

tar source used and the concentration of the coal tar present in the final product.

(2) Salicylic acid, 1.8 to 3 percent.

[56 FR 63568, Dec. 4, 1991, as amended at 59 FR 4001, Jan. 28, 1994]

**§ 358.720 Permitted combinations of active ingredients.**

(a) *Combination of active ingredients for the control of dandruff.* Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(7) provided each ingredient is present within the established concentration and the product is labeled according to § 358.750.

(b) *Combination of control of dandruff and external analgesic active ingredients.* Coal tar identified in § 358.710(a)(1) may be used at a concentration of 1.8 percent coal tar solution, on a weight to volume basis, in combination with menthol, 1.5 percent, in a shampoo formulation provided the product is labeled according to § 358.760.

[72 FR 9852, Mar. 6, 2007]

**§ 358.750 Labeling of drug products for the control of dandruff, seborrheic dermatitis, or psoriasis.**

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following, as appropriate:

(1) "Dandruff (insert product form)" or "antidandruff (insert product form)".

(2) "Seborrheic dermatitis (insert product form)".

(3) "Psoriasis (insert product form)".

(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 terms listed in paragraph (b)(2) or (b)(3) 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 relief of" or "Controls") "the symptoms of" (select one or more of the following, as appropriate: "dandruff," "seborrheic dermatitis," and/or "psoriasis.")

(2) The following terms or phrases may be used in place of or in addition to the words "For the relief of" or "Controls" in the indications in paragraph (b)(1) of this section: "fights," "reduces," "helps eliminate," "helps stop," "controls recurrence of," "fights recurrence of," "helps prevent recurrence of," "reduces recurrence of," "helps eliminate recurrence of," "helps stop recurrence of."

(3) The following terms may be used in place of the words "the symptoms of" in the indications in paragraph (b)(1) of this section: ("skin" and/or "scalp," as appropriate) (select one or more of the following: "itching," "irritation," "redness," "flaking," "scaling,") "associated with."

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

(1) *For products containing any ingredient identified in § 358.710.* (i) "For external use only."

(ii) "Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water."

(iii) "If condition worsens or does not improve after regular use of this product as directed, consult a doctor."

(2) *For any product containing coal tar identified in § 358.710(a), (b), or (c).* (i) "Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application."

(ii) "Do not use for prolonged periods without consulting a doctor."

(3) *For products containing coal tar when formulated to be applied and left on the skin (e.g., creams, ointments, lotions).* "Do not use this product in or around the rectum or in the genital area or groin except on the advice of a doctor."

(4) *For products containing coal tar identified in § 358.710(c) for the control of psoriasis.* "Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription