

panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

“Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.”

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling:

“The Packaging of This Product Contains Dry Natural Rubber.”

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.—

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term “hypoallergenic” on their labeling.

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with §10.30 of this chapter.

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U.S.C. 321(n) and 352(a), (c), and (f)).

[62 FR 51029, Sept. 30, 1997]

EFFECTIVE DATE NOTE: At 62 FR 51029, Sept. 30, 1997, §801.437 was added to subpart H, effective Sept. 30, 1998.

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

- 803.1 Scope.
- 803.3 Definitions.
- 803.9 Public availability of reports.
- 803.10 General description of reports required from user facilities and manufacturers.
- 803.11 Obtaining the forms.
- 803.12 Where to submit reports.
- 803.13 English reporting requirement.
- 803.14 Electronic reporting.
- 803.15 Requests for additional information.
- 803.16 Disclaimers.
- 803.17 Written MDR procedures.
- 803.18 Files.
- 803.19 Exemptions, variances, and alternative reporting requirements.

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

- 803.20 How to report.
- 803.21 Reporting codes.
- 803.22 When not to file.

Subpart C—User Facility Reporting Requirements

- 803.30 Individual adverse event reports; user facilities.
- 803.32 Individual adverse event report data elements.
- 803.33 Semiannual reports.

Subpart D [Reserved]

Subpart E—Manufacturer Reporting Requirements

- 803.50 Individual adverse event reports; manufacturers.
- 803.52 Individual adverse event report data elements.
- 803.53 Five-day reports.
- 803.55 Baseline reports.
- 803.56 Supplemental reports.
- 803.57 Annual certification.
- 803.58 Foreign manufacturers.

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

SOURCE: 60 FR 63597, Dec. 11, 1995, unless otherwise noted.

Subpart A—General Provisions

§803.1 Scope.

(a) This part establishes requirements for medical device reporting.

Under this part, medical device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and manufacturers must also report certain device malfunctions. Additionally, user facilities and manufacturers must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

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

[60 FR 63597, Dec. 11, 1995, as amended at 62 FR 13306, Mar. 20, 1997]

§ 803.3 Definitions.

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

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred. Device user facilities are considered to have “become aware” when medical personnel, as defined in paragraph (r) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such

information about a reportable event. Manufacturers are considered to have “become aware” of an event when:

(1) Any employee becomes aware of a reportable event that is required to be reported within 30 days, or that is required to be reported within 5 days pursuant to a written request from FDA under 803.53(b); and

(2) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (1) Failure;
- (2) Malfunction;
- (3) Improper or inadequate design;
- (4) Manufacture;
- (5) Labeling; or
- (6) User error.

(e)(1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

- (i) Basic design and performance characteristics related to device safety and effectiveness,
- (ii) Intended use and function, and
- (iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic