

§ 803.9

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

Serious injury means an injury or illness that:

- (1) Is life-threatening,
- (2) Results in permanent impairment of a body function or permanent damage to a body structure, or
- (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

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

Shelf life means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

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

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

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

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

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ber for all sites if the primary site provides the name, address, and CMS number for each respective site.)

Work day means Monday through Friday, except Federal holidays.

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

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

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

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

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

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

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

(1) An action brought to enforce section 301(q) of the act, including the failure or refusal to furnish material or information required by section 519 of the act;

(2) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 803.30; or

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

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

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

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

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

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

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

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

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

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

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

(2) [Reserved]

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

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

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

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

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

(3) Submit annual baseline reports.

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

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

If you are a user facility, importer, or manufacturer, you must submit all reports of individual adverse events on FDA MEDWATCH Form 3500A or in an electronic equivalent as approved under § 803.14. You may obtain this

form and all other forms referenced in this section from any of the following:

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

(2) FDA, MEDWATCH (HF-2), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7240;

(3) Division of Small Manufacturers, International, and Consumer Assistance, Office of Communication, Education, and Radiation Programs, Center for Devices and Radiological Health (CDRH) (HFZ-220), 1350 Piccard Dr. Rockville, MD 20850, by e-mail: DSMICA@CDRH.FDA.GOV, or FAX: 301-443-8818; or

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

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

(a) You must submit any written report or additional information required under this part to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

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

(c) If an entity is confronted with a public health emergency, this can be brought to FDA’s attention by contacting the FDA Office of Emergency Operations (HFA-615), Office of Crisis Management, Office of the Commissioner, at 301-443-1240, followed by the submission of an e-mail to emergency.operations@fda.hhs.gov or a fax report to 301-827-3333.

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

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