

Medical Device Reporting for Manufacturers



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

Medical Device Reporting for Manufacturers

Prepared by
Division of Small Manufacturers Assistance
Office of Health and Industry Programs

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Center for Devices and Radiological Health
Rockville, Maryland 20850

FOREWORD

The Center for Devices and Radiological Health (CDRH) 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 insure the safety, effectiveness, and proper labeling of medical and radiation-emitting devices.

CDRH publishes the results of its work in scientific journals and in its own technical documents. Through these documents, 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, the National Technical Information Service, and private publishers. Many reports are also available on the 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. This guidance document is based on the final Medical Device Reporting (MDR) regulation published December 11, 1995, in the *Federal Register*. The final MDR regulation addresses changes mandated by the SMDA and 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 FAX to 301-827-0038 or mailed to the:

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 manufacturers 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/cdrh> and from the National Technical Information Service, Springfield, Virginia 22161, telephone number 703-487-4650.

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ABSTRACT

Benesch, B., Parr, R., and Stockdale, T., Project Officers. Department of Health and Human Services, Center for Devices and Radiological Health, Medical Device Reporting for Manufacturers.

This guidance document describes the new Medical Device Reporting requirements for manufacturers. It is intended for both domestic and foreign medical device manufacturers, and is based on the Medical Device Reporting (MDR) requirement published in the final rule dated December 11, 1995. The MDR regulation provides a mechanism for FDA to identify and monitor significant adverse events involving medical devices, so that problems may be detected and corrected in a timely manner.

The purpose of this document is to provide domestic and foreign manufacturers with:

- a thorough description of the current MDR regulation,
- a clear understanding of their reporting responsibilities,
- guidance to help in the completion of the MDR forms,
- an overview of required written MDR procedures, records and files, and
- information on sources for forms, instructions, and other MDR information.

Although this guidance does not create or confer any rights, for or on any person, and does not operate to bind FDA or the public, it does represent the agency's current thinking on the Medical Device Reporting regulation.

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

On July 31, 1996, the new Medical Device Reporting (MDR) regulation became effective for user facilities and device manufacturers. This document describes the current provisions for device manufacturers.

The MDR regulation provides a mechanism for the Food and Drug Administration (FDA) and manufacturers to identify and monitor significant adverse events involving medical devices. The goals are to detect and correct problems in a timely manner. Although the requirements of the regulation can be enforced through legal sanctions authorized by the Federal Food, Drug and Cosmetic (FD&C) Act, FDA relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation.

The statutory authority for the MDR regulation is section 519 of the FD&C Act as amended by the Safe Medical Devices Act (SMDA) of 1990. The SMDA requires user facilities to report:

- device-related deaths to the FDA and the device manufacturer;
- device-related serious injuries and serious illnesses to the manufacturer, or to FDA if the manufacturer is not known; and
- submit to FDA on a semiannual basis a summary of all reports submitted during that period.

The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. On September 1, 1993, FDA published a final MDR reporting regulation for distributors, including provisions for importers that became effective on October 1, 1993. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed.

The user facility reporting section of SMDA became effective on November 28, 1991. Device manufacturers should familiarize themselves with the user facility requirements and read the guidance document entitled, "Medical Device Reporting for User Facilities." (Refer to *Appendix A*).

Since 1984, domestic manufacturers have been subject to the MDR regulation if they were required to register their establishment with the FDA. The new MDR regulation eliminates this link with registration. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturers, are now subject to the requirements of the MDR regulation, despite registration status.

To carry out the reporting provisions of SMDA, FDA published a tentative final rule in the *Federal Register* (FR) on November 26, 1991, proposing to implement reporting regulations for users and distributors. In addition, the tentative final rule proposed to amend the existing 1984 MDR reporting regulation for manufacturers. On June 16, 1992, President Bush signed into law the Medical Device Amendments of 1992 (Public Law 102-300; the Amendments of 1992), amending certain provisions (section 519 of the FD&C Act) that relate to the reporting of adverse events. The primary impact of the 1992 Amendments on MDR reporting was to define certain terms and to establish a single reporting standard for user facilities, manufacturers and distributors.

The final MDR regulation for user facilities and manufacturers, published in the *Federal Register* on December 11, 1995, addresses the comments received by FDA on the November 29, 1991, tentative final regulation and the changes mandated by the Amendments of 1992.

Significant changes for manufacturers from the 1984 MDR regulation include:

- different time frames for reporting
 - use of standardized reporting forms
 - removal of unanticipated temporary impairments
 - new definitions
 - addition of an FDA disclaimer
 - removal of the “per se” rule
- requirement for foreign manufacturers to have a U.S. Designated Agent (USDA) for reporting MDR events to FDA. (STAYED 7/23/96)

CHANGES AFFECTING THE *FEDERAL REGISTER* FINAL RULE PUBLISHED ON DECEMBER 11, 1995

FDA began to receive comments regarding the regulation, following publication of the December 11, 1995, final rule on Medical Device Reporting for manufacturers and user facilities. FDA staff subsequently met with representatives of the Health Industry Manufacturers Association (HIMA), and other industry representatives to discuss their concerns about the new regulation. Following these discussions, FDA decided to place all or portions of three specific parts of the regulation into abeyance. This means that FDA has revoked/stayed, or delayed these parts from going into effect.

Therefore:

- 1) Foreign manufacturers are **not** required to have a USDA;
- 2) There is no requirement to submit distribution information dictated by sections 803.55(b)(9) and (10) of the baseline reporting requirement. This means that

manufacturers do not fill out data elements 15 and 16 only of the baseline report (Form FDA 3417);

- 3) A foreign manufacturer is fully subject to the medical devices reporting requirements. If a foreign manufacturer already has a USDA, they may forward medical device reports through this agent until further notice. However, if a foreign manufacturer chooses to employ a contact in the United States (U.S.) to forward reports to FDA, FDA views this person as if he or she is an employee of the foreign firm. FDA explains these decisions in the *Federal Register (FR)* notices summarized below; and
- 4) FDA encourages foreign firms to register with FDA by completing a Form FDA 2891, "Initial Registration of Device Establishment."

Below are summaries of each of the four notices.

FEDERAL REGISTER SUMMARIES

1st Notice, *Federal Register*, July 23, 1996: Stay of Effective Date; Revocation of Final Rule (Document available from the CDRH Facts on Demand, Document Number 1074; see *Appendix A*).

In this FR notice, the FDA changed the MDR requirements as follows:

- The effective date of the annual certification provision of the MDR regulation for manufacturers and distributors was stayed.
- Annual certification provisions for manufacturers were stayed to allow FDA to address industry concerns. FDA repropose this provision as described below.
- The existing requirement for distributors to annually certify was revoked (§804.30). It was also repropose, so that manufacturers and distributors would be treated the same regarding certification; and
- The U.S. designated agent requirements for foreign manufacturers were stayed (§803.58).

In addition, foreign manufacturers, as of July 31, 1996, have a responsibility to comply with all remaining medical device reporting requirements. The original medical device reporting regulation that became effective on December 14, 1984, defined a manufacturer required to submit MDR reports, as any person FDA required to register under Part 807. Since foreign manufacturers are not required to register, the December 1984 regulation was not applied to them. The new medical device reporting regulation, published December 11, 1995, no longer defines a manufacturer as a person whom FDA requires to register under Part 807. Under section 803.3(n), a manufacturer is defined as any person who manufactures, prepares, propagates,

compounds, assemblies, or processes a device by chemical, physical, biological, or other procedure(s). Accordingly, foreign manufacturers fit within the new definition of manufacturers that FDA requires to submit MDR reports.

Therefore, as of July 31, 1996, all manufacturers, including foreign manufacturers, are subject to all requirements of 21 CFR Part 803 (MDR Reporting) including, but not limited to:

- the requirements for written MDR procedures (§803.17),
- MDR event files (§803.18),
- individual adverse event reports (§803.50 and §803.52),
- five-day MDR reports (§803.53),
- MDR baseline reports (§803.55), and
- MDR supplemental reports (§803.56).

In addition, the regulations that are now in effect, and will remain in effect during the stay, permit foreign manufacturers to:

- register their companies using Form FDA 2891, “Medical Device Establishment Registration,” [§807.40(a)], and
- submit premarket notifications [510(k)s] (§807.81).

These regulations also require foreign manufacturers to list their devices on Form FDA 2892, medical “Device Listing,” [§807.40(b)]. (Refer to the “Reporting for Foreign Manufacturer” section for the correct version of §807.40.)

2nd Notice, *Federal Register*, July 23, 1996: Medical Device Reporting; Certification and U.S. Designated Agents (USDA); Proposed Rule. (Document available from the CDRH Facts on Demand, Document Number 1075; see *Appendix A*.)

In this FR notice, FDA repropoed the annual certification requirements for manufacturers and distributors. The proposed annual certification changes:

- eliminate the current certification statement;
- substitute a new certification statement that states that the certifying official has;
 - read the MDR regulation,
 - made certain that the manufacturer has established an MDR reporting system, and
 - determined that a certain number of reports, or no reports, have been submitted.

- provide flexibility by allowing firms to identify the certifying agent for annual certification, rather than requiring the certifying agent to be the Chief Executive Officer or the President of the company.

3rd Notice, *Federal Register*, July 31, 1996: Baseline Reports, Stay of Effective Date

(Document available from the CDRH Facts on Demand, Document Number 1096; see *Appendix A*.)

In this FR notice, FDA placed into abeyance, or stayed, the effective date of the provision of the MDR regulation that relates to part of the baseline reporting requirement [21 CFR 803.55(b)(9) and (10)]. Therefore, at this time, FDA will not require any manufacturer to submit denominator data requested in Part II, Items 15 and 16 only on Form FDA 3417, “Baseline Report.” Instead, FDA will initiate a demonstration project to evaluate denominator data. At the completion of this project, FDA will either lift the stay, retain it, or repropose these specific requirements.

4th Notice, *Federal Register*, March 20, 1997: Medical Device Reporting; Annual Certification; Final Rule (Document available from the CDRH Facts on Demand, Document Number 1090; see *Appendix A*).

In this FR notice, FDA amended its medical device manufacturer and distributor certification regulations to allow manufacturers to designate more than one certifying official, each of whom would sign a certification statement for his or her identified organizational component or site; and to amend the certification statement to minimize concerns relating to liability from unintentional reporting errors and indicate that the certifying official is making the certification statements, to the best of his/her knowledge and belief. This action was taken to help FDA carry out its public health protection responsibilities relating to medical devices. This action provides reporting entities with greater flexibility in the certification process while reducing the regulatory burden. This amendment is effective on May 19, 1997, and replaces the requirement that was stayed on July 23, 1996..

A summary of the reporting requirements for manufacturers is provided in Table 1. Reporting requirements for user facilities and distributors are summarized in Table 2.

TABLE 1 - Summary of Reporting Requirements for Manufacturers

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturer	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A	FDA	Within 30 calendar days from becoming aware of an event
Manufacturer	5-day reports on events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA	Form FDA 3500A	FDA	Within 5 work days from becoming aware of an event
Manufacturer	Baseline reports to identify and provide basic data on each device that is subject of an MDR report. At this time, FDA has stayed the requirement for denominator data requested in Part II, Items 15 and 16 on Form 3417.	Form FDA 3417	FDA	With 30 calendar, and 5 work day reports when device or device family is reported for the first time. Interim and annual updates are also required if any baseline information changes after initial submission.
Manufacturer	Annual Certification	Form FDA 3381	FDA	Coincide with firm's annual registration dates.

TABLE 2. - Summary of Reporting Requirements for User Facilities and Distributors

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days
User Facility	Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days
User Facility	Semiannual reports of death & serious injury	Form FDA 3419	FDA	January 1 & July 1
Distributor (includes importers)	Death & serious injury	Form FDA 3500A (optional)	FDA	Within 10 work days
Distributor (includes importers)	Death, serious injury & malfunction	Form FDA 3500A (optional)	Manufacturer	Within 10 work days
Distributor (includes importers)	Annual Certification	Form FDA 3381	FDA	Annually

2 MANUFACTURER REPORTING REQUIREMENTS

Manufacturers must report device-related deaths, serious injuries, and malfunctions to FDA whenever they become aware of information that reasonably suggests that a reportable event occurred (one of their devices has or may have caused or contributed to the event).

WHO MUST REPORT [§803.3(n)]

All manufacturers of finished medical devices commercially distributed in the U. S., including foreign manufacturers who export devices to the U.S., are required to comply with the MDR regulation.

A **manufacturer** [§803.3(n)] is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological or other procedures. The term includes any person who:

- 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;
- initiates specifications for devices manufactured by a second party for subsequent distribution by the person initiating the specifications; or
- manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
- is the US Designated Agent of a foreign manufacturer. STAYED 7/23/96

WHEN AND WHAT TO REPORT [§803.3(q)]

Manufacturers must report all **MDR reportable events** (see definition) to FDA on Form FDA 3500A. Each manufacturer shall review and evaluate all **complaints** (see definition) to determine whether the complaint represents an event which is required to be reported to FDA. A separate Form 3500A is required for each device involved in a reportable event. For example, if a manufacturer receives a report from a user facility which indicates that more than one of the manufacturer's devices may have been involved in a reportable event, a separate report for each device is required. A report is required when a manufacturer **becomes aware** (see definition) of information that reasonably suggests that one of their marketed devices has

or may have caused or contributed to a death, serious injury, or 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.

Serious injury/(Serious illness) [§803.3(aa)(1)] is an injury or illness that:

- is life threatening, even if temporary in nature;
- 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.

A **malfunction** [§803.3(m)] is a failure of the device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. A malfunction should be considered reportable if any one of the following is true:

- the chance of a death or serious injury occurring as a result of a recurrence of the malfunction is **not** remote;
- the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- it causes the device to fail to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device's labeled use, but for any use widely prescribed within the practice of medicine;
- it involves an implant malfunction that would be likely to cause or contribute to death or serious injury, regardless of how the device is used;
- the device is considered life-supporting or life-sustaining, and thus essential to maintaining human life; or
- the manufacturer takes or would be required to take action under section 518 or 519(f) of the FD&C Act as a result of the malfunction of the device or other similar devices.

Reporters do not need to assess the likelihood that a malfunction will recur. The regulation presumes that the malfunction will recur. Furthermore, FDA believes that once a malfunction has caused or contributed to a death or serious injury, a presumption that the malfunction is likely to cause or contribute to a death or serious injury has been established.

This presumption will continue until the malfunction has caused or contributed to no further deaths or serious injuries for two years, or the manufacturer can show, through valid data, that the likelihood of another death or serious injury as a result of the malfunction is remote.

Malfunctions are **not** reportable if they are not likely to result in a death, serious injury or other significant adverse event experience.

A malfunction which is or can be corrected during routine service or device maintenance **must be reported** if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

WHEN NOT TO SUBMIT A REPORT [§803.22]

FDA requires only one medical device report from the manufacturer if they become aware of information from multiple sources regarding the same patient and the same event. Also, for contract manufacturers, FDA would expect only one report from either the specifications developer or the contract manufacturer for one reportable event. Nevertheless, there must be a written agreement which identifies which party is responsible for completing Form 3500A.

In addition, FDA does not require that a manufacturer submit an MDR report:

- when the manufacturer determines that the information that they received is erroneous and a death or serious injury did not occur; or
- when another manufacturer made the device.

Manufacturers should retain documentation of erroneous reports in their MDR files for two years from the date of the event or a period equivalent to the expected life of the device, whichever is longer.

Any reportable event information that is erroneously sent to manufacturer A, for a device made by manufacturer B, should be sent to the FDA (Refer to “Where to Submit Reports” in this chapter) with a cover letter explaining that manufacturer A does not make the device in question.

Again, malfunctions are **not** reportable if they are not likely to result in a death, serious injury or other significant adverse event experience.

TYPES OF REPORTS

There are five types of MDR reports that FDA requires the manufacturer to submit. Each type of report is to be submitted within the mandatory time frame by completing the appropriate form. MDR reports for manufacturers include a:

- 1) 30-day report,
- 2) 5-day report,
- 3) baseline report,
- 4) supplemental report, and
- 5) annual certification.

1) 30-Day Report [§803.50]

Manufacturers are required to submit an individual adverse event (MDR) report to FDA, on form FDA 3500A (mandatory MedWatch form), or electronic equivalent as approved by FDA, **within 30 calendar days** after becoming aware of a reportable death, serious injury, or malfunction. FDA has developed instructions for completing the Form 3500A and a coding manual for specific items on the form (Refer to *Appendix A* for obtaining copies.)

FDA believes that manufacturers have a direct responsibility to inform all employees to forward immediately adverse event information to the appropriate person appointed by those entities to submit MDR reports.

Accordingly, FDA generally considers that a manufacturer becomes aware of an adverse event whenever any employee becomes aware of an adverse event. The 30-day time frame begins the day after receipt of the information that reasonably suggests that an MDR reportable event has occurred.

Manufacturers may receive complaint information via telephone, facsimile, written correspondence, sales representative report, service representative report, scientific article review, internal analyses or direct FDA contact. The manufacturer should make certain that market, sales, engineering, manufacturing, regulatory, installation and service personnel are trained to properly identify and report complaints.

User facilities and distributors will also submit information to the manufacturer on Form 3500A. However, the manufacturer will find that user facilities and distributors may need some guidance regarding when to use Form 3500A. For example, if a user facility calls in a death or a serious injury report, it behooves the manufacturer to remind the user facility to complete a Form 3500A immediately and report a death to FDA. Otherwise, it will be the responsibility of the manufacturer to complete the entire Form 3500A and submit it within 30 days. FDA encourages manufacturers to help user facilities in gaining an understanding of user facility obligations.

Manufacturers may also receive adverse event information from the submission of a voluntary MedWatch report form (Form 3500). When the FDA MedWatch Program Office receives a voluntary Form 3500 involving a medical device, it is forwarded to the Center for Devices and Radiological Health (CDRH) for follow-up. The Office of Surveillance and Biometrics (OSB) within CDRH will forward a copy of the report to the manufacturer for evaluation. If the event is reportable, the reporting time frame for reporting begins when the form is received. The manufacturer has now “become aware” of the event. If a firm decides that the event is reportable, then it must obtain all of the information required on a mandatory Form 3500A and then submit the completed form to FDA.

Sometimes the initial reporter may request confidentiality, preventing the manufacturer from investigating the complaint. In these cases, the manufacturer must evaluate the reportability of the complaint based on the information they can obtain, any information provided in Form 3500, and their knowledge of the product. The manufacturer must base the MDR reportability decision on this information.

2) 5-day report [§803.53]

Upon receiving information about an MDR reportable event, a manufacturer must submit a “5-day report” to FDA on form FDA 3500A or electronic equivalent as approved by FDA, within five work days after: (1) becoming aware that a reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to public health; or (2) becoming aware of an MDR reportable event from which FDA has made a written request for the submission of a 5-day report involving a particular type of medical device or type of event.

Unlike the 30-day report, the 5-day time frame for remedial actions begins the day after 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 has occurred. FDA does not believe that certain employees, such as nontechnical staff, can probably recognize that an adverse event or events may require remedial action to prevent a substantial risk to the public. The 5-day time frame for reports requested by FDA begins when any employee of the manufacturer becomes aware that a reportable event has occurred.

If the manufacturer must submit a 5-day report, the manufacturer should provide any additional information that is not available within the five days in a separate supplemental report on Form 3500A.

Remedial action [§803.3(y)] is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of a reportable event. Not all remedial actions need to be submitted as 5-day reports. *Only remedial actions that are necessary to prevent an unreasonable risk of substantial harm to the public health must be submitted.* If the manufacturer takes a remedial action, but it is NOT to prevent an unreasonable risk of substantial harm to the public health, no 5-day report is required. However, a 30-day report

may be required. The discovery that a remedial action is necessary may be a direct result of one or more MDR reportable events occurring, or may be discovered through the performance of internal analyses using appropriate statistical or other acceptable methodologies. Action taken to fix a single device involved in an MDR reportable event is not remedial action.

FDA has published a Remedial Action Exemption Policy that establishes the conditions under which MDR reportable events, addressed by a remedial action, would no longer be required to be reported under the MDR regulation. The Remedial Action Exemption (RAE) policy document, dated July 30, 1996, replaces the previous RAE policy, dated June 12, 1995. The new document, pursuant to the Medical Device Reporting (MDR) regulation, 21 CFR 803.19, establishes the conditions under which MDR reportable adverse events would no longer be required for deaths, serious injuries and malfunctions involving a product undergoing remedial action. (Refer to *Appendix A*.) This new policy will not affect those RAEs which were submitted before the July 31, 1996, effective date of the final rule. Exemptions authorized under the previous June 12, 1995, RAE policies are hereby reinstated and the manufacturer will not have to submit renewal notifications.

If the manufacturer becomes aware of an MDR reportable event for which FDA has made a written request for the submission of a 5-day report, the manufacturer must submit, without further requests, a 5-day report for each subsequent event of the same nature that involves similar devices for the time period specified in the written request. The FDA identification request may be a result of its review of 30-day reports, inspection reports, user facility reports, or any other information.

FDA will generally relate 5-day report requests to severe, unusual, or unexpected events. The following is one possible scenario. There were a few unexplained pediatric deaths associated with the use of a particular medical device. FDA met with the manufacturer and the manufacturer could detect no reason for the deaths. At this point, FDA may decide to request a 5-day report concerning any other unexplained pediatric deaths for a specified period, for example, six months. This will allow FDA to investigate in a timely manner whether these deaths were an anomaly or whether the device caused or contributed to the deaths.

Manufacturers required to complete 5-day reports for events requiring remedial action should send them to the post office box address for submission of MDR reports, but may call (301) 827-7537 to request instructions if they wish to send their reports via a facsimile.

3) **Baseline report** [§803.55]

Manufacturers must submit a baseline report (accompanying the corresponding Form 3500A) when an event involving the device model or device family is reported **for the first time**. The manufacturer submits a baseline report to FDA using Form 3417, which provides basic device identification information.

As mentioned earlier, FDA published a July 31, 1996 *Federal Register* notice **staying the requirements for distribution data (items 15 and 16) on the Medical Device Baseline Report until further notice.**

The report can be submitted by model type (one baseline report for each model) or by device family (one baseline report for all models in that family). The instructions for completing the baseline report are contained in “Instructions for Completing the Medical Device Baseline Report, “FDA form 3417.” (Refer to *Appendix A.*)

A **device family** [§803.3(e)] is a group of one or more devices manufactured by or for the same manufacturer and having the same:

- basic design and performance characteristics related to device safety and effectiveness;
- intended use and function; and
- device classification and product code.

FDA has classified approximately 1700 generic categories of devices. Each generic category is represented by a classification regulation in 21 CFR 800-1299. FDA has further defined classification regulation through a product code nomenclature system. This information is available from the Product Code Classification Database on the World Wide Web. (Refer to *Appendix A.*)

Devices that differ only in minor features, unrelated to safety or effectiveness, can be considered in the same device family. Factors such as a brand name and common name, or the fact that the devices were introduced into commercial distribution under the same 510(k) or the same premarket approval application (PMA), may be considered in determining the grouping of products into device families.

If the manufacturer chooses the option of submitting a baseline report by device family, they must attach a list of all models in the family to the baseline report. To help manufacturers in submitting baseline reports by device family, FDA has developed a suggested matrix that may be used to list models included in a family. (Refer to the Instructions for Completing Form 3417 in *Appendix A.*)

The basic device identification information, requested on Form 3417, includes: brand name, device family designation, model number, catalog number, and any other device identification number. This information helps insure clear, unambiguous device identification. The information will enable FDA staff to identify the product reported, which is critical in evaluating the extent of the problem.

The baseline form also includes information on the shelf life and expected life of a device. There is no intent, by FDA, to require that all devices have a shelf life or expected life. If there is no shelf life, manufacturers should check “N/A” in the block 11a of Form 3417. If the concept of expected life is not applicable to the device, manufacturers should check “N/A” in

block 11b. If no expected life has been established, then FDA considers the product to have either an indefinite life, or no established expected life. The absence of an expected life will affect how long a manufacturer maintains required MDR event files for the device. (Refer to “MDR Event Files” in *Chapter 3*.)

Baseline reports on systems with multiple components. If a medical device consists of several different stand alone medical device components, and one component is involved in a reportable event, FDA may require a baseline report. If the component is a finished device, bearing its own unique device identifier, then a baseline report is submitted for the component if the suspect device was the component. If the system has a device identifier and identifying the unique component is not possible, then file a baseline report on the entire system. This policy does not apply to kits of assembled devices.

Baseline reports linked to 5-day reports. If a device, which is the subject of a 5-day report, is being reported for the first time, FDA requires a Form 3417 baseline report. The manufacturer should submit as much information as can be obtained on the baseline report that will accompany the 5-day report. If not all the information can be obtained, the manufacturer should explain, in a cover letter, that they cannot obtain all information within the required reporting time frame, and provide an estimated date for submission of the remaining information. At a minimum, the initial baseline report should provide the device identification information, that is, brand, model number, catalog number, product code, and device family.

Annual baseline update [§803.55(b)].

The annual update report shall be submitted at the same time that the firm’s annual registration is required per Part 807.21. Annual baseline updates should cover the time period from the initial baseline report or last annual update, whichever is later, to the present annual registration filing. If the annual registration is due less than six months after the initial baseline report is submitted, then the annual baseline update report would not be required until the next annual registration is due. Manufacturers are required to submit annual baseline update reports, using Form 3417, to notify FDA of any changes in original baseline report information occurring during the twelve-month period preceding their annual registration.

Changes requiring an annual baseline update include:

- the addition of models to a device family,
- changes in information in blocks 1-14.

An annual update to a baseline report does not have to be submitted if, during the previous twelve-month period, there were no MDR reportable adverse events filed with FDA for the current model(s) or for any new model(s) that may have been added to the initial baseline report during that designated time period and there were no other changes in the information previously submitted. This waiver remains in effect until the manufacturer files an adverse event report either for the current model(s), or the manufacturer adds new models after the last

update. In this case, an annual update report is required at the time of the next annual registration and will contain the same information identified above. The update must include the designated information covering the time frame from the last baseline report update to the present. This may be a period longer than 12 months.

Interim baseline update. Manufacturers who submit baseline reports based on a device family may add a new model(s) to a device family. A baseline update report is required for the additions(s). However, if, prior to submission of the annual update, a new model(s) subsequently becomes the subject of an MDR reportable adverse event, then an interim update report is required, to report the new model involved in the event. (See the “Instructions for Completing Form 3417” in *Appendix A*.)

4) Supplemental report [§803.56]

Manufacturers must submit a supplemental report, using Form 3500A, if they obtain additional information denoted as unknown (UNK) or not available (no information at the time, NI) on the original 30-day or 5-day MDR reports. Additionally, a supplemental report is required when new facts prompt the manufacturer to alter any information submitted in the original MDR report. The supplemental information must be submitted on Form 3500A within one month (30 calendar days) following receipt of the information.

The number of follow-ups necessary to obtain MDR information depends upon the nature and severity of the event reported. It is FDA’s position that MDR follow-up investigations should focus on obtaining information and not on the number of attempts. FDA cannot provide an absolute number of attempts to follow-up since the intensity, nature and duration of an MDR follow-up depend upon the firm’s assessment of the risk. Therefore, “adequate” follow-up cannot be characterized by the selection of a pre-determined/averaged number of attempts. Each MDR event can be unique and a standard number of follow-up attempts would not be in the best interest of the public health.

FDA requires that a “good faith effort” be made to obtain information. At least one request for information should be made in writing. Firms must document follow-up attempts and document reasons why MDR information cannot be obtained. A firm’s files should include a record of each attempt to obtain information, and the nature of the response by the reporter. All of this information will be reviewed by FDA to determine if a firm has made a reasonable attempt to follow-up and obtain the required information.

If the initial report contained all the required information, and new information does not change the facts and/or conclusion reported in the original MDR report, a supplemental report is not required. However, the manufacturer should maintain any new information in the manufacturer’s MDR files.

5) Annual certification [§803.57]

Section 510(d) of the Federal Food, Drug, and Cosmetic Act (the act) [21 U.S.C. 360I(d)] provides that each manufacturer, importer, and distributor shall certify that they did file a certain number of medical device reports (MDR's) in the previous twelve months or they did not file any MDR's. In the Federal Register of December 11, 1995 (60 FR 63578), FDA published a final rule implementing this statutory provision by requiring manufacturers to certify that they filed reports for all reportable events required under the rule for the previous twelve months and a numerical summary of MDR's that they submitted, or to certify that they did not receive any reportable events during the reporting period [§803.57 (21 CFR 803.57)]. The final rule required certification to be made by the company's president, chief executive officer (CEO), or other official most directly responsible for the firm's operations. This provision was stayed on July 23, 1996.

In the Federal Register of March 20, 1997 (62 FR 13302), FDA published a final rule amending its medical device manufacturer and distributor certification regulation to allow manufacturers to designate more than one certifying official, each of whom would sign a certification statement for his or her identified organizational component or site; and to amend the certification statement to minimize concerns relating to liability from unintentional reporting errors, and indicate that the certifying official is making the certification statements, to the best of his/her knowledge and belief. This action was taken to help FDA carry out its public health protection responsibilities relating to medical devices. This action provides reporting entities with greater flexibility in the certification process while reducing the regulatory burden. This amendment is effective on May 19, 1997, at which time the existing stay will end.

FDA REQUESTS FOR ADDITIONAL INFORMATION [§803.15]

FDA may determine that protection of the public health requires additional or clarifying information. In these instances, the agency will notify the reporting entity in writing, or by verbal request, of the additional information required. Any request will state the reason for requesting the information, specify the date by which 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.

REPORTING FOR FOREIGN MANUFACTURERS [§803.58 and §807]

As mentioned earlier, on July 23, 1996 FDA published a *Federal Register* notice staying the U.S. Designated Agent (USDA) provision for foreign manufacturers. In addition, FDA stated that it intends to propose that the requirements for the USDA to annually certify and submit premarket notifications [510(k)] for the foreign manufacturer be deleted. The agency has received comments regarding who may best perform the duties of the USDA.

Foreign manufacturers are still subject to the remaining requirements in the MDR regulation and should submit MDR reports directly to FDA.

Due to the stay of the USDA provisions, the 1996 edition of Title 21 of the Code of Federal Regulations (CFR), Parts 800-1299, is incorrect. In particular, section 807.40 is incorrect. The stay has delayed the implementation of the new version of section 807.40. The correct version of section 807.40 is found in the 1995 edition of 21 CFR. The 1995 version is printed below.

§807.40 Establishment registration and device listing for foreign manufacturers of devices.

(a) Foreign device establishments, that export devices into the U.S., are requested to register following the procedures of subpart B of this part, unless exempt under subpart D of this part.

(b) Foreign device establishments that export devices into the U.S., whether or not the establishment is registered, shall comply with the device listing requirements unless exempt from registration as stated in §807.65. Those foreign owners or operators, for which there exists joint ownership and control with a domestic establishment, may have the domestic establishment submit listing information and maintain the historical file. A foreign owner or operator may authorize a domestic initial distributor to submit listing information when joint ownership and control do not exist, only if:

(1) The domestic distributor is the sole initial distributor of a device manufactured by the foreign owner or operator; and

(2) The foreign owner or operator submits a letter to FDA authorizing the initial distributor to list on their behalf and maintain the historical files.

(c) Except for a device imported or offered for import that has in effect an approved exemption for investigational use under section 520(g) of the act, a device may not be imported from a foreign device establishment into the U.S. unless it is listed at the interval specified for updating device listing information in §807.30(b). The device listing information shall be in the English language.

(d) Foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to FDA at the intervals specified for updating device listing information in §807.30(b).

REPORTING FOR USER FACILITIES AND DISTRIBUTORS

User facilities are required to report device-related deaths using MedWatch Form 3500A to the FDA and the manufacturer within 10 working days. They must submit reports of serious injuries only to the manufacturer. However, if the manufacturer is unknown, reports of serious injuries must be submitted to FDA. The user facility is not required, but is encouraged, to report reportable malfunctions to the manufacturer.

Distributors are required to submit deaths and serious injuries to both FDA and the manufacturer within 10 working days. Distributors must also submit reportable malfunctions to the manufacturer, **not** the FDA, within 10 working days. Distributors are requested, **not** required, to use MedWatch Form 3500A for purposes of reporting. In cases where the manufacturer receives information regarding a reportable event, other than by means of a form 3500A, they are required to complete **all** applicable sections of the form.

WHERE TO SUBMIT REPORTS [§803.12]

All MDR reports should be sent to:

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

FDA will accept more than one type of report per envelope. If multiple types of reports are enclosed, the envelope should be labeled indicating each type of report enclosed. In addition, any MDR report may be faxed to FDA following approval. A request for approval of facsimile reports can be obtained by calling 301-827-7537.

To ensure the proper processing of all reports, the outside of the envelope shall be labeled in a specific manner. The mailing and labeling requirements are noted in the following table:

TYPE OF MDR REPORT	IDENTIFICATION OF ENVELOPE (PLACE IN LOWER LEFT-HAND CORNER OF THE ENVELOPE ABOVE BAR CODE LEVEL)
5-Day (Form 3500A)	5-day Report
30-Day (Form 3500A)	30-day Manufacturer Report
Supplemental (Form 3500A)	Manufacturer Supplemental Report
Baseline (Form 3417)	Baseline Report or Annual/Interim Update-Baseline Report
Annual Certification (Form 3381)	Manufacturer Annual Certification Report

WHERE TO REPORT A PUBLIC HEALTH EMERGENCY

If a manufacturer believes that there is a public health emergency, they should contact:

FDA Emergency Operations Branch
 Office of Regional Operations, HFC-162
 Phone: 301-443-1240
 FAX: 301-443-3757

The telephone report should be followed by a facsimile report.

ENGLISH REPORTING REQUIREMENTS [§803.13]

All written or electronic MDR reports, including requested additional information, must be in English.

ELECTRONIC REPORTING [§803.14]

Manufacturers may send MDR reports electronically once they have received written approval from FDA. This includes the use of electronic media such as magnetic tape, disc and computer-to-computer communication. FDA encourages manufacturers to computerize the required report forms. However, a request for an electronic facsimile (reproduction) approval of any form must be made in writing to FDA. The request must include a copy of the proposed form and a sample of a completed form. It is not necessary for a facsimile form to be generated as a two-sided

document. Manufacturers can use programs that automatically create continuation pages when the text exceeds the space allowed for a particular block on a form. FDA is not accepting facsimiles that increase the size of the item block or cause the original form to be significantly modified. The request for facsimile approval should be addressed to the MEDWATCH address designated below. A copy of all the requests for Form 3500 or Form 3500A approval should be forwarded to the Director, Division of Surveillance Systems at the address designated below.

For MedWatch Form 3500A (**Mandatory**) or Form 3500 (**Voluntary**), contact:

MEDWATCH: The FDA Medical Products Reporting Program
Office of the Commissioner, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

For Form 3417 (Baseline) or Form 3381 (Annual Certification) contact:

ATTN.: Computer Generated Form Approval Request
Director, Division of Surveillance Systems
Office of Surveillance and Biometrics, HFZ-530
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

EXEMPTIONS, VARIANCES, AND ALTERNATIVE REPORTING REQUIREMENTS [§803.19]

The **new** MDR regulation includes provisions for waivers from all or some provisions. The regulation explicitly exempts the following three types of persons:

- licensed practitioners who prescribe or administer devices intended for use in humans, and who manufacture or import devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship;
- a person 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 (IDE) regulation (21 CFR Parts 812 and 813) because they are conducting a clinical research study. However, the IDE regulation requires the reporting of unanticipated adverse device effects (21 CFR 812.46); and
- dental or optical laboratories.

In addition, manufacturers can submit requests for exemption from all or part of the requirements of the MDR regulation. This includes variances and alternative reporting requirements. FDA must approve a manufacturer's request in writing before an exemption, variance or alternative reporting can be carried out. An exemption, variance or alternative report approved may also be granted at the discretion of FDA in the absence of a request. FDA can revoke any approval in writing if they decide that the protection of the public health justifies a return to the standard MDR reporting requirements.

A variance may include a modification of the data elements required on the mandatory reporting forms. An alternative report allows a modification in the timing of report submissions and is a type of variance. For example, a firm may request, instead of reporting each event within 30 days after becoming aware, that the reports be submitted every two months, quarterly, semiannually or annually.

When an exemption, variance or alternative report is granted, FDA may impose other reporting requirements to protect public health. Manufacturers must provide any reports or information required by FDA in approving any reporting modifications. The conditions of approval replace or supersede the reporting requirements of the MDR regulation.

Each request for an exemption or variance should include an explanation of the impact of the device problem on the patient and why the requested reporting approval is more appropriate than the standard MDR reporting requirements. Each request should include the following information:

1. Firm identification, including manufacturing site(s) of the device(s),
2. Complete product identification and description,
3. Type of approval requested (i.e., an exemption, a variance, an alternative reporting approval),
4. Type of report(s) involved (e.g., serious injuries, malfunctions),
5. Particular type of event(s) involved,
6. Rationale for the request,
7. Number of reports submitted to date and approximate number reported annually, and
8. Discussion of previous complaint history.

Submit an original and one copy of the request, and label the lower left-hand corner of the envelope with the type of request being made, for example, "Alternative Reporting Request."

Manufacturers should submit requests to:

Director, Division of Surveillance Systems
Office of Surveillance and Biometrics, HFZ-530
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

As of July 31, 1996, the new regulation superseded all previously granted exemptions, variances, and alternative reporting requests from the 1984 MDR regulation.

MDR Exemptions. Since July 30, 1996, FDA has reissued the following four exemptions:

- Remedial Action Exemption - E1996001 - published on July 30, 1996
- Breast Implant Exemption - E1996002 - published on August 7, 1996
- Needlesticks and Blood Exposure Exemption - E1996003 - published on August 9, 1996
- Intraocular Lens Exemption - E1996004 published on August 7, 1996

Copies of these exemptions are available through the CDRH Home Page. (Refer to *Appendix A*.)

Manufacturer Report Number Variances. FDA is aware that some firms are having problems implementing the Manufacturer Report Number (MRN) format required by the regulation. In response to these problems, FDA has issued variances from the reporting requirements. These variances provide the means for the majority of firms to easily generate the MRN. Copies of these variances are available through the CDRH Home Page. (Refer to *Appendix A*.)

In addition, requested alternative report approvals have been reissued.

HOW TO REPORT [§803.20]

There are two versions of the MedWatch form. The **voluntary** MedWatch Form **3500** is for use by consumers and health care professionals for the submission of voluntary reports involving medical devices. These voluntary reports for medical devices are forwarded from the FDA MedWatch Office to the Center for Devices and Radiological Health for review, evaluation and dissemination to the manufacturer.

The **mandatory** MedWatch Form **3500A** is to be used by both user facilities and medical device manufacturers for the reporting of device-related deaths, serious injuries and reportable malfunctions required under the December 11, 1995 MDR regulation. Form 3500A has blocks that must be completed by all reporters, and other blocks designed to be completed by either the user facility or the manufacturer. (Refer to *Appendix A* on how to obtain copies of Form 3500A, and the Coding Manual with full instructions, or the abbreviated instructions for completing MedWatch Form 3500A.)

- Blocks A through E (Excluding Block C) are to be filled out by user facilities or distributors. Blocks A through E include information regarding the patient, the event, the device and the initial reporter. The initial reporter is the person that first contacted the entity required to report regarding the reportable event.

- Block F is to be filled out by the user facilities and distributors. Block F includes information regarding their name, address and the event problem codes. The user facility must enter codes which most accurately describe the event. Codes used for this purpose can be found in the MedWatch Coding Manual. (Refer to *Appendix A*.)
- Blocks G and H are to be filled out by the manufacturer. These blocks include information regarding the manufacturer's name and address, evaluation codes and, if applicable, the type of remedial action taken. The evaluation codes will include the methods, results and conclusion drawn by the manufacturer for the event. These codes also can be found in the MedWatch Coding Manual. (Refer to *Appendix A*.)

Manufacturers are not required to recopy information submitted to them on MedWatch Form 3500A, unless they are copying the information onto an electronic medium. The manufacturer should always include, *without alteration*, a copy of the MedWatch form(s) received from the user facility and distributor, with their own submission. It is important to note that the manufacturer has the responsibility to provide any missing information on the Form 3500A, including any missing event codes or patient information from Blocks A through F. If there is any missing information in these blocks, manufacturers are required to provide the information.

If the manufacturer corrects or supplies information missing in Blocks A, B, D, E or F they should do so on a separate Form FDA 3500A, not the form received from the user facility or distributor. This is the only way that FDA will know which entity is responsible for reporting the information. **Do not make corrections on the original Form 3500A received from the user facility or distributor. The manufacturer may place added or corrected information in Block H.11 of the manufacturer's Form 3500A.** When correcting or supplying missing information from other reporters (User or distributor), the manufacturer should attach a copy of the initial reporter's form 3500A to the manufacturer's report form.

Manufacturers do not have to report events when there is information available that would cause a person qualified to make a medical judgement (for example, physician, nurse, risk manager, or biomedical engineer) to conclude that their device did not cause or contribute to a reportable event. The information used to decide that the event was not reportable must be documented in the MDR files.

REPORTING CODES (CODING MANUAL) [§803.21]

FDA has developed instructions and a coding manual for completing MedWatch Form 3500A entitled "Instructions for Completing Form 3500A with Coding Manual for Form 3500A" (Refer to *Appendix A* to obtain copies.)

3 WRITTEN PROCEDURES, RECORD KEEPING AND PUBLIC DISCLOSURE

WRITTEN PROCEDURES [§803.17]

Manufacturers are required to establish and maintain written procedures for implementation of the MDR regulation. These procedures should include internal systems that:

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

These procedures should also include documentation and record keeping requirements for:

- information that was evaluated to determine if an event was reportable;
- all medical device reports and information submitted to FDA;
- any information that was evaluated during preparation of annual certification report(s); and
- systems that ensure access to information that facilitates timely follow up and inspection by FDA.

Each manufacturer has certain discretion to decide the detail and depth of information that their written MDR procedures contain. FDA suggests that manufacturers provide policy and procedure information regarding “typical” adverse events or product problems that may be MDR reportable. FDA also suggests that the procedures describe the investigation protocol that they will follow, e.g., how many attempts will be made to contact the reporter either by phone, FAX or letter before the investigation is closed; that the complaint records will contain a concise but thorough description of the adverse event or product problem, that the complaint records will be legible, etc. The number of follow-ups necessary to obtain MDR information depends upon the nature and severity of the event reported. It is FDA’s position that MDR follow-up investigations should focus on obtaining information and not on the number of attempts. FDA cannot provide an absolute number of attempts to follow-up since the intensity, nature and duration of an MDR follow-up depend upon the firm’s assessment of the risk. Therefore, “adequate” follow-up cannot

be characterized by the selection of a pre-determined/averaged number of attempts. Each MDR event can be unique and a standard number of follow-up attempts would not be in the best interest of the public health.

FDA requires a “good faith effort” be made to obtain information. At least one request for information should be made in writing. Firms must document follow-up attempts and document reasons why MDR information cannot be obtained. A firm’s files should include a record of each attempt to obtain information, and the nature of the response by the reporter. All of this information will be reviewed by FDA to determine if a firm has made a reasonable attempt to follow up and obtain the required information.

MDR EVENT FILES [§803.18(b)(1)]

Manufacturers must maintain complete MDR files in either written or electronic form. They must identify them prominently as "MDR Files" so they can be found easily. Manufacturers’ MDR files may be maintained as part of their complaint file required under the Quality System (QS) regulation (§820.198). An MDR report submitted to FDA is not considered in compliance with the MDR regulation unless the manufacturer evaluated the event in accordance with the QS regulation, regarding investigation of a possible device failure [See sections 820.198(c), (d) and (e)]. There must be a record of this investigation documented in the complaint file. Manufacturers are to maintain records related to an event (whether reportable or not) for two years from the date of the event or a period equivalent to the expected life of the device, whichever is longer. MDR files may incorporate references to other information sources such as medical records, patient files, and engineering reports.

MDR files must contain:

- information related to the event, including all documentation of deliberations and decision-making processes used to decide whether the event was or was **not** reportable; and
- the original or a copy of the initial record complaint/event. This record should include the available information needed to complete the Form 3500A. The record may be a documented telephone call, a letter or facsimile, a service report, documents related to a lawsuit, a voluntary Form 3500 received from a health care professional or consumer, or a mandatory Form 3500A received from a user facility and/or a distributor,
- copies of any records documenting the firm’s attempts to follow-up and obtain missing or additional information about the event. When the manufacturer cannot obtain information, they must write an explanation of these events for inclusion in the file. In addition, there must be an explanation of why any missing information, required by the MDR regulation, was not obtained and submitted.

- copies of any test reports, laboratory reports, service records and reports, and records of investigations.
- copies of all documentation involving the final assessment of the event, any deliberation and/or decision making processes used to determine whether an MDR report was or was not needed. When applicable, the final assessment should indicate what action (if any) the firm took to assure that the cause of the event is corrected or otherwise mitigated.
- copies of all 3500As submitted to FDA, when applicable. This includes a copy of any 3500As received from user facilities and distributors.
- documents verifying that the event has been evaluated in accordance with the applicable requirements of 21 CFR 820.198.
- references to any other relevant documents or information used during assessment.

Manufacturers must permit any authorized FDA employee to access, copy, and verify the records in the MDR files.

PUBLIC AVAILABILITY OF REPORTS [§803.9]

Any report in FDA's control, including an FDA record of a telephone report, is subject to public disclosure in response to a Freedom of Information (FOI) request. However, before public disclosure, FDA will delete from the report:

- any information that constitutes trade secret, commercial confidential 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, health care professionals, or other hospital employees unless they are the designated MDR contact person.

FDA will disclose, to a patient requesting a report, **all** information in the report concerning them, except for trade secret and confidential commercial information.

FDA has promulgated a regulation [21 CFR §20.63(2)] that extends protection against disclosure of voluntary reports held by medical device, pharmaceutical, and biologics manufacturers by preempting state discovery laws.

When a manufacturer submits an MDR report and it contains information from a user facility, the facility name, address and MDR contact for the facility will be released to the public when

requested. FDA will not, however, release the identity of the patient or any information that can be used to identify the patient, such as the serial number of an implanted device. Nor will it release the name of any person other than the MDR contact.

DISCLAIMERS [§803.16]

The submission of a report or related information to the FDA and its release by FDA, does not necessarily reflect a conclusion by the party submitting the report or the FDA that the report or information is an admission that the manufacturer, their employees, or the device caused or contributed to the reportable event. FDA has included such a disclaimer on the MedWatch Form 3500A at the bottom of the front page. Besides the FDA disclaimer, manufacturers may also include their own disclaimers in MDR reports.

4 ENFORCEMENT

FDA may take the following actions to enforce the MDR regulation.

FDA-INITIATED OR VOLUNTARY RECALLS

Recalls are regulatory actions that enable FDA to remove a hazardous, potentially hazardous, or a misbranded product from the marketplace. Recalls are also used to convey additional information to the user concerning the safe use of the product. Either FDA or the manufacturer can initiate recalls.

CIVIL MONEY PENALTIES

Section 303(f) of the Safe Medical Devices Act of 1990 authorized FDA, after an appropriate hearing, to impose civil money penalties for violations of the FD&C Act that relate to medical devices. In determining the amount of a civil penalty, FDA will take into account the nature, circumstances, extent, and gravity of the violations, the violator's ability to pay, the effect on the violator's ability to continue to do business, and any history of prior violations. The civil money penalty may not exceed \$15,000 for each violation and may not exceed \$1,000,000 for all violations adjudicated in a single proceeding, per person.

WARNING LETTERS

FDA issues written communications to a firm, indicating that the firm may incur more severe sanctions if the violations described in the letter are not corrected. Warning letters are issued to cause prompt correction of violations that pose a hazard to health or that involve economic deception. FDA generally issues the letters before pursuing more severe sanctions.

SEIZURE

A seizure is a civil court action against a specific quantity of goods which enables FDA to remove these goods from commercial channels. After seizure, no one may tamper with the goods except by permission of the court. The court usually gives the owner or claimant of the seized merchandise approximately 30 days to decide a course of action. If they take no action, the court will recommend disposal of the goods. If the owner decides to contest the government's charges, the court will schedule the case for trial. A third option allows the owner of the goods to request permission of the court to bring the goods into compliance with the law. The owner of the goods is required to provide a bond (security deposit) to assure that they will perform the orders of the court, and the owner must pay for FDA supervision of any activities by the company to bring the goods into compliance.

CITATION

A citation is a formal warning to a firm of intent to prosecute the firm if violations of the FD&C Act are not corrected. It provides the firm an opportunity to convince FDA not to prosecute.

INJUNCTION

An injunction is a civil action filed by FDA against an individual or company. Usually, FDA files an injunction to stop a company from continuing to manufacture, package or distribute products that are in violation of the law.

PROSECUTION

Prosecution is a criminal action filed by FDA against a company or individual charging violation of the law for past practices.

5 TERMS AND DEFINITIONS

BECOMES AWARE [§803.3(c)]

Manufacturers are considered to have “become aware” of an MDR reportable event when:

- any employee becomes aware of a reportable event required to be reported within 30 days, or required to be reported within 5 days pursuant to a written request from FDA; or
- 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 event, from any information, including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to public health.

FDA believes these time frames for reporting should be triggered when employees of the reporting entities become aware of events. FDA believes that manufacturers have a direct responsibility to inform all employees to forward immediately adverse event information to the appropriate person designated by the manufacturer as responsible for MDR reporting.

CAUSED OR CONTRIBUTED [§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;
- device malfunction;
- improper or inadequate device design;
- manufacture;
- labeling; or
- user error.

COMPLAINT

Section 820.3(b) of the Quality Systems regulation defines a complaint as, “any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.” All medical device manufacturers are subject to the complaint requirements in 21 CFR Part 820, *Quality System* regulation and to the reporting requirements in 21 CFR Part 803, *Medical Device Reporting* (MDR) regulation. A complaint is any indication of the failure of a device to meet customer or user expectations for quality or to meet performance specifications. A

complaint may be lodged against any finished device released for distribution. Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications is subject to the provisions of 21 CFR 820.198, *Complaint Files*.

DEVICE FAMILY [§803.3(e)]

A “device family” is a group of one or more devices manufactured by or for the same manufacturer and having the same basic design and performance characteristics related to device safety and effectiveness; intended use and function; and device classification and product code.

Devices that differ only in minor ways not related to safety or effectiveness can be considered 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.

DISCLAIMERS [§803.16]

The MDR regulation and Form FDA 3500A, contain a disclaimer statement. FDA provides the disclaimer so that reporters are aware that the MDR information submitted to FDA does not necessarily reflect a conclusion by the reporter, or the 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. In fact, the regulation states that the reporter may deny that the report or information submitted constitutes any type of admission.

The FDA 3500A disclaimer states: “Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.”

The disclaimer in §803.16 states: “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.”

A manufacturer may submit its own disclaimer. At the time the manufacturer submits the first disclaimer, it is entered into a computer database. Once the disclaimer is entered, it will not be modified unless the manufacturer updates the disclaimer and notifies the Office of Surveillance and Biometrics (OSB) (Refer to *Appendix B*) in writing. FDA recommends that firms label the outside of the envelope containing such a change with the words, “DISCLAIMER UPDATE.” Whenever FDA releases a computer-generated copy of the MDR report under the Freedom of Information Act, they will duplicate the manufacturer’s latest disclaimer on the copy.

DISTRIBUTOR [§804.3(d)]

A “distributor” is any person, including an importer, who furthers the marketing of a device from the place of original manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the device or the container, wrapper, or labeling of the device or device package.

EXPECTED LIFE [§803.3(i)]

“Expected life” is the time that a device is expected to remain functional after it is placed into use.

INFORMATION REASONABLY KNOWN

The type of information that is "reasonably known" to the manufacturer is listed in §803.50(b)(i)-(iii). It includes information that can be obtained by contacting a user facility, distributor and/or initial reporter, any information in the manufacturer's possession, or any information that can be obtained by analysis, testing or other evaluation of the device. In applying this requirement, FDA will not ask the manufacturer for information that was not obtainable.

MALFUNCTION [§803.3(m)]

A “malfunction” is a failure of the device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. A malfunction should be considered reportable if any one of the following is true:

- the chance of a death or serious injury resulting from a recurrence of the malfunction is **not** remote;
- the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury;
- the malfunction causes the device to fail to perform its essential function and compromises the device’s therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences. The essential function of a device refers not only to the device’s labeled use, but for any use widely prescribed within the practice of medicine;
- the malfunction involves a long-term device implant that would prevent the implant from performing its function;
- the device is considered life-supporting or life-sustaining, and thus essential to maintaining human life; or

- the manufacturer takes or would be required to take action under section 518 or 519(f) of the FD&C Act as a result of the malfunction of the device or other similar devices.

Reporters do not need to assess the likelihood that a malfunction will recur. The regulation assumes that if a malfunction has occurred once, the malfunction will recur.

Malfunctions are **not** reportable if they are not likely to result in death, serious injury or other significant adverse event experience.

A malfunction which is or can be corrected during routine service or device maintenance **must be reported** if the recurrence of the malfunction is likely to cause or contribute to a death or serious injury if it were to recur.

MANUFACTURER [§803.3(n)]

A “manufacturer” is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological or other procedures. The term includes any person who:

- 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;
- initiates specifications for devices manufactured by a second party for subsequent distribution by the person initiating the specifications;
- manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
- | |
|---|
| is the US Designated Agent of a foreign manufacturer. <u>STAYED 7/23/96</u> |
|---|

MANUFACTURER REPORT NUMBER (MEDWATCH FORM 3500A) [§803.3(o)]

The “Manufacturer Report Number” is the number that identifies each individual adverse event report submitted by a manufacturer. It consists of three parts:

- registration number of the manufacturing site,
- the four digit calendar year the report was submitted, and
- the five digit sequence number of the report submitted during the year.

The manufacturer report number entered in the top right-hand corner of the Form FDA 3500A, and in Block G.9 replaces the FDA assigned MDR report accession number (1984 regulations). Manufacturers no longer have to wait for FDA to assign an MDR report number since the manufacturer report number is self-generated.

MEDICAL PERSONNEL [§803.3(r)]

“Medical personnel” refers to individuals who:

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

MDR REPORTABLE EVENTS [§803.3(q)]

Manufacturers must report all “MDR reportable events” to FDA on Form FDA 3500A. A report is required when a **manufacturer becomes aware** of information that reasonably suggests that one of their **marketed** devices has or may have caused or contributed to a death, serious injury, or 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.

PERMANENT IMPAIRMENT [§803.3(aa)(2)]

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

PERSON QUALIFIED TO MAKE A MEDICAL JUDGEMENT [§803.53(c)(2)]

FDA expects a “person qualified to make a medical judgement” to be a health care professional, e.g., a doctor, a nurse, a biomedical engineer or a risk manager. This person does not have to be an employee of the firm but may be an outside consultant.

REASONABLY SUGGESTS [§803.20(c)]

“Reasonably suggests” includes any information, such as professional, scientific, or medical facts and observations or opinions, that would reasonably suggest that a device has caused or contributed to a reportable event.

REMEDIAL ACTION [§803.3(y)]

“Remedial action” is any action, other than routine maintenance or servicing of a device, necessary to prevent recurrence of a reportable event.

SERIOUS INJURY/SERIOUS ILLNESS [§803.3(aa)(1)]

“Serious injury/(serious illness)” is an injury or illness that:

- is life threatening, even if temporary in nature;
- 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.

SHELF LIFE [§803.3(bb)]

“Shelf life” is the maximum time a device will remain functional from the date of manufacture until it is used in patient care.

USER ERROR

The term “user error” means any error made by the person using the device. A user error may be the sole cause or merely contribute to a reportable event. As with the 1984 regulation, there is the requirement for reports of certain adverse device events caused by user error. For example, device injuries attributed to user error may show that the device is misbranded within the meaning of section 502(f) of the FD&C Act [21 U.S.C. 352(f)] in that the device fails to bear adequate directions for use or adequate warnings. Reports of adverse events that result from user error may alert FDA to the need for improved labeling to prevent future injuries. (Refer to the FR preamble, page 63583, Final Rule, December 11, 1995.)

USER FACILITY [§803.3(f)]

A “user facility” is a hospital, ambulatory surgical facility, nursing home, or outpatient diagnostic or outpatient treatment facility.

WORK DAY [§803.3(ee)]

“Work day” refers to any day Monday through Friday, excluding Federal holidays.

APPENDIX A

SOURCES OF AVAILABLE MDR RELATED DOCUMENTS

SOURCES TO OBTAIN DOCUMENTS FREE OF CHARGE

1) CDRH Home Page (Home Page)

Many FDA MDR related forms and instructions, FDA exemptions and variances, and other MDR-related documents are available through the CDRH Home Page via the **World Wide Web** (WWW). The CDRH Home Page address is *<http://www.fda.gov/cdrh>*.

The CDRH Home Page includes:

- MDR related documents issued by CDRH,
- MDR related *Federal Register* notices,
- Form related instructions,
- MDR related exemptions and variances,
- MDR guidance documents for user facilities, distributors and manufacturers, and
- Product Code Classification data base.

MedWatch software is available. The software can be downloaded and used to complete a Form 3500 or 3500A on a personal computer. A hard copy may then be printed and mailed to FDA. This software is not for use for electronic submission of MDR reports. It just allows the use of a personal computer instead of a typewriter.

To download the software go to: <http://www.fda.gov/cdrh/mdwtchgn.html>
Follow the Instructions. If you have any difficulty call the MedWatch Office at 1-800-FDA-1088 and press zero, or send a facsimile to 301-443-5776.

For additional information on the WWW site, please call the CDRH FOD (see 2 below) and request shelf number 1799. The WWW allows access to information including text, graphics, and files which may be downloaded to a personal computer. The CDRH Home Page is updated frequently to include any new MDR documents or notices issued by CDRH.

To access the MDR section of the CDRH Home Page via the WWW:
(Type) **<http://www.fda.gov/cdrh/mdr.html>**

A list of all available MDR topic areas will be displayed. The list includes MDR forms and instructions and *Federal Register* notices. Many documents are viewable with a pdf reader, which can be downloaded from the Home Page.

The **Internet List Server** will be used to distribute MDR policies, guidance documents, announcements, and Home Page updates via the Internet beginning early 1997. Those with the capability to receive Internet E-mail may wish to subscribe to this service by visiting this page:

<http://list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1>

In response, you will receive a short introduction to the MDR-guide subscription list.

2) CDRH Facts-On-Demand (FOD)

This automated fax system allows anyone to obtain CDRH information, 24 hours a day, seven days a week by calling **800.899.0381** or **301.827.0111** from a touch-tone telephone. To receive a document which will give you a list of all available sources of MDR information; at the first voice prompt press the number one to access DSMA Facts, at the second voice prompt press two, and then enter the document number [799] followed by the pound(#) sign. Then follow the remaining voice prompts to complete your request.

SOURCES AVAILABLE FOR THE PURCHASE OF MDR DOCUMENTS

1) National Technical Information Service (NTIS)

Phone number: 703.487.4650

Fax number: 703.321.8547

For additional information on the NTIS system please, call the CDRH FOD (see 2 above) and request shelf number 3799.

2) Health Care & Industry Organizations (HCIO) - For a list of organizations that have agreed to help in the distribution of this information, please call the CDRH FOD (see 2 above) and request shelf number 4799.

TABLES OF AVAILABLE MDR RELATED DOCUMENTS AND RESOURCES

MEDICAL DEVICE REPORTING FORMS			
Form #	Title	Edition	Sources
FDA-3500A	Mandatory MedWatch	6/93	Home Page, FOD #854, NTIS, HCIO
FDA-3417	Baseline Report	3/96	Home Page, FOD #407, NTIS, HCIO

MEDICAL DEVICE REPORTING GUIDANCE DOCUMENTS		
Title	Edition	Sources
Medical Device Reporting: An Overview	4/96	Home Page, FOD #509, NTIS
Medical Device Reporting for USER FACILITIES	4/96	Home Page, FOD #989, NTIS,
Medical Device Reporting for DISTRIBUTORS	4/96	Home Page, FOD #988, NTIS
Medical Device Reporting for MANUFACTURERS	3/97	Home Page, FOD #987, NTIS
Remedial Action Exemption - E1996001	7/96	Home Page, FOD #188,
Breast Implant Exemption - E1996002	8/96	Home Page, FOD #452,
Needlesticks and Blood Exposure Exemption - E1996003	8/96	Home Page, FOD #250,
Intraocular Lens (IOL) Exemption - E1996004	8/96	Home Page, FOD #216,
Variances(#1-#4) from Report Number Format	7/96	Home Page, FOD # 1059,
Variance (#5) from Report Number Format	8/96	Home Page, FOD #1060
MDR Policy List Server - Information on how to subscribe to the List Server	8/96	FOD #1094
MDR - Interim Compliance Program 7382.830, Attachment E	7/96	FOD #1098

MEDICAL DEVICE REPORTING FEDERAL REGISTER NOTICES		
Title	Edition	Sources
Final Rule: Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and Registration (Docket 91N-0295). Initial Rule (published 12/11/1995)	12/95	Home Page, FOD #336, NTIS

MEDICAL DEVICE REPORTING FEDERAL REGISTER NOTICES		
Title	Edition	Sources
Final Rule: Medical Devices; Medical Device Reporting; Baseline Reports; Stay of Effective Date.	7/96	Home Page, FOD #1096
Final Rule: Medical Devices; Medical Device Distributer and Manufacturer Reporting, Certification Registration, Listing, and Premarket Notification Submission; Stay of Effective Date; Revocation of Final Rule.	7/96	Home Page, FOD #1074
Final Rule: Medical Device Reporting; Annual Certification.	3/97	Home Page, FOD #1090

MEDICAL DEVICE REPORTING FORM INSTRUCTIONS		
Title	Edition	Sources
Instruction for Completing Form 3500A with Coding Manual for Form 3500A	12/95	Home Page, FOD #853, NTIS, HCIO
Abbreviated Instructions for completing Form 3500A		Home Page, FOD #973, NTIS, HCIO
Instructions for Completing Form 3417; Baseline Report	3/97	Home Page, FOD #1061

MEDICAL DEVICE REPORTING VIDEOTAPES			
Title	Edition	Summary	Source
MDR Teleconference (3 hours)	5/96	Discussions of intent and purpose of the MDR regulation, basic requirements, forms, follow-up and close out of reports.	NTIS
MDR Forms for Device Manufacturers (30 minutes)	5/96	Detailed instructions for completing forms 3500A, Form 3417 and Form 3381.	NTIS

APPENDIX B

SOURCES OF MANUFACTURER ASSISTANCE FOR COMPLYING WITH THE MDR REGULATION

FDA realizes that manufacturers will need a variety of resources to help them understand and comply with the MDR regulation. As a result, FDA has provided many documents to help parties who are affected by the regulation. In addition, FDA has identified organizational components within the agency to provide answers to policy questions, filing questions, etc. They will likely develop additional documents as more experience with the new regulation is gained.

Information on how to obtain these documents is available through the CDRH Facts-On-Demand (FOD) system by calling either (800) 899-0381, or (301) 827-0111 and requesting shelf number 799.

FDA is considering various ways of making updates to this appendix periodically available. The most likely mechanism will be to use the CDRH Home Page. (Refer to Appendix A).

The MDR Telephone Number for General Assistance is: (301) 827-7537. FDA will retain this telephone number, which was previously used by manufacturers to report serious injuries and deaths. It will now be used by manufacturers, distributors and user facilities to arrange to fax their medical device reports to FDA. It may also be used to obtain assistance in filling out report forms or for answers to MDR related questions. Manufacturers may also call the number to make 5-day reports of events requiring remedial actions.

See Appendix A for information on accessing MDR-related documents.

General Questions regarding Medical Device Reporting

Division of Small Manufacturers Assistance (HFZ-220)
Office of Health and Industry Programs
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850
Telephone - (301) 443-6597, Toll free -(800) 638-2041
FAX: (301) 443-8818

To request that additional codes be added to the Coding Manual

MDR Coding Manual Coordinator, HFZ-533
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

Assistance regarding MDR policy Interpretation, Exemptions, Variances and Alternative Reporting

ATTN.: Questions

Division of Surveillance Systems (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850
Telephone - (301) 594-2735, Fax - (301) 827-0038

Assistance in completing forms

ATTN.: Questions

Information and Analysis Team (HFZ-531)
Division of Surveillance Systems, Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850
Telephone - (301) 594-2731, Fax - (301) 827-0038