

submitted in accordance with the requirements of §10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the FEDERAL REGISTER.

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under sections 201(n), 502 (a) and (f) of the act.

(Information collection requirements contained in paragraphs (e) and (f) were approved by the Office of Management and Budget under control number 0910-0257)

[47 FR 26989, June 22, 1982, as amended at 54 FR 43771, Oct. 26, 1989; 55 FR 17600, Apr. 26, 1990; 65 FR 3586, Jan. 24, 2000; 65 FR 44436, July 18, 2000; 65 FR 62284, Oct. 18, 2000]

§ 801.433 Warning statements for prescription and restricted device products containing or manufactured with chlorofluorocarbons or other ozone-depleting substances.

(a)(1) All prescription and restricted device products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall, except as provided in paragraph (b) of this section, bear the following warning statement:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and under-

stood by consumers under normal conditions of purchase.

(b)(1) For prescription and restricted device products, the following alternative warning statement may be used:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

This product contains [or is manufactured with, if applicable] *[insert name of substance]*, a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

(2) The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 CFR part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

(3) If the warning statement in paragraph (b)(1) of this section is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the "How supplied" section, which describes special handling and storage conditions on the physician labeling:

NOTE: The indented statement below is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFC's) [or name of other class I substance, if applicable]:

WARNING: Contains [or Manufactured with, if applicable] *[insert name of substance]*, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.

(c) This section does not replace or relieve a person from any requirements imposed under 40 CFR part 82.

[61 FR 20101, May 3, 1996]

§ 801.435 User labeling for latex condoms.

(a) This section applies to the subset of condoms as identified in § 884.5300 of this chapter, and condoms with spermicidal lubricant as identified in § 884.5310 of this chapter, which products are formed from latex films.

(b) Data show that the material integrity of latex condoms degrade over time. To protect the public health and minimize the risk of device failure, latex condoms must bear an expiration date which is supported by testing as described in paragraphs (d) and (h) of this section.

(c) The expiration date, as demonstrated by testing procedures required by paragraphs (d) and (h) of this section, must be displayed prominently and legibly on the primary packaging (i.e., individual package), and higher levels of packaging (e.g., boxes of condoms), in order to ensure visibility of the expiration date by consumers.

(d) Except as provided under paragraph (f) of this section, the expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the product have been subjected to each of the following conditions:

(1) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days;

(2) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between 40 and 50 °C (plus or minus 2 °C) for 90 days; and

(3) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between 15 and 30 °C for the lifetime of the product (real time storage).

(e) If a product fails the physical and mechanical integrity tests commonly used by industry after the completion of the accelerated storage tests described in paragraphs (d)(1) and (d)(2) of this section, the product expiration date must be demonstrated by real time storage conditions described in paragraph (d)(3) of this section. If all of the products tested after storage at temperatures as described in paragraphs (d)(1) and (d)(2) of this section pass the manufacturer's physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging. If the extrapolated expiration date under paragraphs (d)(1) and (d)(2) of this section is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at the end of the stated expiration period as described in paragraph (d)(3) of this section. If the data from tests following real time storage described in paragraph (d)(3) of this section fails to confirm the extrapolated expiration date, the manufacturer must, at that time, relabel the product to reflect the actual shelf life.

(f) Products that already have established shelf life data based upon real time storage and testing and have such storage and testing data available for inspection are not required to confirm such data using accelerated and intermediate aging data described in paragraphs (d)(1) and (d)(2) of this section. If, however, such real time expiration dates were based upon testing of products that were not first left unpackaged for the maximum amount of time as described in paragraph (d)(3) of this section, the real time testing must be confirmed by testing products consistent with the requirements of paragraph (d)(3) of this section. This testing shall be initiated no later than the effective date of this regulation. Until the confirmation testing in accordance with paragraph (d)(3) of this section is completed, the product may remain on the market labeled with the expiration date based upon previous real time testing.

(g) If a manufacturer uses testing data from one product to support expiration dating on any variation of that