

7019. Prescription drugs. (F.D.C. No. 46618. S. Nos. 13-143 T, 13-145 T.)

QUANTITY: 12 1,000-tablet btl. of *Gantrisin* and 3 5,000-tablet btl. of *Ser-pasil* at Chicago, Ill., in possession of G & G Drug Co. (David Greenburg, owner).

SHIPPED: On unknown dates, from Nutley and Summit, N.J.

RESULTS OF INVESTIGATION: The articles had been shipped to an unknown drugstore in the State of Illinois from which the dealer purchased the articles. The articles were intended to be repacked into smaller containers, and were in containers bearing the original labels of their manufacturers. However, the control or lot numbers had been scraped off or otherwise removed from the labels.

LIBELED: 11-2-61, N. Dist. Ill.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were drugs subject to the provisions of 503(b) (1) and their labels failed to bear identifying lot or control numbers from which it was possible to determine the complete manufacturing history of the packages of the drugs as required by regulations.

DISPOSITION: 11-27-61. Default—destruction.

7020. Medi-Quick first aid spray. (F.D.C. No. 46448. S. No. 39-226 T.)

QUANTITY: 65 ctns., each containing 12 3-oz. cans, at Brooklyn, N.Y.

SHIPPED: 9-7-61 and 9-28-61, from Bloomfield, N.J., by Lehn & Fink Products Corp.

LABEL IN PART: (Can) "New Instant Medi-Quick first aid spray * * * Contents are under pressure * * * Active Ingredients: Xylocaine *(Astra For Lidocaine) Benzalkonium Chloride, Hexachlorophene, Isopropanol, 7% by volume. Lehn & Fink Prod. Corp. Bloomfield, N.J."

ACCOMPANYING LABELING: Leaflet entitled "Fights infections! Promotes Healing! New Instant Medi-Quick the complete first aid spray"; and display carton, reading in part "New Instant Medi-Quick * * * Stops Pain with Xylocaine Fights Infection even better than iodine!"

LIBELED: 10-25-61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for skin rashes, insect bites, and poison ivy; that it would effectively fight infection and promote healing; and that it was more effective as an antiseptic than tincture of iodine; and 502(f) (2)—the article contained lidocaine (Xylocaine), a local anesthetic, and its labeling failed to bear the warning statement required for local anesthetics, "Caution—Do not use in the eyes. Not for prolonged use. If the conditions for which the preparation is used persists or if a rash or irritation develops, discontinue use and consult physician."

DISPOSITION: 3-22-62. Default—destruction.

7021. Clear cold tablets. (F.D.C. No. 46892. S. No. 33-818 T.)

QUANTITY: 2 drums containing 190,400 tablets and 117 cases, 12 60-tablet btl. each, at Winona, Minn., in possession of McConnon & Co.

SHIPPED: 3-1-61 and 3-16-61, from Cleveland, Ohio, by Strong Cobb Arner, Inc.

LABEL IN PART: (Drum) "Strong Cobb Arner, Inc., Cleveland, Ohio * * *
 Manufactured for: McConnon & Co., Winona, Minn. Contents 32800 * * *
 Special Tablets * * * Formula Contains at time of manufacture: per tablet
 Pyrilamine Maleate 12.5 mg. Thenylpyramine Hydrochloride 12.5 mg. Alumi-
 num Hydroxide Dried Gel 64.8 mg. Vitamin C (Ascorbic Acid) 25 mg.
 Scopolamine Aminoxide Hydrobromide 0.25 mg. Phenylephrine Hydrochloride
 5 mg. Aspirin 291.6 mg. For the relief of symptoms of colds & hay fever
 * * * Directions * * * Caution * * * Warning"; (btl.) "Clear 60 Tablets
 With Vitamin C."

LIBELED: 1-3-62, Dist. Minn.

CHARGE: 502(f) (2)—when shipped and while held for sale, the labeling failed to bear the required warning statements for articles containing the antihistamines, pyrilamine hydrochloride and thenylpyramine hydrochloride.

DISPOSITION: 3-7-62. Consent—claimed by McConnon & Co. and relabeled.

7022. Soluble calcium capsules. (F.D.C. No. 47609. S. No. 23-360 T.)

QUANTITY: 34 100-capsule labeled btls. and 53 1,000-capsule labeled btls.; 6 cases, 48 100-capsule unlabeled btls. each, and 8 cases, 6 1,000-capsule unlabeled btls. each, at Albuquerque, N. Mex., in possession of Carmel & Co.

SHIPPED: 6-12-61, from St. Louis, Mo., by K-V Pharmacal Co.

LABEL IN PART: (Btl.) "Solu-Cal (Soluble Calcium) For the Treatment of Calcium Deficiency. Each Capsule Contains: 500 mg. (7.7 grains) Calcium Levulinate distributors Carmel & Company * * * Albuquerque, New Mexico" and (case) "#0 Pink Calcium Levulinate Capsules Each Capsule Contains: Calcium Levulinate 0.5 gm. Each capsule supplies 29% of the minimum daily requirement for calcium * * * K-V Pharmacal Company * * * St. Louis, Missouri."

RESULTS OF INVESTIGATION: The individual bottles were labeled by the dealer with the dealer's label.

LIBELED: 5-22-62, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the label statement (case) "Each capsule supplies 29% of the minimum daily requirement for calcium" was false and misleading; while held for sale, the dealer's bottle label contained false and misleading representations that the article was adequate and effective for the treatment of calcium deficiency; and the dealer's bottle label also contained statements comparing the solubility of the article with other calcium compounds, which statements were misleading since the labeling failed to reveal the material fact that the calcium compounds to which the solubility of the article was compared are normally and readily absorbed; and 502(f) (1)—the labeling failed to bear adequate directions for use for the treatment of calcium deficiency, the purpose for which the article was intended.

DISPOSITION: 6-1-62. Consent—claimed by I. C. Carmel, Albuquerque, N. Mex., and released under bond for relabeling.

7023. Medicated lotion. (F.D.C. No. 47374. S. No. 276 T.)

QUANTITY: 234 6-oz. btls. at Oakland Park, Fla.

SHIPPED: 9-27-61, from Winona, Minn., by McConnon & Co.

LABEL IN PART: (Btl.) "6 Fl. Oz. Corsage Medicated Lotion McConnon Quality Products, Winona, Minn."