

product, the manufacturer must document and provide, upon request, an appropriate justification for the application of the testing data to the variation of the tested product.

(h) If a latex condom contains a spermicide, and the expiration date based on spermicidal stability testing is different from the expiration date based upon latex integrity testing, the product shall bear only the earlier expiration date.

(i) The time period upon which the expiration date is based shall start with the date of packaging.

(j) As provided in part 820 of this chapter, all testing data must be retained in each company's files, and shall be made available upon request for inspection by the Food and Drug Administration.

(k) Any latex condom not labeled with an expiration date as required by paragraph (c) of this section, and initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a) and (f) of Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n) and 352(a) and (f)).

[62 FR 50501, Sept. 26, 1997]

§ 801.437 User labeling for devices that contain natural rubber.

(a) Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and protect the public health.

(b) This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

(1) The term "natural rubber latex" means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Prod-

ucts are formed from natural rubber latex by dipping, extruding, or coating.

(2) The term "dry natural rubber" means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping.

(3) The term "contacts humans" means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient.

(c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this section. Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(c)).

(d) Devices 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: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper.

(e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling:

"This Product Contains Dry Natural Rubber."

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display

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 Scope.
 - 803.3 Definitions.
 - 803.9 Public availability of reports.
 - 803.10 General description of reports required from user facilities, importers, 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 and distributor records.
 - 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 Annual reports.

Subpart D—Importer Reporting Requirement

- 803.40 Individual adverse event reporting requirements; importers.
- 803.42 Individual adverse event report data elements.

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.
- 803.58 Foreign manufacturers.

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

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