up to an additional 100 milligrams daily in divided doses as required. The smallest effective dose should be used. Do not exceed 300 milligrams daily. Children under 12 years of age: consult a doctor.

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A [Reserved]

Subpart B—Wart Remover Drug Products

Sec.

Subpart C [Reserved]

Subpart D—Ingrown Toenail Relief Drug Products

Subpart E [Reserved]

Subpart F—Corn and Callus Remover Drug Products

Subpart G—Pediculicide Drug Products

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

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 55 FR 33255, Aug. 14, 1990, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Wart Remover Drug Products

§ 358.101 Scope.

(a) An over-the-counter wart remover 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 of the general conditions 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.

§ 358.103 Definitions.

As used in this subpart:

(a) *Wart remover drug product.* A topical agent used for the removal of common or plantar warts.

(b) *Collodion-like vehicle.* A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) *Plaster vehicle.* A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

§ 358.110 Wart remover active ingredients.

The product consists of any of the following active ingredients within the specified concentration and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 5 to 17 percent in a collodion-like vehicle.

(c) Salicylic acid 15 percent in a karaya gum, glycol plaster vehicle.

§ 358.150 Labeling of wart remover 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 ''wart remover.''

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established 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 removal of common warts. The common wart is easily recognized by the rough 'cauliflower-like' appearance of the surface.''

(2) ''For the removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern.''

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

(1) *For products containing any ingredient identified in § 358.110.* (i) ''For external use only.''

(ii) ''Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.''

(iii) ''If discomfort persists, see your doctor.''

(iv) ''Do not use on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes.''

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g. ''extremely flammable,'' ''flammable,'' ''combustible,'' consistent with 16 CFR 1500.3(b)(10).

(ii) ''Keep away from fire or flame.''

(3) *For any product formulated in a volatile vehicle.* ''Cap bottle tightly and store at room temperature away from heat.''

(4) *For any product formulated in a collodion-like vehicle.* (i) ''If product gets into the eye, flush with water for 15 minutes.''

(ii) ''Avoid inhaling vapors.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing salicylic acid identified in § 358.110(a).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly.'' (If appropriate: ''Cut plaster to fit wart.'') ''Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks.''

(2) *For products containing salicylic acid identified in § 358.110(b).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly. Apply'' (select one of the following, as appropriate: ''one drop'' or ''small amount'') ''at a time with'' (select one of the following, as appropriate: ''applicator'' or ''brush'') ''to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks.''

(3) *For products containing salicylic acid identified in § 358.110(c).* ''Wash affected area.'' (Optional: ''May soak wart in warm water for 5 minutes.'') ''Dry area thoroughly. Gently smooth wart surface with emery file supplied.'' (If appropriate: ''Cut plaster to fit wart.'') ''Apply a drop of warm water to the wart, keeping the surrounding skin dry. Apply medicated plaster at bedtime and leave in place for at least 8 hours. In the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks.''

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

(f) The phrase ''or podiatrist'' may be used in addition to the word ''doctor'' in any of the labeling statements in this section when a product is labeled with the indication identified in § 358.150(b)(2).

[55 FR 33255, Aug. 14, 1990; 55 FR 37403, Sept. 11, 1990, as amended at 57 FR 44495, Sept. 28, 1992; 59 FR 60317, Nov. 23, 1994]

Subpart C [Reserved]

Subpart D—Ingrown Toenail Relief Drug Products

SOURCE: 68 FR 24348, May 7, 2003, unless otherwise noted.

§ 358.301 Scope.

(a) An over-the-counter ingrown toenail relief drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition 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 1 of title 21 unless otherwise noted.

§ 358.303 Definitions.

As used in this subpart:

(a) *Ingrown toenail relief drug product.* A drug product applied to an ingrown toenail that relieves pain or discomfort either by softening the nail or by hardening the nail bed.

(b) *Retainer ring.* A die cut polyethylene foam pad coated on one side with medical grade acrylic pressure-sensitive adhesive. The retainer ring has slots, center-cut completely through the foam with the cut of sufficient size to allow for localization of an active ingredient in a gel vehicle to a specific target area. The retainer ring is used with adhesive bandage strips to place over the retainer ring to hold it in place.

§ 358.310 Ingrown toenail relief active ingredient.

The active ingredient of the product is sodium sulfide 1 percent in a gel vehicle. The gel vehicle is an aqueous, semisolid system with large organic molecules interpenetrated with a liquid.

§ 358.350 Labeling of ingrown toenail relief drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the product, if any, and identifies the product as an ''ingrown toenail relief product'' or as an ''ingrown toenail discomfort reliever.''

(b) *Indications.* The labeling of the product states, under the heading ''Use,'' the following: ''for temporary relief of'' [select one or both of the following: 'pain' or 'discomfort'] ''from ingrown toenails''. Other truthful and nonmisleading statements, describing only the use that has 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 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.

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

(1) ''For external use only'' in accord with § 201.66(c)(5)(i) of this chapter.

(2) ''Do not use [bullet][1] on open sores''.

(3) ''Ask a doctor before use if you have [bullet] diabetes [bullet] poor circulation [bullet] gout''.

(4) ''When using this product [bullet] use with a retainer ring''.

(5) ''Stop use and ask a doctor if [bullet] redness or swelling of your toe increases [bullet] discharge is present around the nail [bullet] symptoms last more than 7 days or clear up and occur again within a few days''.

(d) *Directions.* The labeling of the product contains the following statements under the heading ''Directions'':

(1) ''[Bullet] adults and children 12 years and over:''

(i) ''[Bullet] wash the affected area and dry thoroughly [bullet] place retainer ring on toe with slot over the

[1] See § 201.66(b)(4) of this chapter for definition of bullet.

area where the ingrown nail and the skin meet. Smooth ring down firmly. [bullet] apply enough gel product to fill the slot in the ring [bullet] place round center section of bandage strip directly over the gel-filled ring to seal the gel in place. Smooth ends of bandage strip around toes.''

(ii) ''[Bullet] repeat twice daily (morning and night) for up to 7 days until discomfort is relieved or until the nail can be lifted out of the nail groove and easily trimmed''.

(2) ''[Bullet] children under 12 years: ask a doctor''.

Subpart E [Reserved]

Subpart F—Corn and Callus Remover Drug Products

SOURCE: 55 FR 33261, Aug. 14, 1990, unless otherwise noted.

§ 358.501 Scope.

(a) An over-the-counter corn and callus remover 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 of the general conditions 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.

§ 358.503 Definitions.

As used in this subpart:

(a) *Corn and callus remover drug product.* A topical agent used for the removal of corns and calluses.

(b) *Collodion-like vehicle.* A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) *Plaster vehicle.* A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

§ 358.510 Corn and callus remover active ingredients.

The product consists of any of the following active ingredients within the specified concentrations and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 12 to 17.6 percent in a collodion-like vehicle.

§ 358.550 Labeling of corn and callus remover 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 ''corn and callus remover.''

(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 the additional phrase listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established 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 removal of corns and calluses.''

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain the following statement: ''Relieves pain by removing corns and calluses.''

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

(1) *For products containing any ingredient identified in § 358.510.* (i) ''For external use only.''

(ii) ''Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation.''

(iii) ''If discomfort persists, see your doctor or podiatrist.''

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g., ''extremely flammable,'' ''flammable,'' ''combustible,'' consistent with 16 CFR 1500.3(b)(10).

(ii) ''Keep away from fire or flame.''

(3) *For any product formulated in a volatile vehicle.* ''Cap bottle tightly and store at room temperature away from heat.''

(4) *For any product formulated in a collodion-like vehicle.* (i) ''If product gets into the eye, flush with water for 15 minutes.''

(ii) ''Avoid inhaling vapors.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing salicylic acid identified in § 358.510(a).* ''Wash affected area and dry thoroughly.'' (If appropriate: ''Cut plaster to fit corn/callus.'') ''Apply medicated plaster. After 48 hours remove the medicated plaster. Repeat this procedure every 48 hours as needed for up to 14 days (until corn/callus is removed).'' (Optional: ''May soak corn/callus in warm water for 5 minutes to assist in removal.'')

(2) *For products containing salicylic acid identified in § 358.510(b).* ''Wash affected area and dry thoroughly. Apply'' (select one of the following, as appropriate: ''one drop'' or ''small amount'') ''at a time with'' (select one of the following, as appropriate: ''applicator'' or ''brush'') ''to sufficiently cover each corn/callus. Let dry. Repeat this procedure once or twice daily as needed for up to 14 days (until corn/callus is removed).'' (Optional: ''May soak corn/callus in warm water for 5 minutes to assist in removal.'')

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

[55 FR 33261, Aug. 14, 1990, as amended at 57 FR 44494, Sept. 28, 1992]

Subpart G—Pediculicide Drug Products

SOURCE: 58 FR 65455, Dec. 14, 1993, unless otherwise noted.

§ 358.601 Scope.

(a) An over-the-counter pediculicide drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each condition 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.

§ 358.603 Definition.

As used in this subpart:

Pediculicide drug product. A drug product for the treatment of head, pubic (crab), and body lice.

§ 358.610 Pediculicide active ingredients.

The active ingredients of the product consist of the combination of pyrethrum extract (providing a concentration of pyrethrins of 0.17 to 0.33 percent) with piperonyl butoxide (2 to 4 percent) in a nonaerosol dosage formulation.

[63 FR 43303, Aug. 13, 1998]

§ 358.650 Labeling of pediculicide 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 ''lice treatment.''

(b) *Indications.* The labeling of the product states, under the heading ''Uses,'' the following: ''treats head, pubic (crab), and body lice.'' Other truthful and nonmisleading 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 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.

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

(1) ''For external use only'' in accord with § 201.66(c)(5)(i) of this chapter.

(2) ''Do not use [bullet][1] near eyes [bullet] inside nose, mouth, or vagina [bullet] on lice in eyebrows or eyelashes. See a doctor if lice are present in these areas.''

(3) ''Ask a doctor before use if you are [bullet] allergic to ragweed. May cause breathing difficulty or an asthmatic attack.''

(4) ''When using this product [bullet] keep eyes tightly closed and protect eyes with a washcloth or towel [bullet] if product gets in eyes, flush with water right away [bullet] scalp itching or redness may occur''.

(5) ''Stop use and ask a doctor if [bullet] breathing difficulty occurs [bullet] eye irritation occurs [bullet] skin or scalp irritation continues or infection occurs''.

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) The labeling states ''[bullet] Important: Read warnings before use'' [statement shall appear first and in bold type].

(2) The labeling states ''adults and children 2 years and over:'' [in bold type].

(3) For head lice treatment products ''Inspect [in bold type] [bullet] check each household member with a magnifying glass in bright light for lice/nits (eggs) [bullet] look for tiny nits near scalp, beginning at back of neck and behind ears [bullet] examine small sections of hair at a time [bullet] unlike dandruff which moves when touched, nits stick to the hair [bullet] if either lice or nits are found, treat with this product''.

(4) Select one of the following:

(i) *For shampoo products* ''Treat [in bold type] [bullet] apply thoroughly to (optional, may add ''dry'') hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product to remain for 10 minutes, but no longer [bullet] use warm water to form a lather, shampoo, then thoroughly rinse [bullet] for head lice, towel dry hair and comb out tangles''.

(ii) *For nonshampoo products* ''Treat [in bold type] [bullet] apply thoroughly to (optional, may add ''dry'') hair or other affected area. For head lice, first apply behind ears and to back of neck. [bullet] allow product to remain for 10 minutes, but no longer [bullet] wash area thoroughly with warm water and soap or shampoo [bullet] for head lice, towel dry hair and comb out tangles''.

(5) ''Remove lice and their eggs (nits) [in bold type] [bullet] use a fine-tooth or special lice/nit comb. Remove any remaining nits by hand (using a throwaway glove). [bullet] hair should remain slightly damp while removing nits [bullet] if hair dries during combing, dampen slightly with water [bullet] for head lice, part hair into sections. Do one section at a time starting on top of head. Longer hair may take 1 to 2 hours. [bullet] lift a 1- to 2-inch wide strand of hair. Place comb as close to scalp as possible and comb with a firm, even motion away from scalp. [bullet] pin back each strand of hair after combing [bullet] clean comb often. Wipe nits away with tissue and discard in a plastic bag. Seal bag and discard to prevent lice from coming back. [bullet] after combing, thoroughly recheck for lice/nits. Repeat combing if necessary. [bullet] check daily for any lice/nits that you missed''.

(6) The labeling states ''[bullet] a second treatment must be done in 7 to 10 days to kill any newly hatched lice''.

(7) The labeling states ''[bullet] if infestation continues, see a doctor for other treatments''.

(8) The labeling states ''children under 2 years:'' [in bold type] ''ask a doctor''.

(e) *Other information.* The labeling of the product contains the following statements, as appropriate, under the heading ''Other information.'' This information may appear in a package insert. If a package insert is used, the ''Other information'' section on the outer carton or container label shall include a statement referring to the package insert for additional information.

(1) ''Head lice [highlighted in bold type] [bullet] lay small white eggs (nits) on hair shaft close to scalp [bullet] nits are most easily found on back

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

of neck or behind ears [bullet] disinfect hats, hair ribbons, scarves, coats, towels, and bed linens by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes [bullet] items that cannot be washed (bedspreads, blankets, pillows, stuffed toys, etc.) should be dry-cleaned or sealed in a plastic bag for 4 weeks, then removed outdoors and shaken out very hard before using again [bullet] items that cannot be washed, dry-cleaned, or stored may be sprayed with a product designed for this purpose [bullet] soak all combs and brushes in hot water (above 54 °C (130 °F)) for at least 10 minutes [bullet] vacuum all carpets, mattresses, upholstered furniture, and car seats that may have been used by affected people''.

(2) ''Pubic (crab) lice [highlighted in bold type] [bullet] may be transmitted by sexual contact. Sexual partners should be treated simultaneously to avoid reinfestation [bullet] lice are very small and look like brown or grey dots on skin [bullet] usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface [bullet] may be present on the short hairs of groin, thighs, trunk, and underarms, and occasionally on the beard and mustache [bullet] disinfect underwear by machine washing in hot water (above 54 °C (130 °F)), then using hottest dryer cycle for at least 20 minutes''.

(3) ''Body lice [highlighted in bold type] [bullet] body lice and their eggs (nits) are generally found in the seams of clothing particularly in waistline and armpit area [bullet] body lice feed on skin then return to clothing to lay 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 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.

(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 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.

§ 358.760 Labeling of permitted combinations of active ingredients for the control of dandruff.

The statement 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.

(1) *Combinations of control of dandruff and external analgesic active ingredients*

in § 358.720(b). The label states ''dandruff/anti-itch shampoo'' or ''anti-dandruff/anti-itch shampoo''.

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading ''Uses,'' one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading 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 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) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states ''[bullet] [select one of the following: 'for relief of' or 'controls'] the symptoms of dandruff [bullet] [select one of the following: 'additional' or 'extra'] relief of itching due to dandruff''.

(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 indication in paragraph (b)(1) of this section: ''scalp'' (select one or more of the following: ''itching,'' ''irritation,'' ''redness,'' ''flaking,'' ''scaling'') ''associated with''.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) listed in § 358.750(c)(1) and (c)(2).

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states ''[bullet] wet hair [bullet] apply shampoo and work into a lather [bullet] rinse thoroughly [bullet] for best results, use at least twice a week or as directed by a doctor''.

(2) [Reserved]

[72 FR 9852, Mar. 6, 2007]

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, may have eventual therapeutic or diagnostic implications, but the initial