

for submitting required documents for complying with the MDR reporting requirements and for related documentation.

**C. Impact Assessment**

Based on the cost analysis, the economic impact on manufacturers, U.S. agents for foreign manufacturers, and users of medical devices will not exceed the \$100 million threshold established under Executive Order 12866. Annualized one-time costs of about \$9.1 million will be incurred by industry for establishing and/or documenting procedures for data collection and reporting. In addition, the annual cost of user reporting is

estimated to be \$31.7 million, for a total annualized industry cost of \$40.8 million.

An estimated 51,000 additional death and injury reports are expected as a result of adverse incidents that must be reported under this rule. This is in line with the Congressional Budget Office estimate of 40,000 reports. These incidents generate investigation, data analyses and summaries, and additional reporting requirements. Based on the above estimates, this translates to an average cost per adverse report of \$799.

**1. User Facility Costs**

Table 1 summarizes the total incremental initial and recurring costs

of the reporting requirements for user facilities. These estimates are based on cost data from the Center for Devices and Radiological Health's draft report to Congress, entitled "The Evaluation of Medical Device User Facility Reporting Requirements", 1994. Components of one-time costs include developing procedures and modifying forms for reporting and training personnel. The most significant one-time costs are \$3.0 million for developing procedures and \$2.6 million for "other" startup costs. The total annualized one-time cost to user facilities is estimated to be \$8.9 million.

**TABLE 1.—TOTAL COSTS TO USER FACILITIES BY TYPE OF FACILITY**

(millions of dollars)

Facility type	Number of facilities	One-time cost	Annualized <sup>1</sup>	Annual	Total
Hospitals	6,738	7.9	1.9	7.0	8.9
Nursing homes	25,648	12.7	3.1	5.3	8.4
Ambulatory surgical	1,300	0.7	0.2	0.7	0.9
Outpatient diagnostic	7,578	3.3	0.8	0.7	1.5
Outpatient treatment	4,041	2.5	0.6	1.4	2.0
Emergency medical service	15,600	9.5	2.3	4.1	6.4
<b>Total</b>	<b>60,905</b>	<b>36.6</b>	<b>8.9</b>	<b>19.3</b>	<b>28.2</b>

<sup>1</sup>Annualized over 5 years at a discount rate of 7 percent. (Numbers may not add due to rounding.)

Annual costs include investigation of the event, reporting the event, preparing semiannual reports, and related computer, and other costs. The total annual cost to user facilities is \$19.3 million. Hospitals and nursing homes incur about two-thirds of this cost at \$7.0 million and \$5.3 million, respectively. Major components of annual cost include \$5.4 million to investigate and to prepare the initial reports. Semiannual reports are required only if a facility has a reportable event, and are estimated to cost \$59,000. The most significant costs are for computer and other costs at \$14.8 million. The total first-year costs to user facilities is \$28.2 million.

**2. Manufacturer and U.S. Agent for Foreign Manufacturer Costs**

Manufacturers are currently required under the current good manufacturing practices regulation to investigate complaints and analyze device failures. Manufacturers will now be required to document and maintain their MDR related procedures. The vast majority of manufacturers already have such written procedures in place. Incremental one-time costs for documenting these procedures will be \$105 thousand. Foreign manufacturers will incur additional one-time costs of \$662 thousand to select an agent and notify FDA. Annualized at 7 percent

over 5 years, this translates to \$187 thousand per year.

Manufacturers must also comply with the new reporting requirements. Table 2 presents the expected annual cost of reporting by type of facility and type of report. The major components of annual cost include the followup and reporting of additional adverse medical device events and the submission of baseline reports. MDR followup on user and distributor reports and completion of information on Form 3500A is expected to cost manufacturers \$11.1 million annually for the estimated 51,000 reports from user facilities and distributors. The cost of 8,000 new baseline reports and 12,000 updates will be \$598 thousand.

**TABLE 2.—ANNUAL COST OF REPORTING**

Type of facility	Type of report	Cost (dollars)	Number of reports	Total cost (\$000)
All manufacturers	Followup MDR's from user/distributor facilities	217.60	51,000	11,098
	Baseline report	54.40	8,000	435
	Baseline update	13.60	12,000	163
	Five-day report	233.60	100	23
	Annual certification	26.00	12,145	316
Foreign only	Fees for MDR reporting			134
	Fees for 510(k) filing	110.08	510	56
(All manufacturers-Total)				12,225
U.S. agents for foreign manufacturers	Register and list	16.64	4,812	80

TABLE 2.—ANNUAL COST OF REPORTING—Continued

Type of facility	Type of report	Cost (dollars)	Number of reports	Total cost (\$000)
(U.S. agents for foreign manufacturers—Total).	Notify and document MDR's .....	7.80	5,750	45
	.....	.....	.....	125
Total .....	.....	.....	.....	12,350

In addition, domestic manufacturers and U.S. agents for foreign manufacturers will be required to certify annually the number of reportable events that have occurred. This is a formality in terms of data collection and reporting and is expected to cost \$316 thousand. Foreign manufacturers will incur a fee of \$190 thousand for reporting services conducted by their U.S. agents. Annual costs to U.S. agents are \$125 thousand for registering and listing their foreign manufacturers establishments and products and for complying with reporting requirements. Previously, foreign manufacturers were required to submit premarket notifications or have their initial distributor in the United States do so. Now, U.S. agents will be required to submit premarket notifications for foreign manufacturers. This represents a transfer of existing requirements and therefore, no increase in cost.

3. Total Cost to Industry

Table 3 presents a summary of the total annual costs to industry. Costs are \$28.2 million for user facilities, \$12.4 million for manufacturers, and \$125 thousand for U.S. agents for foreign manufacturers, for a total annual cost to industry of \$40.8 million.

TABLE 3.—TOTAL ANNUALIZED COST TO INDUSTRY  
(in millions of dollars)

Industry	One-time <sup>1</sup>	Annual	Total
User Facilities .....	8.93	19.31	28.24
Manufacturers .....	0.19	12.22	12.41

TABLE 3.—TOTAL ANNUALIZED COST TO INDUSTRY—Continued  
(in millions of dollars)

Industry	One-time <sup>1</sup>	Annual	Total
U.S. agents for foreign manufacturers .....	.....	0.13	0.13
Total	9.12	31.66	40.77

<sup>1</sup> Annualized over 5 years at a discount rate of 7 percent. (Numbers may not add due to rounding.)

4. Small Business Impacts

There is little likelihood that there will be a significant impact on small facilities. The one-time start-up costs range from \$437 to \$1,629 for user facilities, depending on facility type. Annualized at 7 percent for 5 years, these costs range from \$107 to \$397 for user facilities. In addition, estimates of the annual number of additional medical device events attributable to this regulation are about 51,000. Because there are nearly 61,000 user facilities, this averages out to about .8 serious events per facility attributable to the user reporting rule at an annual cost of \$400 per event.

Similarly, small businesses in the medical device manufacturing industry will not be significantly affected, although the industry has a substantial number of small facilities, with about 65 percent of the establishments having fewer than 50 employees. No more than 22 percent of the anticipated \$12 million annual impact of these regulations on manufacturers would be attributable to small establishments, or about \$2.7 million per year. Because there are about 7,300 small medical device establishments (including foreign manufacturers), the average impact on

one small establishment should be less than \$338 annually. Assuming that all of the approximately 4,800 U.S. agents are small, on average, the \$125 thousand impact on any one establishment would be \$26 annually.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). The title, description, and respondent description of the information collections are shown below and an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

*Title:* Reporting and recordkeeping requirements for user facilities and manufacturers of medical devices under the Safe Medical Devices Act of 1990 (SMDA) and the Medical Device Amendments of 1992 (1992 Amendments)(General requirements).

*Description:* This regulation implements provisions of the SMDA and the 1992 amendments regarding user facility reporting of deaths and serious injuries related to medical devices. This regulation also amends regulations regarding device manufacturer reporting of deaths, serious injuries, and certain malfunctions related to medical devices. The purpose of these changes is to improve the protection of the public health while also reducing the regulatory burden on reporting entities.

*Description of Respondents:* Businesses or other for profit organizations, nonprofit organizations, Federal, State, and local governments.

TABLE 4.—ESTIMATED ANNUAL BURDEN FOR REPORTING

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
803.19 .....	100	1.0	100	3.0	300

TABLE 4.—ESTIMATED ANNUAL BURDEN FOR REPORTING—Continued

CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
803.30(a)	700	1.0	700	3.0	2,100
803.30(b)	20,000	1.5	30,000	3.0	90,000
803.33	2,000	1.0	2,000	1.0	2,000
803.50	1,250	40.0	50,000	0.5	25,000
803.53	100	1.0	100	0.5	50
803.55	1,000	20.0	20,000	1.1	22,000
803.56	500	20.0	10,000	1.0	10,000
803.57	12,000	1.0	12,000	1.0	12,000
803.58	5,000	1.0	5,000	1.0	5,000
Total					168,450

<sup>1</sup> Although an initial submission will take an estimated 2 hours to complete, the annual update will take only .5 hours. The average hours per response is therefore 1.1, as reflected here.

TABLE 5.—ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

CFR section	Number of record-keepers	Hours per record-keeper	Total hours
803.18(c)	36,639	0.25	9,160
803.18(e)	625	16.00	10,000
Total			19,160

Although the November 26, 1991, tentative final rule provided a 60-day comment period (extended to 90 days in the January 24, 1992, Federal Register, 57 FR 2861), and this final rule is based on the comments received, FDA Form 3419 (semiannual report), FDA Form 3417 (baseline report), and FDA Form 3381 (annual certification) have not been previously available to OMB or the public for review. Therefore, as required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of this final rule to OMB for its review of these information collection requirements.

In addition, the agency solicits public comment on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

Individuals and organizations may submit comments on the information collection requirements by January 10, 1996, and should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., rm. 10235, 725 17th St. NW., Washington, DC 20503. Attention: Desk Officer for FDA.

Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number. This final rule contains information collection requirements which have been approved under OMB no. 0910-0059 and which expires on March 31, 1996. FDA will publish a notice in the Federal Register prior to the effective date of this final rule of OMB's decision to approve, modify or disapprove the information collection requirements.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner

of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

1. Part 803 is revised to read as follows:

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 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.
- 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 Semiannual reports.

**Subpart D—[Reserved]****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.  
 803.57 Annual certification.  
 803.58 Foreign manufacturers.

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

**Subpart A—General Provisions****§ 803.1 Scope.**

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and must establish and maintain adverse event files. Manufacturers are also required to report certain device malfunctions and submit an annual report to FDA certifying that the correct number of medical device reports were filed during the previous 12-month period or, alternatively, that no reports were required during that same time period. 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.

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

(1) 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 pursuant to a written request from FDA under 803.53(b); and

(2) 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.

(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 (l), (b), (s), (t), and (u), respectively, of this section, which is not a "physician's office," as defined in paragraph (w) of this section. School nurse offices and employee health units are not device user facilities.

(g) [Reserved]

(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) *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.

(n) *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 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.

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

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

(p) *MDR* means medical device report.

(q) *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 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 would be likely to

cause or contribute to a death or serious injury if the malfunction were to recur.

(r) *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.

(s)(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.

(t)(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.

(u) (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.

(v) *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.

(w) *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.

(x) [Reserved]

(y) *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.

(z) [Reserved]

(aa)(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.

(bb) *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.

(cc) [Reserved]

(dd)(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.

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

#### § 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;

(3) A disclosure relating to a manufacturer or distributor adverse event report that is required under section 519(a) of the act; or

(4) 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 General description of reports required from user facilities 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 semiannual reports as described in § 803.33.

(b) [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.

(5) Annual certification to FDA of the number of MDR reports filed during the preceding year as described in § 803.57.

#### § 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 20785, or from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health, 1350 Piccard Dr. (HFZ-220), Rockville, MD 20850, telephone facsimile (FAX) 301-443-8818. FDA Form 3500A may also be obtained from the Food and Drug Administration, MEDWATCH (HF-2), 5600 Fishers Lane, rm. 9-57, Rockville, MD 20850, 301-443-0117.

#### § 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," "Semi-Annual 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.

#### § 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, guidelines, or other procedures developed by the agency for MDR reporting will be deemed to have prior approval for use.

#### § 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 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 semiannual reports or certification; and

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

#### § 803.18 Files.

(a) User facilities 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 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 decisionmaking 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., a distributor or manufacturer).

(2) User facilities 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 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) [Reserved]

(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.

#### § 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, parts 812 and 813 of this chapter, which require reporting of all adverse device effects.

- (3) Dental laboratories, or optical laboratories.

(b) Manufacturers 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 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.

#### 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 and manufacturers of FDA-regulated products. The form has sections that must be completed by all reporters and other sections that must be completed only by the user facility 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 "initial reporter" (i.e., the first person or entity that submitted the information to the user facility, manufacturer, or distributor).

(2) The back part of the form contains sections to be completed by user facilities and manufacturers. User facilities 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) (Reserved)

(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, 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.

##### § 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 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 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 determines that the device was manufactured by another manufacturer. Any reportable event information that is erroneously sent to a manufacturer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured by that firm.

#### 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 Semiannual reports.

(a) Each user facility shall submit to FDA a semiannual report on FDA Form 3419, or electronic equivalent as approved by FDA under § 803.14. Semiannual reports shall be submitted by January 1 (for reports made July through December) and by July 1 (for reports made January through June) of each year. The semiannual 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(dd);
  - (2) Reporting year and period, e.g., January through June or July through December;
  - (3) Facility's name and complete address;
  - (4) Total number of reports attached or summarized;
  - (5) Date of the semiannual 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 semiannual 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, 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 semiannual report is required.

#### Subpart D—[Reserved]

#### 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, distributor and/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, distributors, 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.

##### § 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 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) 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 distributor 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(d)(10) or a distributor, a statement of whether the type of the 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.

##### § 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.

#### § 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).

#### § 803.57 Annual certification.

All manufacturers, including U.S. agents of foreign manufacturers required

to report under this section, shall submit a certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under part 814 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in § 807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date. The reports shall contain the following information:

(a) Name, address, telephone number, and FDA registration number or FDA-assigned identification number of the firm and whether the firm is a manufacturer;

(b) A statement certifying that:

(1) The firm listed in paragraph (a) of this section has filed reports for all reportable events required under this section during the previous 12-month period. The firm shall also provide a numerical summary of MDR reports that it submitted to FDA during the preceding year; or

(2) The firm listed in paragraph (a) of this section did not receive reportable events for any devices manufactured by the firm during the previous 12-month period.

(c) Certification shall be made by the president, chief executive officer, U.S.-designated agent of a foreign manufacturer, or other official most directly responsible for the firm's operations; and

(d) Name of the manufacturer and registration numbers submitted under paragraph (a) of this section shall be the same as those used in submitting the reports required by §§ 803.52, 803.53 and 803.55. Multisite manufacturers who choose to certify centrally must identify the reporting sites, by registration number or FDA-assigned identification number and name covered by the certification, and provide the information required by paragraph (b) of this section for each reporting site.

#### § 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) Certify in accordance with § 803.57;

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

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

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

**PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES**

2. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 513, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374).

3. Section 807.3 is amended by adding new paragraph (r) to read as follows:

**§ 807.3 Definitions.**

(r) *U.S.-designated agent* means the person, residing in the United States, designated and authorized by the owner or operator of a foreign manufacturer who exports devices into the United States and is responsible for:

- (1) Submitting MDR reports,
- (2) Submitting annual certifications,
- (3) Acting as the official

correspondent,

(4) Submitting registration information,

(5) Submitting device listing information, and

(6) Submitting premarket notifications on behalf of the foreign manufacturer.

4. Section 807.20 is amended by adding new paragraph (a)(6) to read as follows:

**§ 807.20** Who must register and submit a device list.

(a) \* \* \*

(6) Acts as the U.S.-designated agent as defined in § 807.3(r).

5. Section 807.22 is amended by revising paragraph (a) to read as follows:

**§ 807.22** How and where to register establishments and list devices.

(a) The first registration of a device establishment shall be on Form FDA-

2891 (Initial Registration of Device Establishment). Forms are available upon request from the Office of Compliance, Center for Devices and Radiological Health (HFZ-307), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, or from Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FDD-2891a (Annual Registration of Device Establishment), which will be furnished by FDA to establishments whose registration for that year was validated under § 807.35(a). The forms will be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 807.21(a). The completed form shall be mailed to the address designated in this paragraph 30 days after receipt from FDA.

6. Section 807.40 is revised to read as follows:

**§ 807.40** Establishment registration and device listing for U.S. agents of foreign manufacturers of devices.

(a) Each foreign device manufacturer who exports devices into the United States shall designate a person as their U.S.-designated agent, who is responsible for:

- (1) Submitting MDR reports,
- (2) Submitting annual certifications,
- (3) Acting as the official

correspondent,

(4) Submitting registration information,

(5) Submitting device listing information, and

(6) Submitting premarket notifications.

(b) The foreign manufacturer shall provide FDA with a statement of authorization for their U.S.-designate to perform MDR reporting duties under part 803 of this chapter, and to register, list, and submit premarket notifications under this part. The foreign manufacturer must provide this statement of authorization along with the name, address, and telephone number of the person initially designated, or any subsequent person designated as the U.S.-designated agent, within 5 days of the initial or subsequent designation. Information shall be sent to the Center for Devices and Radiological Health, Medical Device Reporting, Food and Drug Administration, P.O. Box 3002, Rockville, MD 20847-3002.

(c) The U.S.-designated agent of a foreign device manufacturer that exports devices into the United States is required to register the foreign manufacturer's establishments or places

of business, and to list the foreign manufacturer's devices, in accordance with subpart B of this part, unless exempt under subpart D of this part, and to submit premarket notifications in accordance with subpart E of this part. The information submitted shall be in the English language.

Dated: October 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-29906 Filed 12-8-95; 8:45 am]

BILLING CODE 4160-01-P

**21 CFR Part 5**

**Delegations of Authority; Medical Device Reporting Procedures**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to redelegate to certain officials in the Center for Devices and Radiological Health (CDRH) authorities relating to medical device reporting procedures.

**EFFECTIVE DATE:** December 11, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Kerry G. Rothschild, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4765, or

Ellen R. Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

**SUPPLEMENTARY INFORMATION:** FDA is amending the delegations of authority under part 5 (21 CFR part 5) by adding new § 5.98 *Authority relating to medical device reporting procedures*. In conjunction with CDRH's issuance of a medical device reporting final rule under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), the Commissioner of Food and Drugs (the Commissioner) has decided to delegate to certain officials in CDRH the authority to approve electronic reporting under 21 CFR 803.14, to request the submission of additional information under 21 CFR 803.15, and to grant or revoke exemptions and variances from reporting requirements under 21 CFR 803.19. Delegation of these authorities to the directors and deputy directors of the Office of the Director and the Office of Surveillance and Biometrics, CDRH,

will increase the efficiency of the medical device reporting process.

The authority delegated may be redelegated further only with the Commissioner's approval. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

#### List of Subjects in 21 CFR part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

#### PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701-1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b, 264, 265, 300u-300u-5, 300aa-1, 300aa-25, 300aa-27, 300aa-28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660 (42 U.S.C. 300aa-1 note).

2. New § 5.98 is added to subpart B to read as follows:

§ 5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance

and Biometrics, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

Dated: September 1, 1995.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 95-29905 Filed 12-8-95; 8:45 am]

BILLING CODE 4160-01-F

# G•M•D•N Project

Global Medical Device Nomenclature

## Training Exercise Aims & Objectives

- an understanding of what the GMDN nomenclature will be & how it is to be created
- background to the GMDN project
- training in the Project's software
- opportunity for the Team to start on the work



## What is a Nomenclature?

### Definition:

For the purpose of this project, the ISO 1087 definition has been adopted:

System of terms which is elaborated according to pre-established naming rules.

August, 98

Nomenclature

2

### Other definitions:

#### b) The Concise Oxford dictionary:

A persons or community's system of names for things. The terminology of a science etc. Systematic naming. A catalogue or register.

#### c) Defined by ISO/TC 210/WG3 (document N2):

A system of terms used in a particular field. A system of terms in the relevant medical device field relates to the following:

- product identification and use
- labeling and instructions
- post-market surveillance
- user guides and device comparisons
- review classification and regulatory authority
- maintenance and ordering

## **Generic Device Group,**

The definition of the GMDN nomenclature:

A term for a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics such as brand names, trade names, etc.

A generic device group comprises a set of devices identified by their device type and are grouped together for the purpose of reporting or data retrieval.

August, 98

Nomenclature

5

However, nomenclatures do have their uses. They provide a method of classification which help us to group together objects which have similar features.

The nomenclature will be part of a system (one level), which when fully implemented will provide the platform making it possible to reproduce and exchange device identification and associated data - without the fear of misunderstandings.

### **Uses:**

- product identification and use
- labelling and instructions
- post-market surveillance
- User guides and device comparison
- Maintenance/procedure recommendations
- Purchasing
- Stocks/inventory
- etc

Basically, it is used as a classification method to group similar items (in this case medical devices) together. Information entered into such a classification can be utilized by a whole number of users for many individual purposes.

## The GMDN approach:

### Code:

nonsensical (carries no information) - are unique.

### 3 level:

each level is flat and carries separate information.  
each level is linked.

### Terms are generic:

define a group of products, does not define every device type on the market.

### All terms have a definition:

this makes them understandable to the user.

### Synonyms:

assists the user to locate the term required.

# INTRODUCTION TO THE PROJECT & PLAN

Robert Allen, MDA

**GMDN Purpose**

*Information exchange within Europe*

- Medical Device Directive
  - Article 8 - Safeguard clause
  - Article 10 - Vigilance
  - Article 14 - Class I manufacturers
  - Article 18 - wrongly affixed CE marks
- Active Implantable Medical Device Directive
  - Article 7 - Safeguard clause
  - Article 8 - Vigilance
  - Article 13 - wrongly affixed CE marks

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**GMDN Project Why?**

*Trade agreements requiring information exchange ( MRAs )*



Europe - Australia/New Zealand  
 Europe- Canada  
 Europe - USA  
 .....others to follow

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**Project objectives**

- To create a nomenclature
  - applicable to all medical devices
  - consistent & standardised ( CEN / ISO 15225 )
  - for international use
  - ready as soon as possible
  - credible and acceptable to all potential users
  - suitable for translation into other languages

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## LOTUS NOTES

### GMDN IT Characteristics 1

- DETGs dispersed around the world
- Working on a common set of information
- Information is mostly text, not numbers
- Nature of the work is to reach a consensus
- Discussion within DETGs and between DETGs and EAT

### GMDN IT Characteristics 2

- Changes need to be traceable
- Several sages of approval - "workflow"
- Work to be visible to all
- Restrict update access
- Don't want permanent network connections

### Lotus Notes

- A database system for handling text
- It allows users to work off-line
- Users have their own copies of data
- Replication
- Local response times
- Communication is handled automatically
- High level of skills not required
- Security is built-in

## LOTUS NOTES

### What does the IT system provide?

- Electronic mail
- Application custom-build or GMDN
  - Store candidate list
  - Select/reject/modify terms
  - Approval cycle
  - Discussion facilities built in to application
- Additional discussion databases
- Dial-up access through country node on Infonet network
- UIT run the server
- UIT provide Help Desk

### Agenda for rest of day

- Demonstration of Lotus Notes
- Lotus Notes hands-on exercises
- Demonstration of GMDN application
- Hands-on GMDN application
  
- Plus lunch and refreshment breaks

### Style for rest of day...

- Work in pairs
- Interactive
- Have fun!

## DEVICE EXPERT TASK GROUP

### Device Expert Task Groups

EN ISO 15225 → 12 device categories

∴ 12 DETGs

- 01: Active implantable devices
- 02: Anaesthetic/respiratory devices
- 03: Dental devices
- 04: Electro-medical/mechanical devices
- 05: Hospital hardware
- 06: In vitro diagnostic devices

## DEVICE EXPERT TASK GROUP

### DETG's task

#### Stage 2

Review definitions

- default to ECRI UMDNS
- select other
- modify
- recommend new definition
- Rationale

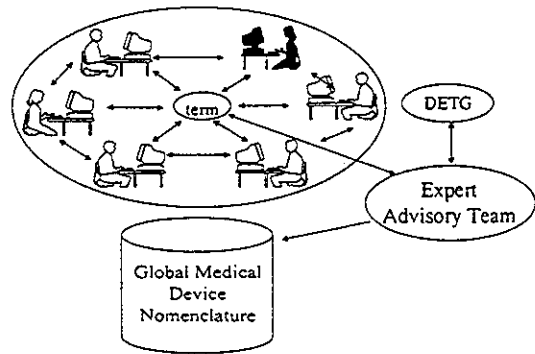
#### Stage 3

- Send recommendations to EAT

### Device Expert Task Groups

- 07: Non-active implantable devices
- 08: Ophthalmic and optical devices
- 09: reusable instruments
- 10: Single use devices
- 11: Technical aids for disabled persons
- 12: Diagnostic and therapeutic radiation devices

### DETG activity & interface with EAT



### DETG's task

#### Stage 1

Review terms in candidate list

- equivalence
- default to ECRI UMDNS
  - accept
  - modify
- other source term
  - accept
  - modify
- recommend new term

### Device Expert Task Group

Terms of reference

Membership

Role

Task

Activity

Interface to EAT