§ 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”: 

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)(i) of this chapter.

(2) “Do not use [bullet] near eyes [bullet] inside nose, mouth, or vagina [bullet] on lice in eyebrows or eye-
lashes. 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 [bul-
let] 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 infor-
mation under the heading “Direc-
tions”:

(1) The labeling states “[bullet] Im-
portant: 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 magni-
fying 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 sec-
tions 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)
[bullet] use a fine-tooth
 or special lice/nit comb. Remove any
remaining nits by hand (using a throw-
away glove). [bullet] hair should re-
main slightly damp while removing
nits [bullet] if hair dries during comb-
ing, dampen slightly with water [bul-
let] for head lice, part hair into sec-
tions. 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, thor-
oughly recheck for lice/nits. Repeat
combing if necessary. [bullet] check
daily for any lice/nits that you
missed”.

(6) The labeling states “[bullet] a sec-
ond treatment must be done in 7 to 10
days to kill any newly hatched lice”.

(7) The labeling states “[bullet] if in-
festation 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 in-
formation may appear in a package in-
sert. 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 informa-
tion.

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