medical devices

Medical Device Reporting for User Facilities

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Medical Device Reporting for User Facilities

Prepared by
Office of Health and Industry Programs
Nancy Lowe, M.A. Consumer Safety Officer
Walter L. Scott, Ph.D. (CAPT. USPHS)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Services
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

FOREWORD

The Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), develops and implements national programs and regulations to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical and radiation-emitting devices.

The Center publishes the results of its work in scientific journals and in its own technical reports. Through these reports, CDRH also provides assistance to industry and to the medical and health professional communities in complying with the laws and regulations mandated by Congress. The reports are sold by the Government Printing Office (GPO) and by the National Technical Information Service (NTIS). Many reports are also available on the Internet/World Wide Web.

We welcome your comments and requests for further information.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

PREFACE

The Safe Medical Devices Act of 1990 (SMDA) imposed significant new reporting requirements on the medical device industry and users of medical devices. SMDA requires user facilities to report device-related deaths and serious injuries to the Food and Drug Administration (FDA) and/or the manufacturer. Although the user facility reporting requirements of SMDA were automatically effective November 28, 1991, this guidance document is based on the final Medical Device Reporting (MDR) rule which was published in the December 11, 1995, *Federal Register*. The final rule also addresses changes mandated by the Medical Device Amendments of 1992.

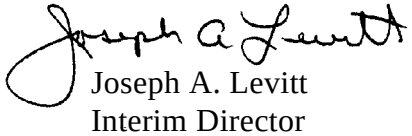
Much of the information in this document is general in nature and may not apply to a specific situation. Questions should be sent by facsimile (FAX) to (301) 827-0039 or mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Surveillance Systems (HFZ-530)
Medical Device Reporting (MDR) Inquiries
1350 Piccard Drive
Rockville, MD 20850

Please include your name, return address, phone number, and (if applicable) FAX number with your questions.

This guidance for user facilities is one of three documents written for a particular audience: user facilities, manufacturers, and distributors. All are available through the Internet/World Wide Web at: **http://www.fda.gov** and after June 1996, from the National Technical Information Service, Springfield, Virginia 22161, telephone no. (703) 487-4650. Other MDR documents are:

- Medical Device User Facility and Manufacturer Reporting, Certification and Registration . . . Final Rules. December 11, 1995, *Federal Register*, pp. 63578-63607.
- Mandatory MedWatch FDA Form 3500A
- Instructions for Completing Form 3500A with Coding Manual for Form 3500A
- Abbreviated Instructions for FDA Form 3500A Specific to MDR
- MDR Semiannual Report Form FDA 3419
- MDR Baseline Report Form FDA 3417
- MDR Annual Certification Form FDA 3381
- Medical Device Reporting: An Overview
- Medical Device Reporting for Distributors
- Medical Device Reporting for Manufacturers (draft)
- *User Facility Reporting Bulletin* - all issues



Joseph A. Levitt
Interim Director
Office of Health and Industry Programs

This guidance does not create or confer any rights, privileges or benefits for or on any person, nor does it operate to bind FDA or any other person. The agency will consider individual circumstances on a case-by-case basis. Where this document reiterates a requirement imposed by statute or regulation, the force and effect as law of the requirement is not changed in any way by virtue of its inclusion in this document.

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1. INTRODUCTION

In 1990, Congress enacted the Safe Medical Devices Act (SMDA) to increase the information that the Food and Drug Administration (FDA) and manufacturers receive about serious problems with medical devices. Although manufacturers and importers of medical devices have been required since 1984 to report to FDA all device-related deaths, serious injuries, and certain malfunctions, numerous reports show widespread under reporting. A 1986 General Accounting Office (GAO) study showed that hospitals reported less than one percent of problems with medical devices and, the more serious the problem with a medical device, the less likely it was to be reported. A GAO follow-up study in 1989 concluded that despite full implementation of the Medical Device Reporting (MDR) regulation, serious under reporting still existed.

Under SMDA, 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. A device user facility is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility **which is not a physician's office**. A medical device is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition and is **not** a drug or biologic. (See sections 5 and 6 for definitions of terms and concepts.) The user facility reporting section of SMDA became effective on November 28, 1991.

To implement SMDA, FDA published a tentative final rule in the November 26, 1991, *Federal Register* and invited comments on the regulation. Over 300 comments were received. Then, on June 16, 1992, the President signed into law the Medical Device Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the Food, Drug, and Cosmetic Act) relating to reporting of adverse events. The primary impact of the 1992 Amend-ments on user facility reporting was to establish a single reporting standard for user facilities, manufacturers, and importers. The final medical device reporting rule published in the December 11, 1995, *Federal Register* addresses the comments received by FDA and the changes mandated by the Amendments of 1992. For easy reference, sections of the MDR regulation are enclosed in brackets following terms and concepts.

The following tables summarize the MDR requirements for user facilities and manufacturers.

Table 1 - Summary of MDR Reporting Requirements

REPORTER	REPORT WHAT?	TO WHOM?	WHEN?
User Facility	Deaths	FDA and Manufacturer	Within 10 work days
	Serious injuries*	Manufacturer FDA only if manufacturer unknown	Within 10 work days
	Semiannual report of deaths and serious injuries	FDA	January 1 and July 1
Manufacturer	30-day reports of deaths, serious injuries* and malfunctions	FDA	30 days from becoming aware
	Baseline report to identify and provide basic data on each device that is subject of a report	FDA	With 30-day report when device is reported for first time
	5-day report on events that require immediate remedial action and other types of events designated by FDA	FDA	Within 5 work days
	Annual certification of compliance with regulation	FDA	When firm submits annual registration

* Serious injury definition no longer necessitates “immediate” intervention, just medical or surgical intervention.

Table 2 - Summary of Other MDR Requirements

REQUIREMENT	APPLIES TO	SUMMARY
Files	User facilities and manufacturers	Records of complaints and MDR reports must be kept for a period of two years or, for manufacturers, the expected life of the device, if longer.
Written MDR Procedures	User facilities and manufacturers	Written procedures must be developed, maintained and implemented for (1) identification, evaluation, and timely submission of MDR reports, and (2) compliance with record keeping requirements.
Exemptions, Variances and Alternative Reporting	User facilities and manufacturers	Investigational devices are exempt. Exemptions, variances or alternatives to any or all of the reporting requirements may be granted upon request or at the discretion of FDA.
Designation of U.S. Agent	Foreign manufacturers	Foreign manufacturers must designate an agent in the U.S. who will register and submit MDR reports, conduct or obtain information about investigations, forward reports to the manufacturer and maintain complaint files on behalf of the manufacturer.

2. USER FACILITY REPORTING REQUIREMENTS

User facilities must report deaths and serious injuries when they become aware of information that reasonably suggests a medical device has or may have caused or contributed to the adverse event. They must also establish and maintain adverse event files.

2.1 Type of reports

User facilities are required to file two types of reports:

- **Individual adverse event reports** [§803.30]

Individual adverse event reports include reports of death and serious injury which are submitted on FDA Form 3500A or an electronic equivalent.

A user facility must report to the device manufacturer **and** FDA whenever the facility has information that reasonably suggests a device has or may have caused or contributed to a patient's ***death***. If a facility has information that reasonably suggests a device has or may have caused or contributed to a patient's **serious injury**, it must report this information to the device manufacturer. If the manufacturer is not known, the report should be sent to FDA.

- **Semiannual reports** [§803.33]

If any individual adverse event report was submitted during the previous 6-month reporting period, a user facility must submit a semiannual report to FDA on FDA Form 3419, or an approved electronic equivalent. Semiannual reports are due by January 1 (for reports made July through December) and by July 1 (for reports made January through June) of each year.

A semiannual report should not be submitted if no individual reports were submitted to FDA or manufacturers during the reporting period.

2.2 Individual adverse event report data elements [§803.32]

User facility reports (using FDA Form 3500A) must contain the following:

- patient information (block A);
- description of adverse event or product problem (block B);
- suspect medical device information (Block D);
- initial reporter information (Block E); and
- user facility information (Block F)

2.3 Semiannual report data elements [§803.33]

A semiannual report must contain the following information:

- user facility's Health Care Facility Administration (HCFA) provider number or number assigned by FDA;
- reporting year and period, e.g., January through June or July through December;
- facility's name and complete address;
- total number of reports attached or summarized;
- date of the semiannual report and the lowest and highest report numbers submitted during the report period; e.g., 1234567890-1995-0001 through 1000;

- name, position title, and complete address of the individual designated as the facility contact person responsible for reporting to FDA, and whether or not that person is a new contact for that facility; and

- information for each reportable event that occurred during the semiannual reporting period including:

  - user facility report number;

  - name and address of the device manufacturer;

  - device brand name and common name;

  - product model, catalog, serial, and lot number;

  - a brief description of the event reported to the manufacturer and/or FDA; and

  - where the report was submitted, i.e., to FDA, manufacturer, distributor, etc.

In lieu of submitting a summary of each reported event, a user facility may complete only Part 1 of FDA Form 3419 and attach a copy of each mandatory report (FDA Form 3500A, or an approved electronic equivalent) filed during the reporting period. The copies and envelope should be clearly identified as "Semiannual Report."

2.4 When to report [§803.20]

All individual reports of death and serious injury must be submitted within **10 work days** from the time that any medical personnel of the facility becomes aware of a reportable event.

Semiannual reports are due on January 1 and July 1.

2.5 "Information that reasonably suggests" [§803.20(c)]

Information that reasonably suggests that a medical device has caused or contributed to a MDR reportable event (i.e., a death or serious injury) includes any information such as professional, scientific, or medical facts and observations or opinions that a device has caused or may have caused or contributed to a reportable event.

2.6 "Information that is reasonably known" to user facilities [§803.30].

User facilities must provide all information that is reasonably known to them. This includes information found in documents in the possession of the user facility and any information that becomes available as a result of reasonable follow-up 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.

2.7 Requests for additional information [§803.15]

FDA may determine that protection of the public health requires additional or clarifying information for an MDR report. In these instances and when additional information is beyond the scope of FDA reporting forms, or is not readily accessible, the agency will notify the user facility of the additional information that is required. Any request will 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 FDA.

2.8 When not to file [§803.22]

If a user facility becomes aware of information from multiple sources regarding the same patient and same event, only one MDR report is required. An MDR report is not required if the user facility determines that the information received is erroneous, because a device-related adverse event did not occur. Documentation of such reports must also be retained in the facility's MDR files for two (2) years.

2.9 Exemptions, variances, and alternative reporting. [§803.19]

Upon written application or at its own discretion, FDA may grant a user facility an exemption, a variance, or an alternative form of reporting and may change the frequency of reporting. When FDA grants an exemption, variance, or alternative form of reporting, it may impose other reporting requirements to ensure the protection of public health. It may also revoke or modify any exemption, variance, or alterative form of reporting, if necessary.

2.10 English reporting requirements [§803.13]

All required MDR reports must be in English.

2.11 Reporting codes [§803.21]

FDA has developed a coding manual for completing FDA Form 3500A. The manual contains hundreds of codes for adverse events and will be updated as needed. The manual is available from various sources (see 2.13 for specifics).

2.12 Electronic reporting [§803.14]

Any MDR report may be submitted electronically with **prior written consent** from the FDA. Such consent is revocable. Electronic report submissions include alternative reporting media (magnetic tape, disc, FAX, etc.) and computer-to-computer communi-cation. Any electronic report meeting electronic reporting standards, guidelines, or other procedures developed by FDA for MDR, will be deemed to have prior approval for use.

2.13 Where to get forms and coding manual [§803.11]

FDA forms 3500A and 3419, instructions, and the coding manual necessary to complete 3500A are available through the Internet at:

http://www.fda.gov

After June 1996, the above documents and other MDR guidance will be available from:

National Technical Information Service
Springfield, VA 22161
Telephone number (703) 487-4650.

See Preface for a complete listing of documents.

2.14 Where to submit reports. [§803.12]

All individual adverse event reports, semiannual reports, and any additional information should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Each report **and** its envelope should be specifically identified, e.g., Semiannual Report or User Facility Report.

If a user facility believes that there is a public health emergency, it should contact:

FDA Emergency Operations Branch,
Office of Regional Operations,
HFC-162
Telephone number (301)443-1240

The telephone report should be followed by a FAX report to 301-443-3757.

3. WRITTEN PROCEDURES, RECORD KEEPING, AND PUBLIC DISCLOSURE

User facilities must develop, implement, and maintain written procedures for reporting adverse medical device events. In addition to reporting device-related deaths and serious injuries, user facilities must establish and maintain MDR files.

3.1 **Written procedures** [§803.17]

Written procedures include internal systems that provide:

- for timely and effective identification, communication, and evaluation of adverse events;
- a standardized review process and procedure for determining whether or not an event is reportable; and
- procedures to assure the timely transmission of complete reports.

User facilities must also establish, implement, and maintain written procedures to assure compliance with documentation and record-keeping requirements. This includes:

- information that was evaluated to determine if an event was reportable;
- all MDR reports and information submitted to FDA and manufacturers;
- any information that was evaluated for the purpose of preparing the submission of semiannual reports; and
- systems that ensure access to information that facilitates timely followup and inspection by FDA.

3.2 **Files** [§803.18]

User facilities must establish and maintain MDR event files. MDR event files are written or electronic files maintained by the user facility. They must be prominently identified as such and filed to facilitate timely access. MDR files must contain:

- information in the possession of the user facility or references to information related to the event. This includes all documentation of the reporting decisions and decision-making process; and
- copies of all completed MDR forms and other information submitted to FDA, distributors, and manufacturers.

Records related to an adverse event, whether reported or not, must be kept for two (2) years from the date of the event. A user facility must permit FDA employees to have access, at all reasonable times, to all required records for copying and verification.

3.3 **Public availability of reports** [§803.9]

Certain information from MDR reports, including any FDA record of a telephone report, is available for public disclosure. Before public disclosure of a report, FDA will delete from the report:

- any information that constitutes trade secret or confidential commercial or financial information;

- any personal, medical, and similar information (including the serial number of implanted devices) which would constitute an unwarranted invasion of personal privacy; and

- any names and other identifying information of a third party voluntarily submitting an MDR report. This includes physicians, healthcare professionals, or other hospital employees, unless they are designated the MDR contact person.

FDA will disclose to a patient requesting a report all information in the report concern-ing that patient.

FDA will not disclose the identity of a user facility which makes a report except in connection with:

- an action brought to enforce the medical device reporting require-ments, including the failure or refusal to furnish material or information;

- a communication to a manufacturer of a device which is the subject of a report required by a user facility;

- a disclosure relating to an MDR report required by a manufacturer or distributor; or

- a disclosure to employees of the Department of Health and Human Services and to the Department of Justice or to duly authorized committees and subcommittees of the U.S. Congress.

3.4 **Disclaimers** [§803.16]

Submission of a report or information under MDR, as well as any release by FDA of that report or information, does not necessarily reflect that FDA or the submitter admit or conclude that the device, the user facility, or its employees caused or contributed to the reportable event.

MedWatch Form 3500A contains a disclaimer statement at the bottom of the front page.

4. ENFORCEMENT

FDA has criminal and civil penalty authority to enforce the MDR requirements.

4.1 Authority to enforce MDR

- **Criminal penalty authority:** Failure to comply with the MDR requirements is a prohibited act under the Food, Drug and Cosmetic Act (FD&C Act). Commission of a prohibited act may subject user facilities to injunction proceedings under Section 302 and criminal penalties under Section 303 of the FD&C Act.

Criminal penalties may be up to a $1,000 fine and one year imprisonment for the first offense if the offense was unintentional, and up to $10,000 and three years imprisonment for subsequent offenses, or for intentional offense.

- **Civil penalty authority**: Failure to comply with MDR reporting requirements may result in civil penalties if the failure is a significant or knowing departure from the requirements, or a risk to public health. Civil penalties are fines imposed administratively by FDA for noncompliance with the provisions of SMDA. A person who receives a civil penalty is entitled to a hearing before an Admini-strative Law Judge (ALJ). The ALJ's decision may be appealed to the Commissioner of FDA, and the Commissioner's decision may be appealed to a U.S. Court of Appeals. Penalties may not exceed $15,000 per violation or $1,000,000 for all violations adjudicated in a single proceeding.

5. DEFINITIONS

The MDR regulation contains some general terms that apply to user facilities, importers, and manufacturers, as well as terms specific to user facility reporting. For easy reference, sections of the MDR regulation are included in brackets following the term. The following definitions generally apply to user facilities, but the reader should refer to the MDR rule for complete definitions.

5.1 Ambulatory Surgical Facility [§803.3(b)]

"Ambulatory Surgical Facility" (ASF) means a distinct entity that operates for the primary purpose of furnishing same day out-patient 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 the MDR regulation regardless of whether or not it is licensed by a Federal, State, municipal, or local government, or accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report the event regardless of the nature or location of the medical service provided by the ASF.

5.2 "Becomes Aware" [§803.3(c)]

A user facility "becomes aware" of an MDR reportable event when medical personnel, who are employed by or formally affiliated with the facility, acquire information that reasonably suggests that a reportable event has occurred. "Medical personnel" is defined in 5.9.

5.3 "Caused or Contributed to" [§803.3(d)]

A device may have "caused or contributed to" a patient's death or serious injury, if the death or serious injury was or may have been attributed to the device or the device may have been a factor in the death or serious injury because of:

- device failure;
- malfunction;
- improper or inadequate device design;
- manufacture;
- labeling; or
- user error

5.4 Device user facility [§803.3(f)]

"Device user facility" or "user facility" means a hospital (see definition 5.5), ambulatory surgical facility (see 5.1), nursing home (see 5.10), outpatient diagnostic facility (see 5.11), or outpatient treatment facility (see 5.12) which is not a "physician's office" (see 5.14) as defined under [§803.3 (w)]. School nurse offices and employee health units are not user facilities.

5.5 Hospital [§803.3(i)]

"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. Hospital includes general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (i.e., 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 the MDR regulation regardless of whether or not it is licensed by a Federal, State, municipal, or local government or 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.

5.6 Malfunction [§803.3(m)]

A malfunction is failure of a device to meet its performance specifications or to 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. (See 6.14 for user facilities.)

5.7 MDR [§803.3(p)]

"MDR" means a medical device report.

5.8 MDR Reportable Event [§803.3(q)]

An "MDR reportable event" is an event about which a user facility becomes aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

5.9 Medical Personnel [§803.3(r)]

"Medical personnel" means an individual who:

- is licensed, registered, or certified by a State, territory, or other governing body to administer health care;
- has received a diploma or a degree in a professional or scientific discipline;
- is an employee responsible for receiving medical complaints or adverse event reports; or
- is a supervisor of such persons.

5.10 Nursing Home [§803.3(s)]

"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:

- skilled nursing care and related services for persons who require medical or nursing care;
- hospice care to the terminally ill; or
- services for the rehabilitation of the injured, disabled, or sick.

A nursing home is subject to this regulation regardless of whether or not it is licensed by a Federal, State, municipal, or local government, or whether or not it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for report-ing, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

5.11 Outpatient Diagnostic Facility [§803.3(t)]

"Outpatient diagnostic facility" means a distinct entity that:

- operates for the primary purpose

ofconducting medical diagnostic tests on patients;

- does not assume ongoing responsibility for patient care; and
- 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.

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 the MDR regulation regardless of whether or not it is licensed by a Federal, State, municipal, or local government or is accredited by a recognized accreditation organization. If an adverse event meets the criteria for report-ing, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

5.12 Outpatient Treatment Facility [§803.3(u)]

"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 healthcare. Outpatient treatment facilities include ambulance providers, rescue services, and home healthcare 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.

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 the MDR regulation regardless of whether or not it is licensed by a Federal, State, municipal, or local government or whether or not 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.

5.13 Patient of the Facility [§803.3(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 purpose of the MDR regulation, the definition encompasses employees of the faculty 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.

5.14 Physician's Office [§803.3(w)]

"Physician's office" means a facility that operates as the office of a physician or other healthcare professionals (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.

5.15 Serious Injury [§803.3(aa)]

"Serious injury" means an injury or illness that is:

- life threatening;
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent damage or impairment.

5.16 Permanent [§803.3(aa)(2)]

Permanent damage or impairment is irreversible damage or impairment that is not trivial.

5.17 User Facility Reporting Number [803.3(dd)]

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

- the user facility's 10-digit Health Care Financing Administration (HCFA) number. If the HCFA number is less than 10 digits, fill the remaining spaces with zeros;
- the four-digit calendar year in which the report is submitted; and
- the four-digit sequence number of the reports submitted for the year, starting with 0001. For example, a complete number will appear as follows: 1234567890-1996-0001.

If a facility has more than one HFCA number, it must select one number that will be used for all of its MDR reports.

5.18 Work day [§803.3(ee)]

"Work day" means Monday through Friday, excluding Federal holidays.

6. FREQUENTLY ASKED QUESTIONS

The following are questions that FDA is frequently asked. They provide background information on MDR and attempt to explain some of FDA's policy decisions.

6.1 Why did Congress require medical device reporting for user facilities?

Congress enacted the Safe Medical Devices Act of 1990 (SMDA) based on its review of the 1976 Amendments to the Food, Drug, and Cosmetic (FD&C) Act. Congress believed that significant changes were needed in the statutes, so that FDA could better protect the public health.

As a result of Congressional hearings and studies conducted by the General Accounting Office, Congress concluded that FDA received less than adequate information about problems with medical devices. With better information, FDA can take appropriate actions to protect the public from hazardous medical devices.

6.2 How do the Medical Device Amendments of 1992 affect medical device reporting?

The Medical Device Amendments of 1992 modified the reporting of adverse device events as follows:

- **Adoption of a single reporting standard**

Section 5(a) of the 1992 Amendments revised the reporting requirements for user facilities to report whenever the facility receives or otherwise becomes aware of information that reasonably suggests that a device "has or may have caused or contributed" to the death, serious illness, or serious injury of a patient of the facility. This statutory language change adopts a single standard for manufacturers, importers, and user facilities to determine when injuries caused by devices must be reported to FDA.

- **Single definition of types of injuries that must be reported**

Section 5(a) of the 1992 Amendments adopted a single definition for the types of injuries that user facilities, manufacturers, importers, and distributors must report. The definition now requires reporting of an injury or illness that is:

- life-threatening; or
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

It deleted the SMDA requirement that an injury must require "immediate medical or surgical intervention" to preclude permanent impairment or damage in order to qualify as a reportable adverse event.

- **New authority to require reporting of "other significant adverse device experiences"**

The 1992 Amendments also authorized FDA to issue regulations requiring the reporting of "significant adverse device experiences" other than deaths, serious injuries, or serious illnesses that the agency determines are necessary to be reported. This

provision will be implemented in a future regulation.

6.3 What is the relationship between medical device reporting and user facility reporting?

User facility reporting is a component or subset of FDA's Medical Device Reporting (MDR) program. Since 1984, manufacturers and importers have been required to report device-related deaths, serious injuries, and certain malfunctions. SMDA amended the medical device provisions of the Food, Drug, and Cosmetic Act by requiring user facilities to notify manufacturers and/or FDA of reportable events.

6.4 What is MedWatch and how does it relate to MDR and user facility reporting?

MedWatch is FDA's postmarket surveillance program for reporting adverse events associated with all medical products (drugs, medical devices, biologics, and special nutritional products) regulated by FDA. Medical Device Reporting (MDR) is part of MedWatch, and user facility reporting is a subset of MDR.

6.5 What is the effective date of the final MDR reporting requirements?

The user facility reporting section of SMDA has been in effect since November 28, 1991, even though a final regulation for MDR had not been published. Although the original effective date for the final MDR rule was
April 11, 1996, FDA has extended the date to July 31, 1996. This will provide additional time for user facilities and manufacturers to prepare for the new requirements.

6.6 Our facility has more than one HCFA number. Which one should we use?

If a facility has more than one HCFA number, it must select one to use for all MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000-1995-0-001), 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 the 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. A primary site must provide FDA the name, address, and HCFA number for each respective site with its first report.

6.7 What is a device?

The Food, Drug, and Cosmetic Act defines the term "device" as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is:

- recognized in the official *National Formulary*, or the *United States Pharmacopeia*, or any supplement to them;
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or
- intended to affect the structure or any function of the body of man or other animals, and which is not a drug, i.e., the product does not achieve its primary intended

purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

Examples of medical devices (for which FDA has received MDR reports) are hospital beds, heart valves, ventilators, patient restraints, x-ray machines, defibrillators, and bandages. Generally, if it is used in medical practice and it is not a drug or biologic, it is a device.

6.8 Are ambulances and rescue services required to report device-related adverse events?

Yes. Ambulances and rescue services fall within the definition of user facility, because they are outpatient treatment facilities. Be-cause of the critical risks posed by potential malfunctions of devices used by such services, FDA has included them in the definition of a user facility.

6.9 Why are home healthcare agencies required to report under MDR?

FDA included home healthcare agencies in the definition of a user facility because of the critical risks posed by potential malfunctions of devices used in home healthcare.

Home healthcare agencies (as well as their device distributors) are likely to be the first to learn of problems with critical home healthcare devices such as apnea monitors, ventilators, infusion pumps, etc.

6.10 Are foreign user facilities required to report under MDR?

No. Only those user facilities located outside the United States that are operated by the U.S. Government are required to report under MDR.

6.11 Does an HMO have to report?

User facilities (see 5.4 for definition) that are part of an HMO or which belong to an HMO must report.

6.12 Does a user facility need to designate a contact person? [§803.32(e)(4)]

Yes. A facility must designate a contact person with whom FDA can conduct its correspondence relating to MDR. A third party may act as a contact person and submit reports for a user facility.

6.13 Are user facilities required to investigate adverse events?

In the final MDR rule, FDA has clarified that a user facility must report only information that is "reasonably known" to it and is not required to investigate adverse events by obtaining or evaluating information that is not reasonably known.

Reasonably known information includes information found in documents in the posses-sion of the user facility and any information that becomes available as a result of reasonable followup within the facility. Of course, the user facility must still make an initial determination as to whether or not an event should be reported under MDR.

6.14 If a device malfunctions but does not cause a death or serious injury, should a report be filed?

User facilities are encouraged, but are not required, to report malfunctions that do not result in a death or serious injury. Although these reports are voluntary, FDA recommends that Form 3500A be used to report to the manufacturer, since this form provides for more detail about the event and the device. Such reports provide important information to the manufacturer and FDA concerning device safety.

6.15 What does "permanent damage" or "permanent impairment" mean in the definition for "serious injury?"

"Permanent" means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage. While some cosmetic damage may be considered trivial, not all cosmetic damage would be considered trivial.

6.16 Is "temporary damage" from use of a device reportable under MDR?

Yes, if the "temporary damage" was "life-threatening." Life-threatening events that may have been caused by or contributed to a device must be reported, regardless of whether or not the damage was "temporary." However, temporary damage that is not life threatening is not reportable.

6.17 Is an "incident file" the same as an "MDR event file?"

Because of comments received to the proposed definition of "incident files," FDA has changed the definition and renamed it "MDR event files." MDR event files include MDR reports filed (with FDA or other entities) and any documents related to the adverse event. This includes documents relating to deliberations and decision-making processes used to determine if an event is an MDR reportable event (even if the facility decides not to submit an MDR.)

The final MDR regulation also allows the user facility to incorporate certain information by reference (such as medical records, patient files, and engineering reports) rather than include them in the MDR event file.

6.18 Can a patient's identity be protected?

Yes. A patient's identity will be protected, because FDA does not release any patient identifiers to the public. A reporter may submit an identifier in lieu of a patient's name. If FDA requires further patient information, the request will be on an exception basis.

6.19 Can MDR reports submitted to FDA be used as evidence in a civil action?

SMDA states that reports are not admissible into evidence or otherwise used in any civil action involving private parties, unless the facility, individual, or physician who made the report knew that the information in the report was false.

6.20 Is the identity of a reporter of an MDR event, such as a physician at the hospital, releasable under the Freedom of Information Act?

No. FDA will not disclose the identity of physicians or other employees of the user facility, although the identity of the user facility and MDR contact may be disclosed under certain circumstances described in 3.3. However, the user facility's MDR contact person in Block F of MedWatch Form 3500A is releasable.

6.21 Is "user/operator error" reportable under MDR?

Yes. The language of SMDA, as amended by the Medical Device Amendments of 1992, requires reporting of **all** instances that reasonably suggest a device has or may have caused or contributed to a device-related death, serious injury, or serious illness. FDA needs to be aware of events that

are related to user error any time such an error has or may have caused or contributed to a reportable event. By receiving information about user problems, FDA can determine whether or not additional measures are necessary to resolve the problem, e.g., relabeling or redesign of the device.

6.22 Must a user facility allow the manufacturer of a device (involved in a patient's death or serious injury) access to it?

FDA has no legal authority to require that a device be returned to the manufacturer or that a manufacturer have access to the device. However, FDA believes that the manufacturer of a device should evaluate any problems with its device. FDA encourages users to permit
access to or return of the device to the manufacturer for evaluation.

6.23 Does MDR really help prevent device problems?

Yes. For example, a review of MDR reports concerning patient restraints revealed 34 deaths and 11 injuries. FDA's review also found that many incidents were the result of improper use of the device or inadequate monitoring of the restrained patient. In response to these findings, FDA issued a safety alerts to warn the public about dangers associated with the use of patient restraints. In addition, FDA designated restraints as prescrip-tion devices and issued a letter to manufacturers to revise their labeling to prevent such improper use. Without the MDR reports, FDA would not have known that these actions were needed to protect the public health.

In 1995, FDA received over 100,000 MDR reports, many of which were submitted by user facilities.

Appendix A

Form Approved: OMB No. 0910-0291 Expires: 1/31/96
See OMB statement on reverse

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

Mfr report #

UF/Dist report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient identifier
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex
☐ female
☐ male

4. Weight
_____ lbs
or
_____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: _____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # – for product problems only (if known)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: _____

5. Expiration date (mo/day/yr)

6.
model # _____
catalog # _____
serial # _____
lot # _____
other # _____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name & address

phone #

2. Health professional?
☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA
☐ yes ☐ no ☐ unk

FDA

FDA Form 3500A (5/93)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

Page ___ of ___

FDA Use Only

F. For use by user facility/distributor–devices only

1. Check one ☐ user facility ☐ distributor
2. UF/DIst report number
3. User facility or distributor name/address
4. Contact person
5. Phone Number
6. Date user facility or distributor became aware of event (mo/day/yr)
7. Type of report ☐ initial ☐ follow-up # ___
8. Date of this report (mo/day/yr)
9. Approximate age of device
10. Event problem codes (refer to coding manual) patient code ___ - ___ - ___ device code ___ - ___ - ___
11. Report sent to FDA? ☐ yes ___ (mo/day/yr) ☐ no
12. Location where event occurred ☐ hospital ☐ home ☐ nursing home ☐ outpatient treatment facility ☐ outpatient diagnostic facility ☐ ambulatory surgical facility ☐ other: ___ specify
13. Report sent to manufacturer? ☐ yes ___ (mo/day/yr) ☐ no
14. Manufacturer name/address

G. All manufacturers

1. Contact office – name/address (& mfring site for devices)
2. Phone number
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ___
4. Date received by manufacturer (mo/day/yr)
5. (A) NDA # ___ IND # ___ PLA # ___ pre-1938 ☐ yes OTC product ☐ yes
6. If IND, protocol #
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up # ___
8. Adverse event term(s)
9. Mfr. report number

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ___
2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ___
4. Device manufacture date (mo/yr)
5. Labeled for single use? ☐ yes ☐ no
6. Evaluation codes (refer to coding manual) method ___ - ___ - ___ - ___ results ___ - ___ - ___ - ___ conclusions ___ - ___ - ___ - ___
7. If remedial action initiated, check type ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ___ ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/ adjustment
8. Usage of device ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

FDA Form 3500A - back

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CDRH Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002	**MEDICAL DEVICE REPORTING** **SEMIANNUAL USER FACILITY REPORT** **PART 1 - COVER SHEET**	OMB: 0910-0059 Exp. Date: 02/28/99

If MDR reports were not submitted to either the FDA or a device manufacturer during this reporting period, DO NOT submit a semiannual report.

PART 1 INSTRUCTIONS

Complete one copy of the following information as a cover page for the semiannual report and return to the address listed above. This report should NOT include reports that are not required but have been submitted voluntarily.

1. REPORT PERIOD	2. USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER)
☐ JAN - JUN ____ (Y Y Y Y) ☐ JUL - DEC ____ (Y Y Y Y)	

3. USER FACILITY INFORMATION	4. USER FACILITY CONTACT INFORMATION
a. Name	a. Name
b. Street Address	b. Street Address
c. City d. State e. ZIP Code	c. City d. State e. ZIP Code
f. Country/Postal Code *(if not U.S.)*	f. Country/Postal Code *(if not U.S.)* g. Telephone Number *(Include area code and extension)* ( )

5. TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED _____

a. Lowest Report Number _____ - ____ - ____
(HCFA or FDA Provided No.) (Year) (Sequence No.)

b. Highest Report Number _____ - ____ - ____
(HCFA or FDA Provided No.) (Year) (Sequence No.)

For each report in the range of report numbers listed above, attach a completed copy of Part 2 of this form, or a photocopy of the completed MedWatch FDA Form 3500A for the event that was sent to FDA and/or the manufacturer. In addition, attach a sheet listing report numbers in the above range that are not included in this report and explain why.

6. SIGNATURE OF CONTACT	7. DATE OF REPORT
	__/__/____ (M M / D D / Y Y Y Y)

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please **DO NOT** RETURN this form to this address.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3419 (3/96) *(Continue on Page 2, if necessary)* **PAGE 1** EF

MEDICAL DEVICE REPORTING
SEMIANNUAL USER FACILITY REPORT

PART 2 - SUMMARY OF EVENT

PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the six-month reporting period covered by this Semiannual Report.

1. USER FACILITY EVENT REPORT NUMBER

_____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

2. WHERE WAS REPORT SUBMITTED? *(Check all that apply)*

☐ FDA ☐ Manufacturer ☐ Distributor ☐ Other _____

3. MANUFACTURER INFORMATION

a. Name

b. Street Address

c. City d. State e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

4. DEVICE INFORMATION

a. Brand Name

b. Common Name

c. Model Number

d. Serial Number

e. Lot Number

f. Catalog Number

5. BRIEF DESCRIPTION OF EVENT

Appendix C

ABBREVIATED INSTRUCTIONS FOR FDA FORM 3500A SPECIFIC TO MEDICAL DEVICE REPORTING

GENERAL INSTRUCTIONS

1. Complete all sections and items that apply and type all entries.
2. Use the following codes when information is not available for any item: **NA** - not applicable; **NI** - no information yet but maybe later; **UNK** - unknown.
3. Enter dates in following format: **MM/DD/YY** (e.g., June 3, 1995 = 06/03/95. If exact date not known, provide best estimate. Use **YYYY** for year 2000 and beyond.
4. Enter the user facility report number or distributor report number and/or manufacturer report number in upper right corner of page 1. This has the format **NNNNNNNNNN-YYYY-XXXXX** where Ns represent the 10-character HCFA number of the user facility or the 7 digit registration or identification number of the manufacturer or distributor; **YYYY** is the year of the report and **XXXXX** is the 4 or 5 digit sequence number of the report for the reporting year (see 21 CFR 803 or guidelines).
5. Attach a continuation page(s) when entries exceed allowed space and indicate the report section and block number on each page.
6. Use the coding manual to complete blocks F10, H3, & H6. Ordering information for the Coding Manual, Document Number 799, is available by FAX at (800) 899-0381 or (301) 827-0111.
7. If more than one patient was involved in the same event, complete section A and blocks B2, B5, B6, B7, D10, and F10 for each patient. Enter the corresponding patient identifier in each block.
8. If more than one suspect medical device is involved, complete section D for each. Complete section F for one device and blocks F9, F10, F13 and F14 for each additional device. Pair each section D with its corresponding section F by marking each as follows: “Device 1", “Device 2", etc.

SPECIFIC INSTRUCTIONS

A. Patient information

A1 Use an identifier, do not use patient’s name or SSN.

A2 Give patient’s age or best estimate and indicate the time unit used (years, months, days).

B. Adverse event or product problem

B1 Check box 1 if adverse event and/or box 2 if product problem. Adverse event is used when reporting a death or serious injury. Product problem is used for a malfunction that could lead to a death or serious injury if it were to recur.

B2 Check appropriate event outcome. Check “disability” if the device may have caused or contributed to a permanent injury or impairment.

B5 Provide a complete description of event. Do not use the name of any person or institution. If space is inadequate, use continuation sheet(s) as necessary.

D. Suspect medical device

D The Suspect Medical Device is the device that may have caused or contributed to the MDR reportable event or the device that malfunctioned. It is important that the device be properly identified and that all applicable information in this block be completed.

F. For use by user facility/distributor-devices only

F2 Use the same report number as used on page 1 (see item 4 of General Instructions).

F7 If follow-up report, record the user facility or distributor initial report number in block F2 and the sequence number of this follow-up in the blank after “follow-up”, e.g., for first follow-up enter “1”, for second enter “2.” Do not repeat previously submitted information on a follow-up report.

F10 Enter up to 3 “patient” and 3 “device” codes that most accurately describe the event. Place only one code in each box. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems during the event.

G. All manufacturers

G1 Enter the full name and address of the manufacturer reporting site (contact office) including contact name. The name and address of the manufacturing site, if different, must also be included in this block.

G3 Check source of reported information. If “literature” is checked, attach a copy of the article (in English) and record the literature citation in block H10. Check the “study” box when reporting an RPS/DPS study or postapproval study.

G5-6 Not for medical device use.

G7 Check “5-day” if five-day report, “Initial” if first or initial submission, or “follow-up” if follow-up or supplemental submission. If follow-up report, do not repeat previously submitted information. Place manufacturer report number of initial report in block G9 and the follow-up sequence number on the blank line in block G7 after “follow-up”.

G8 Not for medical device use.

H. Device manufacturers only

H3 If device was evaluated, be sure to attach an evaluation summary.

H5 If the question is not relevant to the device (e.g., an x-ray machine), check “no”.

H6 Codes must be entered for conclusions even if the device was not evaluated.

H7 Check all that apply.

H10 Enter any additional information, evaluation, or clarification. Do not duplicate previous information.

H11 Provide the following additional, corrected or missing information, identifying each data item by the applicable block and item number:

(1) any information missing on the user facility or distributor report, including any missing or incomplete event codes required by block F10,

(2) information corrected on the user facility or distributor report form after verification, including any corrected event codes required by block F10

(3) for each event code provided by the user facility or distributor in block F10, a statement of whether the type of event represented by the code is addressed in the device labeling, e.g., code # 1738 - labeled, code # 1701 - not labeled, and

(4) an explanation of why any required information was

not provided and the steps taken to obtain such information.