

§ 349.79

§ 349.79 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of this part.

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of this part.

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of this part. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

§ 349.80 Professional labeling.

The labeling of any OTC ophthalmic demulcent drug product provided to health professionals (but not to the general public) may contain instructions for the use of these products in professional eye examinations (i.e. gonioscopy, electroretinography).

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

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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 64 FR 27687, May 21, 1999, part 352 was added, effective May 21, 2001. At 65 FR 36319, June 8, 2000, the effective date was delayed until Dec. 31, 2002. At 66 FR 67485, Dec. 31, 2001, the effective date was stayed until further notice.

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: $SPF \text{ value} = \frac{MED \text{ (protected skin (PS))}}{MED \text{ (unprotected skin (US))}}$, 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) 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.

[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:

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- (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.
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§ 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