

or PMA number, if applicable, and whether the device is currently the subject of an approved post-market study under section 522 of the act;

(7) Date the device was initially marketed and, if applicable, the date on which the manufacturer ceased marketing the device;

(8) Shelf life, if applicable, and expected life of the device;

(9) The number of devices manufactured and distributed in the last 12 months and, an estimate of the number of devices in current use; and

(10) Brief description of any methods used to estimate the number of devices distributed and the method used to estimate the number of devices in current use. If this information was provided in a previous baseline report, in lieu of resubmitting the information, it may be referenced by providing the date and product identification for the previous baseline report.

EFFECTIVE DATE NOTE: At 61 FR 39869, July 31, 1996, in §803.55, paragraphs (b)(9) and (10) were stayed indefinitely.

§803.56 Supplemental reports.

When a manufacturer obtains information required under this part that was not provided because it was not known or was not available when the initial report was submitted, the manufacturer shall submit to FDA the supplemental information within 1 month following receipt of such information. In supplemental reports, the manufacturer shall:

(a) Indicate on the form and the envelope, that the reporting form being submitted is a supplemental report. If the report being supplemented is an FDA Form 3500A report, the manufacturer must select, in Item H-2, the appropriate code for the type of supplemental information being submitted;

(b) Provide the appropriate identification numbers of the report that will be updated with the supplemental information, e.g., original manufacturer report number and user facility report number, if applicable;

(c) For reports that cross reference previous reports, include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s).

§803.57 Annual certification.

(a) All manufacturers required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under §803.14. The date for submission of certification coincides with the date for the firm's annual registration, as designated in §807.21 of this chapter. Foreign manufacturers shall submit their certification by the date on which they would be required to register under §807.21 of this chapter if they were domestic manufacturers. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The manufacturer shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A manufacturer may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or manufacturing sites owned by the firm. In this circumstance, the firm may designate more than one certifying official, each of whom will sign a certification statement pertaining to his/her respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the reporting site and whether the firm is a manufacturer;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for each manufacturing site covered by the certification and the number of reports submitted for devices manufactured at each site;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under this part;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the reporting site submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

(d) The name of the manufacturer and the registration number submitted under paragraph (c)(1) of this section shall be the same as the reporting site that submitted the reports required by §§ 803.52, 803.53, and 803.55. Multireporting site manufacturers who choose to certify centrally must identify the reporting sites, by registration number and name covered by the certification, and provide the information required by paragraphs (c)(2) and (c)(3) of this section for each reporting site.

[62 FR 13306, Mar. 20, 1997]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.57 was stayed indefinitely.

§ 803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with §807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and §807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§ 803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation

and evaluation of the event to comport with the requirements of §803.50;

(3) Certify in accordance with §803.57;

(4) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(5) Maintain complaint files in accordance with §803.18; and

(6) Register, list, and submit pre-market notifications in accordance with part 807 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.58 was stayed indefinitely.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

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AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 58 FR 46519, Sept. 1, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 804.1 Scope.

(a) FDA is requiring medical device distributors to report deaths, serious illnesses, and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, device distributors are required to establish and maintain complaint files