

[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.

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

Subpart A—General Provisions

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352.1 Scope.
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Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.
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¹See § 201.66(b)(4) of this chapter for definition of bullet.

Subpart C—Labeling

352.50 Principal display panel of all sunscreen drug products.
352.52 Labeling of sunscreen drug products.
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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.