

§ 350.60

[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

Sec.

352.1 Scope.

352.3 Definitions.

Subpart B—Active Ingredients

352.10 Sunscreen active ingredients.

352.20 Permitted combinations of active ingredients.

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

21 CFR Ch. I (4-1-07 Edition)

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: $SPF \text{ value} = \text{MED (protected skin (PS))} / \text{MED (unprotected skin (US))}$, 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 than 2 as measured by the testing procedures established in subpart D of this part:

- (a) Aminobenzoic acid (PABA) up to 15 percent.
- (b) Avobenzone up to 3 percent.
- (c) Cinoxate up to 3 percent.
- (d) [Reserved]
- (e) Dioxybenzone up to 3 percent.
- (f) Homosalate up to 15 percent.
- (g) [Reserved]
- (h) Menthyl anthranilate up to 5 percent.
- (i) Octocrylene up to 10 percent.
- (j) Octyl methoxycinnamate up to 7.5 percent.
- (k) Octyl salicylate up to 5 percent.
- (l) Oxybenzone up to 6 percent.
- (m) Padimate O up to 8 percent.

(n) Phenylbenzimidazole sulfonic acid up to 4 percent.

(o) Sulisobenzone up to 10 percent.

(p) Titanium dioxide up to 25 percent.

(q) Trolamine salicylate up to 12 percent.

(r) Zinc oxide up to 25 percent.

[64 FR 27687, May 21, 1999]

EFFECTIVE DATE NOTE: At 67 FR 41823, June 20, 2002, §352.10 was amended by revising paragraphs (f) through (n), effective Sept. 1, 2002. This amendment could not be incorporated because at 66 FR 67485, Dec. 31, 2001 the effective date was stayed until further notice. For the convenience of the user, the text is set forth as follows:

§ 352.10 Sunscreen active ingredients.

- * * * * *
- (f) Ensulizole up to 4 percent.
- (g) Homosalate up to 15 percent.
- (h) [Reserved]
- (i) Meradimate up to 5 percent.
- (j) Octinoxate up to 7.5 percent.
- (k) Octisalate up to 5 percent.
- (l) Octocrylene up to 10 percent.
- (m) Oxybenzone up to 6 percent.
- (n) Padimate O up to 8 percent.
- * * * * *

§ 352.20 Permitted combinations of active ingredients.

The SPF of any combination product is measured by the testing procedures established in subpart D of this part.

(a) *Combinations of sunscreen active ingredients.* (1) Two or more sunscreen active ingredients identified in §352.10(a), (c), (e), (f), and (h) through (r) may be combined with each other in a single product when used in the concentrations established for each ingredient in §352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(2) Two or more sunscreen active ingredients identified in §352.10(b), (c), (e), (f), (i) through (l), (o), and (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in §352.10. The concentration of each active ingredient must be sufficient to