

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)).

NOTE TO §801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses “cold seal” adhesives.

[62 FR 51029, Sept. 30, 1997, as amended at 63 FR 46175, Aug. 31, 1998]

PART 803—MEDICAL DEVICE REPORTING

Subpart A—General Provisions

Sec.

- 803.1 What does this part cover?
- 803.3 How does FDA define the terms used in this part?
- 803.9 What information from the reports do we disclose to the public?
- 803.10 Generally, what are the reporting requirements that apply to me?
- 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?
- 803.12 Where and how do I submit reports and additional information?
- 803.13 Do I need to submit reports in English?
- 803.14 How do I submit a report electronically?
- 803.15 How will I know if you require more information about my medical device report?
- 803.16 When I submit a report, does the information in my report constitute an admission that the device caused or contributed to the reportable event?
- 803.17 What are the requirements for developing, maintaining, and implementing written MDR procedures that apply to me?
- 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?
- 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

Subpart B—Generally Applicable Requirements for Individual Adverse Event Reports

- 803.20 How do I complete and submit an individual adverse event report?
- 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?
- 803.22 What are the circumstances in which I am not required to file a report?

Subpart C—User Facility Reporting Requirements

- 803.30 If I am a user facility, what reporting requirements apply to me?
- 803.32 If I am a user facility, what information must I submit in my individual adverse event reports?
- 803.33 If I am a user facility, what must I include when I submit an annual report?

Subpart D—Importer Reporting Requirements

- 803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?
- 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

Subpart E—Manufacturer Reporting Requirements

- 803.50 If I am a manufacturer, what reporting requirements apply to me?
- 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?
- 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?
- 803.55 I am a manufacturer, in what circumstances must I submit a baseline report, and what are the requirements for such a report?
- 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?
- 803.58 Foreign manufacturers.

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

SOURCE: 70 FR 9519, July 13, 2005, unless otherwise noted

Subpart A—General Provisions

§ 803.1 What does this part cover?

(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup and baseline reports. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical

device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.

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

§ 803.3 How does FDA define the terms used in this part?

Some of the terms we use in this part are specific to medical device reporting and reflect the language used in the statute (law). Other terms are more general and reflect our interpretation of the law. This section defines the following terms as used in this part:

Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, as amended.

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.

Become aware means that an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

(1) If you are a device user facility, you are considered to have “become aware” when medical personnel, as defined in this section, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.

(2) If you are a manufacturer, you are considered to have become aware of an