

(iii) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete number will appear as follows: 1234560000–1995–0001.)

(2) If a facility has more than one HCFA number, it must select one that will be used for all of its MDR reports. If a facility has no HCFA number, it should use all zeros in the appropriate space in its initial report (e.g., 0000000000–1995–0001) and FDA will assign a number for future use. The number assigned will be used in FDA's record of that report and in any correspondence with the user facility. All zeros should be used subsequent to the first report if the user does not receive FDA's assigned number before the next report is submitted. If a facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

(ee) *Work day* means Monday through Friday, excluding Federal holidays.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4118, Jan. 26, 2000]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, in §803.3, paragraph (n)(4) was stayed indefinitely.

§ 803.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(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. FDA will disclose to a patient who requests a report, 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 voluntarily submitting an adverse event report.

(c) FDA may not disclose the identity of a device user facility which 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 which is the subject of a report required 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.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.10 General description of reports required from user facilities, importers, and manufacturers.

(a) *Device user facilities.* User facilities must submit the following reports, which are described more fully in subpart C of this part.

(1) User facilities must submit MDR reports of individual adverse events within 10 days after the user facility becomes aware of an MDR reportable event as described in §§803.30 and 803.32.

(i) User facilities must submit reports of device-related deaths to FDA and to the manufacturer, if known.

(ii) User facilities must submit reports of device-related serious injuries to manufacturers, or to FDA, if the manufacturer is unknown.

(2) User facilities must submit annual reports as described in §803.33.

(b) Importers must submit MDR reports of individual adverse events within 30 days after the importer becomes aware of an MDR reportable event as described in §803.3. Importers must submit reports of device-related deaths or serious injuries to FDA and to the manufacturer and reports of malfunctions to the manufacturer.

(c) *Device manufacturers.* Manufacturers must submit the following reports as described more fully in subpart E of this part:

(1) MDR reports of individual adverse events within 30 days after the manufacturer becomes aware of a reportable

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death, serious injury, or malfunction as described in §§ 803.50 and 803.52.

(2) MDR reports of individual adverse events within 5 days of:

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

(ii) Becoming aware of an MDR reportable event for which FDA has made a written request, as described in § 803.53.

(3) Annual baseline reports as described in § 803.55.

(4) Supplemental reports if they obtain information that was not provided in an initial report as described in § 803.56.

(5) Annual certification to FDA of the number of MDR reports filed during the preceding year as described in § 803.57.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20875; from the Food and Drug Administration, MEDWATCH (HF-2), 5600 Fishers Lane, Rockville, MD 20857, 301-827-7240; from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health (HFZ-220), 1350 Piccard Dr. Rockville, MD 20850, FAX 301-443-8818; or from <http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html> on the Internet.

[65 FR 17136, Mar. 31, 2000]

§ 803.12 Where to submit reports.

(a) Any written report or additional information required under this part shall be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, PO Box 3002, Rockville, MD 20847-3002.

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(b) Each report and its envelope shall be specifically identified, e.g., "User Facility Report," "Annual Report," "Importer Report," "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Emergency Operations Branch (HFC-162), Office of Regional Operations, at 301-443-1240, and should be followed by the submission of a FAX report to 301-443-3757.

(d) A voluntary telephone report may be submitted to, or information regarding voluntary reporting may be obtained from, the MEDWATCH hotline at 800-FDA-1088.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 4119, Jan. 26, 2000]

§ 803.13 English reporting requirement.

(a) All reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

(b) All reports required in this part which are submitted on an electronic medium shall be submitted to FDA in a manner consistent with § 803.14.

§ 803.14 Electronic reporting.

(a) Any report required by this part may be submitted electronically with prior written consent from FDA. Such consent is revocable. Electronic report submissions include alternative reporting media (magnetic tape, disc, etc.) and computer-to-computer communication.

(b) Any electronic report meeting electronic reporting standards, guidance documents, or other procedures developed by the agency for MDR reporting will be deemed to have prior approval for use.

[60 FR 63597, Dec. 11, 1995, as amended at 65 FR 56480, Sept. 19, 2000]

§ 803.15 Requests for additional information.

(a) FDA may determine that protection of the public health requires additional or clarifying information for medical device reports submitted to