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.

§ 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 drugs unless directed to do so by a doctor.''

(5) *For products containing any ingredient identified in § 358.710(b) or (c) for the control of seborrheic dermatitis or psoriasis.* ''If condition covers a large area of the body, consult your doctor before using this product.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions.'' More detailed directions applicable to a particular product formulation may also be included.

(1) *For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated to be applied and then washed off after brief (a few minutes) exposure (e.g, shampoos, preshampoo rinses, postshampoo rinses).* ''For best results use at least twice a week or as directed by a doctor.''

(2) *For products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated so as to be applied and left on the skin or scalp (e.g., creams, ointments, lotions, hairgrooms).* ''Apply to affected areas one to four times daily or as directed by a doctor.''

(3) *For products containing active ingredients for the control of seborrheic dermatitis or psoriasis of the skin when formulated as soaps.* ''Use on affected areas in place of your regular soap.''

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 371; 42 U.S.C. 262.

§ 361.1 Radioactive drugs for certain research uses.

(a) Radioactive drugs (as defined in § 310.3(n) of this chapter) are generally recognized as safe and effective when administered, under the conditions set forth in paragraph (b) of this section, to human research subjects during the course of a research project intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry, but not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial). Certain basic research studies, e.g., studies to determine whether a drug localizes in a particular organ or fluid space and to describe the kinetics of that localization,