(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 colloidion-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.


Subpart G—Pediculicide Drug Products

Source: 58 FR 65455, Dec. 14, 1993, unless otherwise noted.
(1) “For external use only” in accord with §201.66(c)(5)(1) of this chapter.

(2) “Do not use [bullet] 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] wash area thoroughly with warm water and soap or shampoo [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 throw-away 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..."
Food and Drug Administration, HHS

§ 358.703

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 byproduct 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.