

(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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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

or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

**§ 804.3 Definitions.**

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b)-(c) [Reserved]

(d) *Distributor* means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 804.3(k).

(e) *Distributor Report Number* means the number that uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports shall use their seven digit FDA registration number, calendar year that the report is received, and a sequence number. For example, the complete number will appear as follows: 1234567-1991-0001. Distributor report numbers shall also be required on FDA form 3500A.

(f) *FDA* means the Food and Drug Administration.

(g) [Reserved]

(h) *Incident files* are those files containing documents or other information, which are related to adverse events that may have been caused by a device.

(i) *Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness* means information, including professional, scientific, or medical facts, observations,

or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

(j) *Malfunction* means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(k) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically, biologically, or by other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(l) *MDR* means medical device report.

(m) *MDR reportable event* means: