

Analysis showed that the article consisted of isopropyl alcohol, containing 1.5 mg. of estradiol and 1.8 mg. of alpha-estradiol per fluid ounce.

LIBELED: 8-30-57, W. Dist. N.Y.

CHARGE: 502(e) (2)—when shipped and while held for sale, the label of the article failed to bear the common or usual name of each active ingredient and the proportion of isopropyl alcohol contained in the article; 502(f) (1)—the labeling of the article failed to bear adequate directions for use, and it did not comply with any of the exempting regulations; and 503(b) (4)—the article was a drug subject to 503(b) (1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-1-57. Default—destruction.

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

5467. Nutrilite food supplement. (F.D.C. No. 40605. S. No. 30-785 M.)

INFORMATION FILED: 1-6-58, S. Dist. Ohio, against P. E. Lockwood and Harley A. Dudgeon, Kings Creek, Ohio.

ALLEGED VIOLATION: In the course of a sales talk given at Kings Creek, Ohio, on 7-10-57, the defendants made oral representations to the persons present, holding the article out as a treatment for ulcers, rheumatoid arthritis, strokes, high blood pressure, varicose veins, migraine headaches, asthmatic conditions, prostate trouble, eye trouble, and calming the nerves.

LABEL IN PART: (Pkg.) "Nutrilite Junior Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502(f) (1)—the label of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which it was intended, namely, the diseases, symptoms, and conditions set forth above.

PLEA: Guilty.

DISPOSITION: 1-27-58. Each defendant fined \$250.

5468. Oil of wintergreen and aspirin tablets. (F.D.C. No. 40950. S. Nos. 48-754/5 M.)

QUANTITY: 1 55-gal.-size drum containing 4 gals., and 125 doz. 1-oz. btl., 97 doz. 2-oz. btl., 33 doz. 4-oz. btl., and 5 1-gal. jugs of *oil of wintergreen*, and 152 cases, each containing 6 doz. 100-tablet btl., of *aspirin*, at Chicago, Ill., in possession of Dr. Sachs Laboratories.

SHIPPED: Between 7-6-57 and 10-31-57, from Lyndhurst and Newark, N.J., and Norwich, N.Y.

LABEL IN PART: (Btl.) "Oil of Wintergreen (Methyl Salicylate) U.S.P. Synthetic" and "Health-A-Teria Aspirin 5 Grains Each Acetylsalicylic Acid U.S.P. * * * Packed for Health-A-Teria, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: The *oil of wintergreen* and the *aspirin tablets* in the above-mentioned btl. were repacked by the consignee from bulk stock shipped as described above.

LIBELED: 11-12-57, N. Dist. Ill.; amended 11-21-57.

*See also Nos. 5462, 5463, 5465, 5466.

CHARGE: 502(f) (1)—the labeling of the *aspirin tablets*, while held for sale, failed to bear adequate directions for use since, in lieu of a dosage statement for children under 3 years of age, the labeling failed to state that for the 3-year and under age group a physician should be consulted; and 502(f) (2)—the labeling of the *oil of wintergreen* and the *aspirin tablets*, while held for sale, failed to bear warnings against misuse by children since their labelings failed to warn that such articles should be kept out of reach of children.

DISPOSITION: 11-22-57. Consent—claimed by Dr. Sachs Laboratories and relabeled.

5469. Herb tea. (F.D.C. No. 40933. S. No. 49-037 M.)

QUANTITY: 133 4-oz. boxes at Chicago, Ill., in possession of W. W. Laboratories.

SHIPPED: During April 1957, from New York, N.Y.

LABEL IN PART: (Box) "Hartz Mountain Brand Herb Tea"; (bulk drum) "Special Cut & Sifted Tea Mixture Formula 68 Containing the following: Alex Senna, Mandrake, Elder Flowers, Aniseed, Fennel Seed, Red Clover Tops, Linden Flowers and Leaves, Dog grass, Sassafras Bark of Root Natural, Uva Ursi."

RESULTS OF INVESTIGATION: The article was shipped, as described above, in bulk drums; and, upon receipt at Chicago, it was repackaged and labeled by the consignee.

LIBELED: 11-7-57, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the box label of the article contained false and misleading representations that the article was an adequate and effective treatment for regulating the stomach, providing perfect health, enabling one to achieve a ripe old age, and eliminating constantly accumulating body poisons; 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502(f) (2)—the article was essentially a laxative, and its labeling failed to bear adequate warnings against excessive use as a laxative and against use where symptoms of appendicitis are present.

DISPOSITION: 12-5-57. Default—destruction.

DRUGS FOR VETERINARY USE

5470. C-Ran and Stil-Ran. (F.D.C. No. 40706. S. Nos. 70-281/2 M.)

QUANTITY: 87 boxes, 6 vials each, of *C-Ran*, and 77 boxes, 5 vials each, of *Stil-Ran*, at Wayne, Pa.

SHIPPED: Between 5-23-57 and 9-12-57, from Baltimore, Md., by Morjac Co.

LABEL IN PART: (Box) "C-Ran * * * Each Ampoule Contains 6 cc. Ascorbic Acid Solution In the Form of Sodium Ascorbate Equal to 2 gm. Ascorbic Acid (40,000) Units Vitamin C" and "Stil-Ran * * * Diethylstilbestrol Solution."

LIBELED: 10-18-57, E. Dist. Pa.

CHARGE: 502(a)—when shipped, the box labels of the articles contained false and misleading representations that the *C-Ran* was effective for overcoming breeding difficulties in cows and that the *Stil-Ran* was effective for treating the condition of retained placenta in cows; and 502(f) (1)—the *Stil-Ran* was a drug which was not safe for animal use except under the supervision of a licensed veterinarian, and the label failed to bear the statement "Caution: