

§ 358.701

their eggs [bullet] disinfect clothing by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] do not seal clothing in a plastic bag because nits can remain dormant for up to 30 days”.

[68 FR 75417, Dec. 31, 2003]

Subpart H—Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis

SOURCE: 56 FR 63568, Dec. 4, 1991, unless otherwise noted.

§ 358.701 Scope.

(a) An over-the-counter dandruff, seborrheic dermatitis, or psoriasis drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

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

§ 358.703 Definitions.

As used in this subpart:

(a) *Coal tar*. The tar used for medicinal purposes that is obtained as a by-product during the destructive distillation of bituminous coal at temperatures in the range of 900 °C to 1,100 °C. It may be further processed using either extraction with alcohol and suitable dispersing agents and maceration times or fractional distillation with or without the use of suitable organic solvents.

(b) *Dandruff*. A condition involving an increased rate of shedding of dead epidermal cells of the scalp.

(c) *Psoriasis*. A condition of the scalp or body characterized by irritation, itching, redness, and extreme excess shedding of dead epidermal cells.

(d) *Seborrheic dermatitis*. A condition of the scalp or body characterized by irritation, itching, redness, and excess shedding of dead epidermal cells.

(e) Selenium sulfide, micronized. Selenium sulfide that has been finely

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ground and that has a median particle size of approximately 5 micrometers (µm), with not more than 0.1 percent of the particles greater than 15 µm and not more than 0.1 percent of the particles less than 0.5 µm.

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

§ 358.710 Active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) *Active ingredients for the control of dandruff*. (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

(2) Pyrithione zinc, 0.3 to 2 percent when formulated to be applied and then washed off after brief exposure.

(3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.

(4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(6) Selenium sulfide, micronized, 0.6 percent.

(7) Sulfur, 2 to 5 percent.

(b) *Active ingredients for the control of seborrheic dermatitis*. (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal tar source used and the concentration of the coal tar present in the final product.

(2) Pyrithione zinc, 0.95 to 2 percent when formulated to be applied and then washed off after brief exposure.

(3) Pyrithione zinc, 0.1 to 0.25 percent when formulated to be applied and left on the skin or scalp.

(4) Salicylic acid, 1.8 to 3 percent.

(5) Selenium sulfide, 1 percent.

(c) *Active ingredients for the control of psoriasis*. (1) Coal tar, 0.5 to 5 percent. When a coal tar solution, derivative, or fraction is used as the source of the coal tar, the labeling shall specify the identity and concentration of the coal

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.

Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(6) provided each ingredient is present within the established concentration and the product is labeled for the control of dandruff.

EFFECTIVE DATE NOTE: At 72 FR 9852, Mar. 6, 2007, § 358.720 was revised, effective Apr. 5, 2007. For the convenience of the user, the revised text is set forth as follows:

§ 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.

§ 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