

§ 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).”

§ 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

¹ See § 201.66(b)(4) of this chapter.

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”).

(2) *Additional indications.* In addition to the indications provided in paragraph (b)(1) of this section, the following may be used for products containing any ingredient in § 352.10:

(i) *For products that provide an SPF of 2 to under 12.* Select one or both of the following: “[bullet]” (select one of the following: “provides minimal,” “provides minimum,” “minimal,” or “minimum”) “protection against” (select one of the following: “sunburn” or “sunburn and tanning”), or “[bullet] for skin that sunburns minimally”.

(ii) *For products that provide an SPF of 12 to under 30.* Select one or both of the following: “[bullet]” (select one of the following: “provides moderate” or “moderate”) “protection against” (select one of the following: “sunburn” or “sunburn and tanning”), or “[bullet] for skin that sunburns easily”.

(iii) *For products that provide an SPF of 30 or above.* Select one or both of the following: “[bullet]” (select one of the following: “provides high” or “high”) “protection against” (select one of the following: “sunburn” or “sunburn and tanning”), or “[bullet] for skin highly sensitive to sunburn”.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings:”

(1) *For products containing any ingredient in § 352.10.* (i) “When using this product [bullet] keep out of eyes. Rinse with water to remove.”

(ii) “Stop use and ask a doctor if [bullet] rash or irritation develops and lasts”.

(2) *For products containing any ingredient identified in § 352.10 marketed as a lip protectant or lipstick.* The external use only warning in § 201.66(c)(5)(i) of this chapter and the warning in paragraph (c)(1)(i) of this section are not required.

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the head-

ing “Directions.” More detailed directions applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.) may also be included.

(1) *For products containing any ingredient in § 352.10.* (i) “[bullet] apply” (select one or more of the following, as applicable: “liberally,” “generously,” “smoothly,” or “evenly”) “(insert appropriate time interval, if a waiting period is needed) before sun exposure and as needed”.

(ii) “[bullet] children under 6 months of age: ask a doctor”.

(2) *In addition to the directions provided in § 352.52(d)(1), the following may be used for products containing any ingredient in § 352.10.* “[bullet] reapply as needed or after towel drying, swimming, or” (select one of the following: “sweating” or “perspiring”).

(3) *If the additional directions provided in § 352.52(d)(2) are used, the phrase “and as needed” in § 352.52(d)(1) is not required.*

(4) *For products marketed as a lip protectant or lipstick.* The directions in paragraphs (d)(1) and (d)(2) of this section are not required.

(e) *Statement on product performance—*
(1) *For products containing any ingredient identified in § 352.10, the following PCD labeling claims may be used under the heading “Other information” or anywhere outside of the “Drug Facts” box or enclosure.*

(i) *For products containing active ingredient(s) that provide an SPF value of 2 to under 12.* (Select one of the following: “minimal” or “minimum”) “sun protection product.”

(ii) *For products containing active ingredient(s) that provide an SPF value of 12 to under 30.* “moderate sun protection product.”

(iii) *For products containing active ingredient(s) that provide an SPF value of 30 or above.* “high sun protection product.”

(2) *For products containing any ingredient identified in § 352.10, the following labeling statement may be used under the heading “Other information” or anywhere outside of the “Drug Facts” box or enclosure.* “Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.” Any

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variation of this statement will cause the product to be misbranded under section 502 of the act.

(f) *Products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes) and that meet the criteria established in § 201.66(d)(10) of this chapter.* The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the title, headings, and information described in § 201.66(c)(1), (c)(3), and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:

(i) The active ingredients (§ 201.66(c)(2) of this chapter) shall be listed in alphabetical order.

(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."

(iii) The "external use only" warning in § 201.66(c)(5)(i) of this chapter may be omitted.

(iv) The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) of this chapter may be omitted, provided the information after the heading "Warnings" states: "Keep out of eyes." and "Stop use if skin rash occurs."

(v) The warning in § 201.66(c)(5)(x) of this chapter may be limited to the following: "Keep out of reach of children."

(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.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(1), (c)(3), and (c)(7), and the

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horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

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

§ 352.60 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 the applicable OTC drug monographs. 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 the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "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. 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 by § 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.

(1) In addition, the labeling of the product may contain any of the "other allowable statements" that are identified in the applicable monographs.