

§ 352.50

21 CFR Ch. I (4–1–07 Edition)

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) *Combinations of sunscreen and skin protectant active ingredients.* Any single sunscreen active ingredient or any permitted combination of sunscreen active ingredients when used in the concentrations established for each ingredient in §352.10 may be combined with one or more skin protectant active ingredients identified in §347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of this chapter. The concentration of each sunscreen 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, and the product must be labeled according to §352.60.

(c) [Reserved]

[64 FR 27687, May 21, 1999, as amended at 68 FR 33380, June 4, 2003]

EFFECTIVE DATE NOTE: At 67 FR 41823, June 20, 2002, §352.20 was amended by revising paragraphs (a)(1) through (a)(2), 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:

§352.20 Permitted combinations of active ingredients.

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(a) *Combinations of sunscreen active ingredients.* (1) Two or more sunscreen active ingredients identified in §352.10(a), (c), (e), (f), (g), and (i) 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), (g), (j) through (m), (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.

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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).”