

## Food and Drug Administration, HHS

## § 358.103

chlorophyllin copper complex identified in § 357.810(b).

(2) [Reserved]

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

(1) *For products containing bismuth subgallate identified in § 357.810(a).* Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: consult a doctor.

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily in divided doses as required. If odor is not controlled, take 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.

358.101 Scope.

358.103 Definitions.

358.110 Wart remover active ingredients.

358.150 Labeling of wart remover drug products.

#### Subparts C–E [Reserved]

#### Subpart F—Corn and Callus Remover Drug Products

358.501 Scope.

358.503 Definitions.

358.510 Corn and callus remover active ingredients.

358.550 Labeling of corn and callus remover drug products.

#### Subpart G—Pediculicide Drug Products

358.601 Scope.

358.603 Definition.

358.610 Pediculicide active ingredients.

358.650 Labeling of pediculicide drug products.

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

358.701 Scope.

358.703 Definitions.

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

358.720 Permitted combinations of active ingredients.

358.750 Labeling of drug products for the control of dandruff, seborrheic dermatitis, or 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

## 21 CFR Ch. I (4-1-03 Edition)

### § 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]

### Subparts C–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 colloid-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 “pediculicide (lice treatment)” or “lice treatment.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following: “For the treatment of head, pubic (crab), and body lice.” 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.

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

(1) "Use with caution on persons allergic to ragweed."

(2) "For external use only. Do not use near the eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina, as irritation may occur. Keep out of eyes when rinsing hair. Adults and children: Close eyes tightly and do not open eyes until product is rinsed out. Also, protect children's eyes with washcloth, towel or other suitable material, or by a similar method. If product gets into the eyes, immediately flush with water."

(3) "If skin irritation or infection is present or develops, discontinue use and consult a doctor. Consult a doctor if infestation of eyebrows or eyelashes occurs."

(4) The word "physician" may be substituted for the word "doctor" in any of the warning statements in this paragraph.

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

(1) *For all products.* "Important: Read warnings before using." [statement in boldface type]

(2) *For nonshampoo products.* "Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Wash area thoroughly with warm water and soap or shampoo. A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be done in 7 to 10 days to kill any newly hatched lice."

(3) *For products formulated for use as a shampoo.* "Apply to affected area until all the hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Add sufficient warm water to form a lather and shampoo as usual. Rinse thoroughly. A fine-toothed comb or a special lice/nit removing comb may be used to help remove dead lice or their eggs (nits) from hair. A second treat-

ment must be done in 7 to 10 days to kill any newly hatched lice."

(e) *Other required statements.*

(1) "*Head Lice:* Head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp. The nits are most easily found on the nape of the neck or behind the ears. All personal headgear, scarfs, coats, and bed linen should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry-cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this purpose. Personal combs and brushes may be disinfected by soaking in hot water (above 130 °F) for 5 to 10 minutes. Thorough vacuuming of rooms inhabited by infected patients is recommended."

(2) "*Pubic (Crab) Lice:* Pubic lice may be transmitted by sexual contact; therefore, sexual partners should be treated simultaneously to avoid re-infestation. The lice are very small and look almost like brown or grey dots on the skin. Pubic lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface. In hairy individuals, pubic lice may be present on the short hairs of the thighs and trunk, underarms, and occasionally on the beard and mustache. Underwear should be disinfected by machine washing in hot water; then drying, using the hot cycle for at least 20 minutes."

(3) "*Body Lice:* Body lice and their eggs are generally found in the seams of clothing, particularly in the waistline and armpit area. They move to the skin to feed, then return to the seams of the clothing where they lay their eggs. Clothing worn and not laundered before treatment should be disinfected by the same procedure as described for head lice, except that sealing clothing in a plastic bag is not recommended for body lice because the nits (eggs) from these lice can remain dormant for a period of up to 30 days."

[58 FR 65455, Dec. 14, 1993, as amended at 64 FR 13296, Mar. 17, 1999]

**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.**

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, may have eventual therapeutic or diagnostic implications, but the initial studies are considered to be basic re-

search within the meaning of this section.

(b) The conditions under which use of radioactive drugs for research are considered safe and effective are:

(1) *Approval by Radioactive Drug Research Committee*. A Radioactive Drug Research Committee, composed and approved by the Food and Drug Administration in accordance with paragraph (c) of this section, has determined, in accordance with the standards set forth in paragraph (d) of this section, that:

(i) The pharmacological dose is within the limits set forth in paragraph (b)(2) of this section;

(ii) The radiation dose is within the limits set forth in paragraph (b)(3) of this section;

(iii) The radiation exposure is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain;

(iv) The study meets the other requirements set forth in paragraph (d) of this section regarding qualifications of the investigator, proper licensure for handling radioactive materials, selection and consent of research subjects, quality of radioactive drugs used, research protocol design, reporting of adverse reactions, and approval by an appropriate Institutional Review Committee; and

(v) The use of the radioactive drug in human subjects has the approval of the Radioactive Drug Research Committee.

(2) *Limit on pharmacological dose*. The amount of active ingredient or combination of active ingredients to be administered shall be known not to cause any clinically detectable pharmacological effect in human beings. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously, e.g., under a “Investigational New Drug Application” or for a therapeutic use in accordance with labeling for a drug approved under part 314 of this chapter, the total amount of active ingredients including the radionuclide shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredients excluding the radionuclide.

(3) *Limit on radiation dose*. The amount of radioactive material to be