

"Uses," the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (b). Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or 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 Federal Food, Drug, and Cosmetic Act (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. In addition to the required information identified in this paragraph (b), the labeling of the product may contain any of the "other allowable statements" that are identified in the applicable monographs, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(1) *Combinations of skin protectant and external analgesic active ingredients in § 347.20(b).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), any or all of the allowable indications for external analgesic drug products may be used if the product is labeled for concurrent symptoms.

(2) *Combinations of skin protectant and first aid antiseptic active ingredients in § 347.20(c).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(1), the required indications for first aid antiseptic drug products should be used.

(3) *Combinations of skin protectant and sunscreen active ingredients in § 347.20(d).* In addition to any or all of the indications for skin protectant drug products in § 347.50(b)(2)(i), the required indications for sunscreen drug products should be used and any or all of the additional indications for sunscreen drug products may be used.

(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 section of the applicable OTC drug monographs unless otherwise stated in this paragraph (c).

(1) *For combinations containing a skin protectant and a sunscreen*

*identified in §§ 347.20(d) and 352.20(b).* The warnings for sunscreen drug products in § 352.60(c) of this chapter are used.

(2) [Reserved]

(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 the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *For combinations containing a skin protectant and a sunscreen identified in §§ 347.20(d) and 352.20(b).* The directions for sunscreen drug products in § 352.60(d) of this chapter are used.

(2) [Reserved]

## PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 9. The authority citation for 21 CFR part 352 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 10. The stay of 21 CFR part 352 published at 66 FR 67485, December 31, 2001, is lifted.

■ 11. Section 352.20 is amended by adding paragraph (b) to read as follows:

### § 352.20 Permitted combinations of active ingredients.

\* \* \* \* \*

(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.

■ 12. Section 352.52 is amended by revising the heading in paragraphs (c)(2) and (d)(4) and by revising paragraphs (f)(1)(ii) and (f)(1)(vi) to read as follows:

### § 352.52 Labeling of sunscreen drug products.

\* \* \* \* \*

(c) \* \* \*

(2) *For products containing any ingredient identified in § 352.10 marketed as a lip protectant or lipstick.*

\* \* \* \* \*

(d) \* \* \*

(4) *For products marketed as a lip protectant or lipstick.* \* \* \*

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: "Use [in bold type] helps protect against sunburn." For a lip protectant product, the heading and the indication required by § 201.66(c)(4) may be limited to: "Use [in bold type] helps protect against sunburn and chapped lips."

\* \* \* \* \*

(vi) For a lip protectant product or lipstick, the warnings "Keep out of eyes" in § 352.52(f)(1)(iv) and "Keep out of reach of children" in § 352.52(f)(1)(v) and the directions in § 352.52(d) may be omitted.

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13. Section 352.60 is amended by revising paragraphs (b)(2), (c), and (d) to read as follows:

### § 352.60 Labeling of permitted combinations of active ingredients.

\* \* \* \* \*

(b) \* \* \*

(2) For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), any or all of the applicable indications for sunscreens in § 352.52(b) and the indication for skin protectants in § 347.50(b)(2)(i) of this chapter should be used. For products marketed as a lip protectant, the indication in § 352.52(f)(1)(ii) should be used.

(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 section of the applicable OTC drug monographs, except that the warning for skin protectants in § 347.50(c)(3) of this chapter is not required for permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). For products marketed as a lip protectant or lipstick, § 352.52(f)(1)(iii), (f)(1)(iv) (except