

SHIPPED: Between 7-7-58 and 8-26-58, from Massachusetts and Vermont to New Hampshire and Maine.

LABEL IN PART: (Tag attached to bags) "CHICK STARTER MEDICATED" and "BLUE SEAL ALL-MASH GROW and LAY MEDICATED"; (invoice) "Growing Mash-Spec. Mix."

CHARGE: 501(d) (2)—products containing sulfaquinoxaline and no glycarbylamide had been substituted for products containing glycarbylamide and no sulfaquinoxaline; 502(a)—the statement on the labels of the *Chick Starter* and the *Blue Seal Mash*, namely, "Glycarbylamide * * * 0.002%" was false and misleading since the products did not contain glycarbylamide; and 502(e) (2)—the labels of all products failed to bear the common or usual name of the active ingredient sulfaquinoxaline contained in the products.

PLEA: Nolo contendere.

DISPOSITION: 2-29-60. Fine of \$300 against each defendant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6057. Various vitamin and mineral tablets. (F.D.C. No. 43612. S. Nos. 41-963/76 P.)

QUANTITY: 2 bulk ctns., each containing 15,000 capsules, and 9 cases, each containing 12 100-capsule btl., of vitamin A 25,000 U.S.P. Units; 2 bulk ctns., containing a total of about 21,000 capsules, and 11 cases, each containing (Howco brand) 12 100-capsule btl., and (Apothecary brand) 5 cases, each containing 24 100-capsule btl. of vitamin A 50,000 U.S.P. Units; 1 bulk ctn., containing about 22,000 capsules, 3 cases, each containing 24 150-capsule btl., and 150 unlabeled 150-capsule btl. of multiple vitamins; 1 bulk ctn., containing about 4,000 capsules, and 9 100-capsule btl. of Improved Vitamin Formula with Minerals and B₁₂; 1 bulk ctn. containing about 40,000 tablets of vitamin B₁₂ 5 mcg.; 1 bulk ctn., containing about 8,000 tablets, and 25 cases, each containing 12 100-tablet btl., of vitamin B₁₂ 10 mcg.; 1 bulk ctn., containing about 30,000 tablets, and 7 cases, each containing 12 100-tablet btl. of vitamin B₁ (thiamine) 25 mg.; 1 bulk ctn., containing about 30,000 tablets, and 13 cases, each containing 12 100-tablet btl., of vitamin B₁ (thiamine) 50 mg.; 1 bulk ctn., containing about 100,000 tablets, and 13 cases, each containing 12 100-tablet btl., of vitamin C (ascorbic acid) 50 mg.; 1 bulk ctn., containing about 90,000 tablets, and 60 250-tablet btl. of vitamin C (ascorbic acid) 250 mg.; 1 bulk ctn., containing about 281,000 tablets, 1 bulk ctn., containing about 117,000 tablets, 316 100-tablet btl. (Howco brand), and 7 cases, each containing 24 100-tablet btl. (Apothecary brand), of vitamin C (ascorbic acid) 100 mg., and 1 ctn. containing about 10,000 tablets and 13 cases, each containing 12 100-tablet btl. of vitamin B₁₂ 5 mcg., at Seattle, Wash., in possession of Howe Products, Inc.

SHIPPED: Between 1-29-59 and 6-26-59, from Detroit, Mich.; San Francisco, Calif.; and Brooklyn, N.Y.

LABEL IN PART: (Btl.) "Howco Vitamin A * * * 25,000 [or "50,000"] U.S.P. Units * * * Distributor Howe & Co. Seattle"; "Apothecary Brand Multiple Vitamins * * * As a dietary supplement for children and adults"; "Apothecary Brand Improved Therapeutic Vitamin Formula with Minerals and B₁₂ * * * Distributed by Apothecary Products, Co., Seattle, Wash."; "Howco

*See also Nos. 6042, 6045, 6046, 6048, 6051, 6053, 6054, 6056.

Vitamin B₁₂ Activity (from cobalemin concentrate NF) 10 mcg.”; “Howco Vitamin B-1 * * * 25 mg. [or “50 mg.”]”; “Howco Vitamin C * * * 50 mg.”; “Howco Vitamin C Ascorbic Acid USP 250 mg. [or “100 mg.”].”

ACCOMPANYING LABELING: Display cards entitled “Quality Vitamins,” which hold one bottle and are used to display the “Apothecary Brand,” and leaflets entitled “Vitamin Data” which accompany all the articles.

RESULTS OF INVESTIGATION: The articles in the bottles were repacked and relabeled by the dealer from bulk stock shipped as described above.

The display cards and the leaflets were printed locally at the dealer's request.

LIBELED: 11-3-59, W. Dist. Wash.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles contained false and misleading representations as follows:

Vitamin A 25,000 and 50,000 U.S.P. Units (bulk and repacked), the statements “Common Name, Anti-infective; Anti-ophthalmic * * * Function, Aids Growth & Vitality—Necessary for Reproduction * Helps Prevent Infection, * * * Deficiency Symptoms, Low resistance to Infection—Retarded Growth—Loss of Vigor—Night Blindness” were false and misleading since the article was not an adequate and effective treatment for, or preventive of, such conditions, since these conditions, namely, infections, low resistance to infections, ophthalmic disorders, retarded growth, low vitality, sterility, loss of vigor, and night blindness, implied or suggested by the labeling are rarely, if ever caused by a deficiency of vitamin A, and then only after a prolonged deficiency of vitamin A in the diet; and the statement “Natural Sources, Green vegetables, Tomatoes, Eggs, Butter” was false and misleading since vitamin A is abundantly available in many articles of food which comprise the normal diet and not only in those foods listed in the labeling.

Multiple vitamins (bulk and repacked), the statements “Function, One Capsule daily supplies a daily ration of all essential vitamins. Nutritional Supplement General resistance to colds and infections. Deficiency Symptoms Lack of resistance to colds and infections. Poor appetite and digestion” were false and misleading since the article was not an adequate and effective treatment for, or preventive of, lack of resistance to colds and infections, and the conditions, namely, poor appetite and digestion, are rarely, if ever, caused by a deficiency of the vitamins in the article and then only after a prolonged deficiency of such vitamins in the diet; such deficiencies being very rare in this country, since the vitamins listed on the label of the article are abundantly available in the many articles of food which comprise the normal diet.

Improved Therapeutic Vitamin Formula (bulk and repacked), the statements “Function, Aids people with high vitamin requirements. Correction of known vitamin and mineral deficiencies. Deficiency Symptoms, Lack of general good health and energy—colds and infections, sluggish skin” were false and misleading since the article was not an adequate and effective treatment for colds and infections; colds and infections are not symptoms of vitamin deficiencies; and the conditions, lack of general good health, and energy, listed for the article and the vitamins contained therein, are rarely, if ever, caused by a deficiency of these vitamins and minerals and then only after a prolonged deficiency of such vitamins and minerals in the diet; such deficiencies being very rare in this country since the vitamins and minerals contained in the article, as listed on the label, are abundantly available in the many articles

of food which comprise the normal diet and not only in those listed in the labeling.

Vitamin B₁₂, 5 mcg. and 10 mcg. (bulk and repacked), the statements "Common Name—Anti-pernicious-anemia principle. Function, Helps prevent certain anemias, promotes growth. Deficiency Symptoms, Certain anemias, retarded growth in children Natural Source Liver (Beef)" were false and misleading since anemia is not a symptom of dietary deficiency of vitamin B₁₂; the article is not an adequate and effective treatment for pernicious anemia or any other anemia, vitamin B₁₂ is abundantly available in the many articles of food which make up the normal diet, and not only in the one listed in the labeling of the article; and since the condition, retarded growth, listed for the article, is rarely caused by a deficiency of vitamin B₁₂.

Vitamin B₁ (thiamine) 25 mg. and 50 mg. (bulk and repacked), the statements "Common Name—Anti-neuritic; Anti-beriberi. Function, Aids appetite and digestion. Helps some form of neuritis. Stimulates body activity, Deficiency Symptoms, Loss of appetite—fatigue—neuritis—depression. Natural Source, Yeast, wheat germ, milk" were false and misleading since vitamin B₁ is abundantly available in the many articles of food which comprise the normal diet and not only in those listed in the labeling of the article; and since the listed conditions, neuritis, poor appetite and digestion, loss of appetite, fatigue, depression, are rarely caused by a deficiency of vitamin B₁ and then only after a prolonged deficiency of vitamin B₁ in the diet; and the article is not a stimulant to body activity except in severe cases of beriberi which is an extremely rare condition in this country.

Vitamin C (ascorbic acid) (bulk and repacked), the statements "Function, Assists in proper formation of bones and teeth—prevents scurvy. Deficiency Symptoms, Scurvy—tooth decay—hemorrhage—muscular weakness. Natural Source, Lemons, Oranges, Tomatoes, Grapefruit" were false and misleading since vitamin C is abundantly available in other articles of food which comprise the normal diet and not only in those listed in the labeling of the article; and since the listed conditions, tooth decay, hemorrhage, and muscular weakness are rarely caused by a deficiency of vitamin C and then only after a prolonged deficiency of vitamin C in the diet.

DISPOSITION: 11-23-59. Consent—claimed by Howe Products, Inc., and relabeled.

6058. Silhouettes capsules. (F.D.C. No. 43580. S. No. 75-206 P.)

QUALITY: 1 bulk drum containing about 7,000 capsules and 22 ctns., each containing 6 14-capsule boxes, at Chicago, Ill., in possession of N.D.L., Inc.

SHIPPED: 9-12-59, from Long Island City, N.Y.

LABEL IN PART: (Bulk drum) "Timed Disintegration Capsules Phenyl Propanolamine Hydrochloride 75 mgm. Each capsule contains 75 mgm. Phenyl Propanolamine Hydrochloride in a special timed disintegration base that provides for prolonged therapeutic effect for about 6 to 10 hours" and (box) "Silhouettes * * * An Effective Aid to Appetite Control Active Ingredient: 75 Mgs. Phenyl Propanolamine Hydrochloride."

RESULTS OF INVESTIGATION: The tablets in the boxes were repacked and relabeled from tablets in the bulk drum shipped as described above.

LIBELED: 10-7-59, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the labeling of the article and the name "Silhouettes" contained false and misleading representations that the article