

Subpart C—Labeling

§ 350.50 Labeling of antiperspirant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiperspirant.”

(b) *Indications.* The labeling of the product states, under the heading “Uses,” the phrase listed in paragraph (b)(1) of this section and may contain any additional phrases listed in paragraphs (b)(2) through (b)(5) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in paragraphs (b)(1) through (b)(5) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) For any product, the labeling states [select one of the following: “decreases,” “lessens,” or “reduces”] “underarm” [select one of the following: “dampness,” “perspiration,” “sweat,” “sweating,” or “wetness”].

(2) The labeling may state “also [select one of the following: ‘decreases,’ ‘lessens,’ or ‘reduces’] underarm [select one of the following: ‘dampness,’ ‘perspiration,’ ‘sweat,’ ‘sweating,’ or ‘wetness’] due to stress”.

(3) For products that demonstrate standard effectiveness (20 percent sweat reduction) over a 24-hour period, the labeling may state [select one of the following: “all day protection,” “lasts all day,” “lasts 24 hours,” or “24 hour protection”].

(4) For products that demonstrate extra effectiveness (30 percent sweat reduction), the labeling may state “extra effective”.

(5) Products that demonstrate extra effectiveness (30 percent sweat reduction) sustained over a 24-hour period may state the claims in paragraphs (b)(3) and (b)(4) of this section either individually or combined, e.g., “24 hour extra effective protection”, “all day

extra effective protection,” “extra effective protection lasts 24 hours,” or “extra effective protection lasts all day”.

(c) *Warnings.* The labeling of the product contains the following statements under the heading “Warnings”:

(1) “Do not use on broken skin”.

(2) “Stop use if rash or irritation occurs”.

(3) “Ask a doctor before use if you have kidney disease”.

(4) *For products in an aerosolized dosage form.* (i) “When using this product [bullet]¹ keep away from face and mouth to avoid breathing it”.

(ii) The warning required by § 369.21 of this chapter for drugs in dispensers pressurized by gaseous propellants.

(d) *Directions.* The labeling of the product contains the following statement under the heading “Directions”: “apply to underarms only”.

EFFECTIVE DATE NOTE: At 69 FR 61149, Oct. 15, 2004, the limitation of the enhanced duration claim to 24 hours (21 CFR 350.50 (b)(3) and (b) (5)) was stayed until further notice.

Subpart D—Guidelines for Effectiveness Testing

§ 350.60 Guidelines for effectiveness testing of antiperspirant drug products.

An antiperspirant in finished dosage form may vary in degree of effectiveness because of minor variations in formulation. To assure the effectiveness of an antiperspirant, the Food and Drug Administration is providing guidelines that manufacturers may use in testing for effectiveness. These guidelines are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These guidelines are available on the FDA’s Web site at <http://www.fda.gov/cder/otc/index.htm> or on request for a nominal charge by submitting a Freedom of Information (FOI) request in writing to FDA’s FOI Staff (HFI-35), 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857.

¹ See § 201.66(b)(4) of this chapter for definition of bullet.