

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.303 Definitions.

As used in this subpart:

(a) *Acne*. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes.

(b) *Acne blemish*. A flaw in the skin resulting from acne.

(c) *Acne drug product*. A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

(d) *Acne pimple*. A small, prominent, inflamed elevation of the skin resulting from acne.

(e) *Blackhead*. A condition of the skin that occurs in acne and is characterized by a black tip.

(f) *Whitehead*. A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin.

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following when labeled according to § 333.350.

(a) Resorcinol 2 percent when combined in accordance with § 333.320(a).

(b) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b).

(c) Salicylic acid 0.5 to 2 percent.

(d) Sulfur 3 to 10 percent.

(e) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

EFFECTIVE DATE NOTE: At 75 FR 9776, Mar. 4, 2010, § 333.310 was revised, effective Mar. 4, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following:

(a) Benzoyl peroxide, 2.5 to 10 percent.

(b) Resorcinol, 2 percent, when combined with sulfur in accordance with § 333.320(a).

(c) Resorcinol monoacetate, 3 percent, when combined with sulfur in accordance with § 333.320(b).

(d) Salicylic acid, 0.5 to 2 percent.

(e) Sulfur, 3 to 10 percent.

(f) Sulfur, 3 to 8 percent, when combined with resorcinol or resorcinol monoacetate in accordance with § 333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(a) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(b) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

EFFECTIVE DATE NOTE: At 75 FR 9776, Mar. 4, 2010, § 333.320 was revised, effective Mar. 4, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(b) may be combined with sulfur identified in § 333.310(f).

(b) Resorcinol monoacetate identified in § 333.310(c) may be combined with sulfur identified in § 333.310(f).

§ 333.350 Labeling of acne 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 an “acne medication,” “acne treatment,” “acne medication” (insert dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”), or “acne treatment” (insert dosage form, e.g., “cream,” “gel,” “lotion,” or “ointment”).

(b) *Indications*. The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, 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.

(1) “For the” (select one of the following: “management” or “treatment”) “of acne.”