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PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 34291, June 9, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 350.1 Scope.

(a) An over-the-counter antiperspirant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

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

§ 350.3 Definition.

As used in this part:

Antiperspirant. A drug product applied topically that reduces the production of perspiration (sweat) at that site.

Subpart B—Active Ingredients

§ 350.10 Antiperspirant active ingredients.

The active ingredient of the product consists of any of the following within the established concentration and dosage formulation. Where applicable, the ingredient must meet the aluminum to chloride, aluminum to zirconium, and aluminum plus zirconium to chloride atomic ratios described in the U.S. Pharmacopeia-National Formulary. The concentration of ingredients in paragraphs (b) through (j) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in an aerosol or nonaerosol dosage form. The concentration of ingredients in paragraphs (k) through (r) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in a nonaerosol dosage form. The labeled declaration of the percentage of the active ingredient should exclude any water, buffer components, or propellant.

(a) Aluminum chloride up to 15 percent, calculated on the hexahydrate form, in an aqueous solution nonaerosol dosage form.

(b) Aluminum chlorohydrate up to 25 percent.

(c) Aluminum chlorohydrex polyethylene glycol up to 25 percent.

(d) Aluminum chlorohydrex propylene glycol up to 25 percent.

(e) Aluminum dichlorohydrate up to 25 percent.

(f) Aluminum dichlorohydrex polyethylene glycol up to 25 percent.

(g) Aluminum dichlorohydrex propylene glycol up to 25 percent.

(h) Aluminum sesquichlorohydrate up to 25 percent.

(i) Aluminum sesquichlorohydrex polyethylene glycol up to 25 percent.

(j) Aluminum sesquichlorohydrex propylene glycol up to 25 percent.

(k) Aluminum zirconium octachlorohydrate up to 20 percent.

(l) Aluminum zirconium octachlorohydrex gly up to 20 percent.

(m) Aluminum zirconium pentachlorohydrate up to 20 percent.

(n) Aluminum zirconium pentachlorohydrex gly up to 20 percent.

(o) Aluminum zirconium tetrachlorohydrate up to 20 percent.

(p) Aluminum zirconium tetrachlorohydrex gly up to 20 percent.

(q) Aluminum zirconium trichlorohydrate up to 20 percent.

(r) Aluminum zirconium trichlorohydrex gly up to 20 percent.

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 Division of Freedom of Information (address is located on

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

the agency's web site at *http://www.fda.gov*.

[68 FR 34291, June 9, 2003, as amended at 76 FR 31470, June 1, 2011; 79 FR 68115, Nov. 14, 2014]

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

Subpart A—General Provisions

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352.1 Scope.
352.3 Definitions.

Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.
352.20 Permitted combinations of active ingredients.

Subpart C—Labeling

352.50 Principal display panel of all sunscreen drug products.
352.52 Labeling of sunscreen drug products.
352.60 Labeling of permitted combinations of active ingredients.

Subpart D—Testing Procedures

352.70 Standard sunscreen.
352.71 Light source (solar simulator).
352.72 General testing procedures.
352.73 Determination of SPF value.
352.76 Determination if a product is water resistant or very water resistant.
352.77 Test modifications.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 64 FR 27687, May 21, 1999, unless otherwise noted.

EFFECTIVE DATE NOTE: At 68 FR 33381, June 4, 2003, part 352 was stayed until further notice, effective June 4, 2004.

Subpart A—General Provisions

§ 352.1 Scope.

(a) An over-the-counter sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 352.3 Definitions.

As used in this part:

(a) *Minimal erythema dose (MED).* The quantity of erythema-effective energy (expressed as Joules per square meter) required to produce the first perceptible, redness reaction with clearly defined borders.

(b) *Product category designation (PCD).* A labeling designation for sunscreen drug products to aid in selecting the type of product best suited to an individual's complexion (pigmentation) and desired response to ultraviolet (UV) radiation.

(1) *Minimal sun protection product.* A sunscreen product that provides a sun protection factor (SPF) value of 2 to under 12.

(2) *Moderate sun protection product.* A sunscreen product that provides an SPF value of 12 to under 30.

(3) *High sun protection product.* A sunscreen product that provides an SPF value of 30 or above.

(c) *Sunscreen active ingredient.* An active ingredient listed in § 352.10 that absorbs, reflects, or scatters radiation in the UV range at wavelengths from 290 to 400 nanometers.

(d) *Sun protection factor (SPF) value.* The UV energy required to produce an MED on protected skin divided by the UV energy required to produce an MED on unprotected skin, which may also be defined by the following ratio: SPF value = MED (protected skin (PS))/MED (unprotected skin (US)), where MED (PS) is the minimal erythema dose for protected skin after application of 2 milligrams per square centimeter of the final formulation of the sunscreen product, and MED (US) is the minimal erythema dose for unprotected skin, *i.e.*, skin to which no sunscreen product has been applied. In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a UV radiation filter.

Subpart B—Active Ingredients

§ 352.10 Sunscreen active ingredients.

The active ingredient of the product consists of any of the following, within the concentration specified for each ingredient, and the finished product provides a minimum SPF value of not less