

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.) "Nutralite 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.