(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*, or FAX: 240–276–3151;

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

[72 FR 17399, Apr. 9, 2007]

§ 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*.

[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,