usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; 502(f)(2)—its labeling failed to bear the warning relating to blood dyscrasias which may be associated with its use; 502(1)—it contained chloramphenicol, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507; and 503(b)(4)—it was a drug which was subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Chlorhidrate De Neohetramine, 502(c)—while held for sale, the information required to appear on the label did not appear in such terms as to render it likely to be understood by the ordinary individual under customary conditions of purchase and use since such information was not printed in the English language; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; and 502(f)—its labeling failed to bear (1) adequate directions for use and (2) a warning that the user should not drive a car or operate machinery since the product may cause drowsiness.

Terramycin, 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer or distributor and (2) an accurate statement of the quantity of contents; 502(e)(1)—it failed to bear a label containing the common or usual name of the drug; 502(f)(1)—its labeling failed to bear adequate directions for use; and 503(b)(4)—it was a drug which was subject to the provisions of Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that an article labeled Homicebrin was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 1-8-60. Default—destruction.

DRUG FOR VETERINARY USE

6044. Medicated feed. (F.D.C. No. 43195. S. Nos. 52-634 P.)

QUANTITY: 18 50-lb. bags at Mankato, Minn.

SHIPPED: 4-10-59, from Muscatine, Iowa, by Grain Processing Corp.

LABEL IN PART: (Tag) "From Grain Processing Corp. Muscatine, Iowa. Antibiotic Bacitracin Feed Supplement 10 Grams Bacitracin/Lb."

LIBELED: 6-22-59, Dist. Minn.

CHARGE: 502(1)—when shipped, the article contained manganese bacitracin, and it was not from a batch with respect to which a certificate or release had been issued in accordance with regulations.

DISPOSITION: 8-6-59. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6045. Dur-Den-Col. (F.D.C. No. 43037. S. No. 6-248 P.)

QUANTITY: 15 cases, 12 btls. each, at Johnson City, Tenn.

SHIPPED: 3-5-59, from Norton, Va., by Southwest Pharmaceutical Corp., Inc.

LABEL IN PART: (Btl.) "Dur-Den" Col * * * ingredients per fluid ounce—Tinc. Phytolacca 0.25 cc. Sodium Salicylate 0.43 gm. Potassium Iodide 43 mg. Methyl Salicylate * * * 12 fluid ounces."

*See also Nos. 6041, 6043.

RESULTS OF INVESTIGATION: Examination showed that each bottle contained 2.41 grams of sodium salicylate and 0.252 grams (252 milligrams) of potassium iodide per fluid ounce.

LIBELED: 5–29–59, E. Dist. Tenn.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; 502(a)—the label statement "ingredients per fluid ounce * * * Sodium Salicylate 0.43 gm. Potassium Iodide 43 mg." was false and misleading; and 502(f)(2)—the labeling of the article failed to warn that the article should be kept out of the reach of children and that if pain persisted or redness was present in conditions affecting children under 12 years of age, one should consult a physician immediately.

DISPOSITION: 11–19–59. Default—destruction.

6046. Dermo-G ointment. (F.D.C. No. 41926. S. No. 7–242 P.)

QUANTITY: 9,108 cartoned ½-oz. metal tubes, and 5,031 cartoned 2-oz. metal tubes, at Manchester, N.H., in possession of Dermo-G, Inc.

SHIPPED: Prior to 3–20–58, from New York, N.Y.

LABEL IN PART: (Tube & ctn.) "Dermo-G * * * Active Ingredients: Sodium Borate (borax) Precipitated sulphur together with a soothing penetrating base containing no poisonous or harmful ingredients."

ACCOMPANYING LABELING: Leaflets entitled "Dermo-G Relieves Many Skin Worries" and "Dermo-G The Amazing Skin Ointment"; window and store fliers; a number of empty cartons for use in packaging the article; and a number of pieces of stationery.

LIBELED: 7–14–58, Dist. N.H.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for eczema, acne, pimples, barber's itch, itchy scalp, sunburn, household burns, piles, hemorrhoids, poison ivy, poison oak, fever blisters, and psoriasis; and 502(f)(2)—the article was offered for piles and hemorrhoids, and its labeling failed to warn that the article should not be used in case of rectal bleeding, an indication of a serious condition, and the labeling of the article also failed to warn against use of the article in conditions such as sunburn, household burns, poison ivy, hemorrhoids, fever blisters, etc., in which conditions the presence of a high concentration of sulfur would aggravate rather than help the condition.

DISPOSITION: 11–17–59. Consent—claimed by Dermo-G, Inc., and relabeled.

6047. Shai Skin-Trete. (F.D.C. No. 42900. S. No. 33–804 P.)

QUANTITY: 49 cartoned 2-oz. btls. at Philadelphia, Pa., in possession of Rosal Laboratories, Ltd.

SHIPPED: During September or October 1958, from New York, N.Y., by Rosal Laboratories, Ltd.

LABEL IN PART: (Ctn. and btl.) "Shai Skin-Trete Lanolin Added * * * Rosal Laboratories, Ltd., Philadelphia and New York."

ACCOMPANYING LABELING: Leaflets entitled "Shai by Rosal Laboratories, Ltd."

RESULTS OF INVESTIGATION: The leaflets were printed locally for the dealer.

LIBELED: 3–24–59, E. Dist. Pa.