

LABEL, IN PART: "Hope Mineral Tablets with B-Vitamins Dietary Supplement. Each tablet contains 20 mgm. Iron; $\frac{1}{2}$ mgm. Vitamin B₁; 1 mgm. Vitamin B₂; and 5 mgm. Niacin. Also contains traces of other minerals (elements) extracted from a natural clay" or "Forty Hope Mineral Tablets Dietary Supplement Each tablet contains 20 mgm. of Iron and traces of other minerals (extracted from a natural clay) plus $\frac{1}{2}$ mgm. Vitamin B₁, 1 mgm. Vitamin B₂, 5 mgm. Niacin and $\frac{1}{2}$ mcg. Vitamin B₁₂."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rheumatism, headaches, weak kidneys, arthritis, stomach ailments, neuritis, dizzy spells, nervousness, bloating, acids, toxins, lack of energy, lack of vitality, sleepless nights, underweight, irritability, bad complexion, bad breath, frequent rising at night, vague pains, digestive disturbances, weakness, weak sexual powers, poor appetite, poor lactation, weakened reproductive powers, paleness, general run-down condition, heartburn, stomach gas, weak back, lumbago, decaying teeth, failing eyesight, and dullness, which were the conditions for which the article was intended. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the portion of the product at Cedar Rapids, Iowa, namely, clippings which were from local newspapers and which accompanied the article, was false and misleading. The labeling contained statements which represented and suggested that the article was an effective treatment for vague pains, bad breath, headaches, digestive disturbances, dizzy spells, lack of vitality and energy, paleness, numbness, heartburn, stomach gas, bad complexion, tiredness, listlessness, irritability, general run-down feeling, nervousness, lack of appetite, and sleeplessness. The article was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: Between May 12 and September 4, 1952. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3749. Adulteration and misbranding of tincture of belladonna and tincture of Hyoscyamus. U. S. v. Standard Drug Co., Inc., and Jacob Starr. Plea of guilty by corporation; plea of nolo contendere by individual. Fine of \$500 against each defendant. (F. D. C. No. 32740. Sample Nos. ~~4028~~-L, 22774-L, 22775-L, 22931-L.)

4-843d

INFORMATION FILED: February 29, 1952, District of New Jersey, against Standard Drug Co., Inc., Newark, N. J., and Jacob Starr, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about August 31, 1950, and February 15 and April 5 and 26, 1951, from the State of New Jersey into the States of Massachusetts and New York.

LABEL, IN PART: "Tincture of Belladonna" and "Tincture of Hyoscyamus."

NATURE OF CHARGE: *Tincture of belladonna.* Adulteration, Section 501 (b), the article purported to be and was represented as "*Belladonna Tincture*," a drug, the name of which is recognized in the United States Pharmacopeia; and its strength differed from the official standard since the article yielded from each 100 cc. less than 27 mg. of the alkaloids of belladonna leaf, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "*Tincture of Belladonna U. S. P.*" was false and misleading since it represented and suggested that the article was "*Belladonna Tincture*," as defined in the United States Pharmacopeia, whereas the article was not "*Belladonna Tincture*" as therein defined.

Tincture of Hyoscyamus. Adulteration, Section 501 (b), the article purported to be and was represented as "*Hyoscyamus Tincture*," a drug, the name of which is recognized in the United States Pharmacopeia; and its strength differed from the official standard since the article yielded from each 100 cc. less than 3.4 mg. of the alkaloids of *Hyoscyamus*, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "*Tincture of Hyoscyamus U. S. P.*" was false and misleading since it represented and suggested that the article was "*Hyoscyamus Tincture*," as defined in the United States Pharmacopeia, whereas the article was not "*Hyoscyamus Tincture*" as therein defined.

DISPOSITION: May 2, 1952. A plea of guilty having been entered by the corporation and a plea of nolo contendere by the individual, the court imposed a fine of \$1,000 against each defendant. On July 2, 1952, the court reduced the fine against each defendant to \$500.

3750. Adulteration and misbranding of procaine penicillin G in aqueous suspension. U. S. v. 20 Packages * * *. (F. D. C. No. 32386. Sample No. 10947-L.)

LIBEL FILED: January 3, 1952, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about February 13, 1951, from Atlanta, Ga.

PRODUCT: 20 packages, each containing 10 tubes, of *procaine penicillin G in aqueous suspension* at Chattanooga, Tenn. Analysis showed that the potency per tube varied from 208,000 units to 248,000 units.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "Each Tubex contains 300,000 units crystalline procaine penicillin G" was false and misleading as applied to the article, the potency of which was less than that stated on the label.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 24, 1952. Default decree of condemnation and destruction.

3751. Adulteration of posterior pituitary injection. U. S. v. 45 Vials * * *. (F. D. C. No. 32513. Sample Nos. 25917-L, 26130-L.)

LIBEL FILED: February 11, 1952, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 15, 1951, by Gold Leaf Pharmacal Co., Inc., from New Rochelle, N. Y.

PRODUCT: 45 vials, each containing 10 cc., of *posterior pituitary injection* at Philadelphia, Pa.