(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).

(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.

§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”: