Form 3500A to submit mandatory reports about FDA-regulated products.

(1) If you are a user facility, importer, or manufacturer, you must complete the applicable blocks on the front of FDA Form 3500A. The front of the form is used to submit information about the patient, the event, the device, and the "initial reporter" (i.e., the first person or entity who reported the information to you).

(2) If you are a user facility, importer, or manufacturer, you must complete the applicable blocks on the back of the form. If you are a user facility or

importer, you must complete block F. If you are a manufacturer, you must complete blocks G and H. If you are a manufacturer, you do not have to recopy information that you received on a Form 3500A unless you are copying the information onto an electronic medium. If you are a manufacturer and you are correcting or supplying information that is missing from another reporter's Form 3500A, you must attach a copy of that form to your report form. If you are a manufacturer and the information from another reporter's Form 3500A is complete and correct, you may fill in the remaining information on the same form and submit it to us.

(b) To whom must I submit reports and when?

(1) If you are a user facility, you must submit MDR reports to:

(i) The manufacturer and to us no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or

(ii) The manufacturer no later than 10 work days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to us.

(2) If you are an importer, you must submit MDR reports to:

(i) The manufacturer and to us, no later than 30 calendar days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or

(ii) The manufacturer, no later than 30 calendar days after receiving information that a device you market has malfunctioned and that this device

or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(3) If you are a manufacturer, you must submit MDR reports to us:

(i) No later than 30 days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(ii) No later than 30 days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; or

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

(c) What kind of information reasonably suggests that a reportable event has occurred?

(1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude 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. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep

in your MDR event files (described in § 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MEDWATCH Medical Device Reporting Code Instruction Manual contains adverse event codes for use with FDA Form 3500A. You may obtain the coding manual from CDRH's Web site at *http://www.fda.gov/cdrh/mdr/373.html*; and from the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850, FAX: 301–443–8818, or e-mail to *DSMICA@CDRH.FDA.GOV.*

(b) We may sometimes use additional coding of information on the reporting forms or modify the existing codes. If we do make modifications, we will ensure that we make the new coding information available to all reporters.

§ 803.22 What are the circumstances in which I am not required to file a report?

(a) If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one medical device report.

(b) You are not required to submit a medical device report if:

(1) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 803.18.

(2) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you

receive reportable event information in error, you must forward this information to us with a cover letter explaining that you did not manufacture or import the device in question.

Subpart C—User Facility Reporting Requirements

§ 803.30 If I am a user facility, what reporting requirements apply to me?

(a) You must submit reports to the manufacturer or to us, or both, as specified below:

(1) *Reports of death.* You must submit a report to us as soon as practicable but no more than 10 work days after the day that you become 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 your facility. You must also submit the report to the device manufacturer, if known. You must report information required by § 803.32 on FDA Form 3500A or an electronic equivalent approved under § 803.14.

(2) *Reports of serious injury.* You must submit a report to the manufacturer of the device no later than 10 work days after the day that you become 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 your facility. If the manufacturer is not known, you must submit the report to us. You must report information required by § 803.32 on FDA Form 3500A or an electronic equivalent approved under § 803.14.

(b) What information does FDA consider "reasonably known" to me? You must submit all information required in this subpart C that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable followup within your facility. You are not required to evaluate or

investigate the event by obtaining or evaluating information that you do not reasonably know.

§ 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if reasonably known to you, as described in § 803.30(b). These types of information correspond generally to the elements of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit 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 (Form 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it 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 preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit 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; if so, the date it was returned to the manufacturer; and

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

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to you, or to the 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 us, if known.

(e) User facility information (Form 3500A, Block F). You must submit the following:

(1) An indication that this is a user facility report (by marking the user facility box on the form);

(2) Your user facility number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

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

(7) Type of report (initial or followup); if it is a followup, you must include the report number of the initial report;

(8) Date of your report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to the "MEDWATCH Medical Device Reporting Code Instructions");

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

(12) Location where the event occurred;

(13) Whether the 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 If I am a user facility, what must I include when I submit an annual report?

(a) You must submit to us an annual report on FDA Form 3419, or electronic equivalent as approved by us under § 803.14. You must submit an

annual report by January 1, of each year. You must clearly identify your annual report as such. Your annual report must include:

(1) Your CMS provider number used for medical device reports, or the number assigned by us for reporting purposes in accordance with § 803.3;

(2) Reporting year;

(3) Your name and complete address;

(4) Total number of reports attached or summarized;

(5) Date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period (e.g., 1234567890–2004–0001 through 1000);

(6) Name, position title, and complete address of the individual designated as your contact person responsible for reporting to us and whether that person is a new contact for you; and

(7) Information for each reportable event that occurred during the annual reporting period including:

(i) 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 us; and

(vi) Where the report was submitted, i.e., to the manufacturer, importer, or us.

(b) In lieu of submitting the information in paragraph (a)(7) of this section, you may submit a copy of FDA Form 3500A, or an electronic equivalent approved under § 803.14, for each medical device report that you submitted to the manufacturers and/or to us during the reporting period.

(c) If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

Subpart D—Importer Reporting Requirements

§ 803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?

(a) *Reports of deaths or serious injuries.* You must submit a report to us, and a copy of this report to the manufacturer, as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become 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 your marketed devices may have caused or contributed to a death or serious injury. This report must contain the information required by § 803.42, on FDA form 3500A or an electronic equivalent approved under § 803.14.

(b) *Reports of malfunctions.* You must submit a report to the manufacturer as soon as practicable but no later than 30 calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through your own research, testing, evaluation, servicing, or maintenance of one of your devices, that reasonably suggests that one of your devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. This report must contain information required by § 803.42, on FDA form 3500A or an electronic equivalent approved under § 803.14.

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

You must include the following information in your report, if the information is known or should be known to you, as described in § 803.40. These types of information correspond generally to the format of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit 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 (Form 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it 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, 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 patient history, including preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit 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 explanation (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 report products that were used to treat the event.)

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:

(1) Name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, 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 us, if known.

(e) Importer information (Form 3500A, Block F). You must submit the following:

(1) An indication that this is an importer report (by marking the importer box on the form);

(2) Your importer report number;

(3) Your address;

(4) Your contact person;

(5) Your contact person's telephone number;

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

(7) Type of report (initial or followup). If it is a followup report, you must include the report number of your initial report;

(8) Date of your report (month, day, year);

(9) Approximate age of device;

(10) Event problem codes—patient code and device code (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);

(11) Whether a report was sent to us 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 If I am a manufacturer, what reporting requirements apply to me?

(a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of

information, from any source, that reasonably suggests that a device that you market:

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

(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

(b) What information does FDA consider "reasonably known" to me?

(1) You must submit all information required in this subpart E that is reasonably known to you. We consider the following information to be reasonably known to you:

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

(ii) Any information in your possession; or

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

(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.

(3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under § 803.56.

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

You must include the following information in your reports, if known or reasonably known to you, as described in § 803.50(b). These types of information correspond generally to the format of FDA Form 3500A:

(a) Patient information (Form 3500A, Block A). You must submit 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 (Form 3500A, Block B). You must submit the following:

(1) Identification of adverse event or product problem;

(2) Outcomes attributed to the adverse event (e.g., death or serious injury). An outcome is considered a serious injury if it 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, 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) Other relevant patient history including preexisting medical conditions.

(c) Device information (Form 3500A, Block D). You must submit the following:

(1) Brand name;

(2) Type of device;

(3) Your 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 you, and if so, the date it was returned to you; and

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

(d) Initial reporter information (Form 3500A, Block E). You must submit the following:

(1) Name, address, and phone number of the reporter who initially provided information to you, or to the user facility 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 us, if known.

(e) Reporting information for all manufacturers (Form 3500A, Block G). You must submit the following:

(1) Your reporting office's contact name and address and device manufacturing site;

(2) Your telephone number;

(3) Your report sources;

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

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

(6) Your report number.

(f) Device manufacturer information (Form 3500A, Block H). You must submit 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 you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;

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

(5) Whether the device was labeled for single use;

(6) Evaluation codes (including event codes, method of evaluation, result, and conclusion codes) (refer to FDA MEDWATCH Medical Device Reporting Code Instructions);

(7) Whether remedial action was taken and the type of action;

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

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

(10) Your additional narrative; and/or

(11) Corrected data, including:

(i) Any information missing on the user facility report or importer report, including any event codes that were not reported, or information corrected on these forms after your verification;

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

(iii) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under § 803.14, no later than 5 work days after the day that you become aware that:

(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. You may become aware of the need for remedial action from any information, including any trend analysis; or

(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must 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. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

§ 803.55 If I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?

(a) You must submit a baseline report for a device when you submit the first report under § 803.50 involving that device model. Submit this report on FDA Form 3417 or an electronic equivalent approved under § 803.14.

(b) You must update each baseline report annually on the anniversary month of the initial submission, after the initial baseline report is submitted. Report changes to baseline information 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). In each baseline report, you must include the following information:

(1) Name, complete address, and establishment registration number of your reporting site. If your reporting site is not registered under part 807, we will assign a temporary number for use in MDR reporting until you register your reporting site in accordance with part 807. We will inform you of the temporary MDR reporting number;

(2) FDA registration number of each site where you manufacture the device;

(3) Name, complete address, and telephone number of the individual who you have designated as your MDR contact, and the date of the report. For foreign manufacturers, we require a confirmation that the individual submitting the report is the agent of the manufacturer designated under § 803.58(a);

(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 that you 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. This includes additional 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 your 510(k) premarket notification number or PMA number, if applicable, and whether the device is currently the subject of an approved postmarket study under section 522 of the act;

(7) Date that you initially marketed the device and, if applicable, the date on which you stopped marketing the device;

(8) Shelf life of the device, 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 that you used to estimate the number of devices distributed and 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.

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

If you are a manufacturer, when you obtain information required under this part that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to us within 1 month of the day that you receive this information. On a supplemental or followup report, you must:

(a) Indicate on the envelope and in the report that the report being submitted is a supplemental or followup report. If you are using FDA form 3500A, indicate this in Block Item H–2;

(b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (e.g., your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and

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

§ 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;

(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.

Dated: 2/17/05

February 17, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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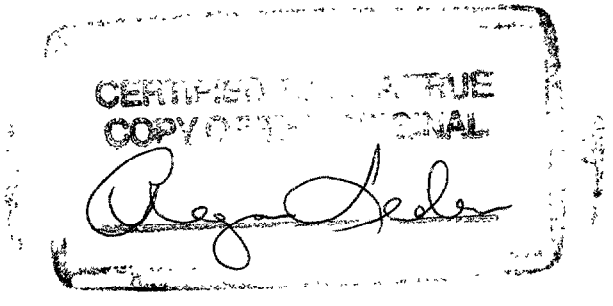
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