

§ 352.1

2001. At 65 FR 36319, June 8, 2000, the effective date was delayed through Dec. 31, 2002.

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 centi-

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meter 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) Avobenzene 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) Sulisobenzene 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.

§ 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 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.

(b)-(c) [Reserved]

Subpart C—Labeling

§ 352.50 Principal display panel of all sunscreen drug products.

In addition to the statement of identity required in §352.52, the following labeling statements shall be prominently placed on the principal display panel:

(a) *For products that do not satisfy the water resistant or very water resistant sunscreen product testing procedures in § 352.76.* (1) *For products with SPF values up to 30.* “SPF (insert tested SPF value of the product up to 30).”

(2) *For products with SPF values over 30.* “SPF 30” (select one of the following: “plus” or “+”). Any statement accompanying the marketed product that states a specific SPF value above 30 or similar language indicating a person can stay in the sun more than 30 times longer than without sunscreen will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) *For products that satisfy the water resistant sunscreen product testing procedures in § 352.76.* (1) (Select one of the following: “Water,” “Water/Sweat,” or “Water/Perspiration”) “Resistant.”

(2) “SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the water resistant sunscreen product testing procedures in § 352.76).”

(c) *For products that satisfy the very water resistant sunscreen product testing procedures in § 352.76.* (1) “Very” (select one of the following: “Water,” “Water/Sweat,” or “Water/Perspiration”) “Resistant.”

(2) “SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the very water resistant sunscreen product testing procedures in § 352.76).”

§ 352.52 Labeling of sunscreen 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 a “sunscreen.”

(b) *Indications.* The labeling of the product states, under the heading “Uses,” all of the phrases listed in paragraph (b)(1) of this section that are applicable to the product and may contain any of the additional phrases listed in paragraph (b)(2) of this section, as appropriate. Other truthful and non-misleading statements, describing only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of 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 products containing any ingredient in § 352.10.* (i) “[bullet]¹ helps prevent sunburn [bullet] higher SPF gives more sunburn protection”.

(ii) *For products that satisfy the water resistant testing procedures identified in § 352.76.* “[bullet] retains SPF after 40 minutes of” (select one or more of the following: “activity in the water,” “sweating,” or “perspiring”).

(iii) *For products that satisfy the very water resistant testing procedures identified in § 352.76.* “[bullet] retains SPF after 80 minutes of” (select one or more of the following: “activity in the water,” “sweating,” or “perspiring”).

¹ See § 201.66(b)(4) of this chapter.