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(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]

§ 803.12 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) Food and Drug Administration, Center for Devices and Radiological Health, Division of Small Manufacturers, International and Consumer Assistance, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993–0002;

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


§ 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.

[72 FR 17399, Apr. 9, 2007, as amended at 75 FR 20914, Apr. 22, 2010]