§ 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":

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