

## § 803.11

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

[70 FR 9519, July 13, 2005, as amended at 73 FR 33695, June 13, 2008]

## § 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:

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

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

(c) 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](mailto:DSMICA@CDRH.FDA.GOV), or FAX: 240-276-3151;

(d) On the Internet at <http://www.fda.gov/medwatch/getforms.htm>.

[72 FR 17399, Apr. 9, 2007]

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## § 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](mailto: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>.

[70 FR 9519, July 13, 2005, as amended at 71 FR 1488, Jan. 10, 2006]

## § 803.13 Do I need to submit reports in English?

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

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

## § 803.14 How do I submit a report electronically?

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

(b) If your electronic report meets electronic reporting standards, guidance documents, or other MDR reporting procedures that we have developed,

you may submit the report electronically without receiving our prior written consent.

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

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

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

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

No. A report or other information submitted by you, and our release of that report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

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

If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

(a) Internal systems that provide for:

(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;

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

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

(b) Documentation and record-keeping requirements for:

(1) Information that was evaluated to determine if an event was reportable;

(2) All medical device reports and information submitted to manufacturers and/or us;

(3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and

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

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

(a) If you are a user facility, importer, or manufacturer, you must establish and maintain MDR event files. You must clearly identify all MDR event files and maintain them to facilitate timely access.

(b)(1) For purposes of this part, “MDR event files” are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, engineering reports), in lieu of copying and maintaining duplicates in this file. Your MDR event files must contain:

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

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

(2) If you are a user facility, importer, or manufacturer, you must permit any authorized FDA employee, at all reasonable times, to access, to copy,