

§ 358.701

21 CFR Ch. I (4-1-01 Edition)

(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 reinfestation. 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