

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 "Hope Mineral Tablets Dietary Supplement Each tablet contains 20 mgm. of iron. Also contains traces of other minerals (extracted from a natural clay) plus $\frac{1}{2}$ mgm. Vitamin B₁, 1 mgm. Vitamin B₂, and 5 mgm. Niacin." (Some of the labels declared also " $\frac{1}{2}$ 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 arthritis, stomach ailments, neuritis, dizzy spells, nervousness, bloating, rheumatism, headaches, weak kidneys, lack of vitality, weak back, acids, toxins, aching back, lumbago, sleepless nights, bad breath, bad complexion, decaying teeth, failing eyesight, lack of energy, underweight, irritability, frequent risings at night, lack of appetite, leg pains, digestive disturbances, vague pains, weakness, heartburn, numbness, paleness, stomach gas, listlessness, tiredness, powers weakened, general rundown feeling, weak sexual powers, and lack of ambition and sparkle, 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 article at Monroe, Wis., and Richmond, Calif., 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 adequate and effective treatment for arthritis, stomach ailments, neuritis, rheumatism, headaches, weak kidneys, dizzy spells, nervousness, bloating, acids, toxins, lack of vitality and energy, aching back, lumbago, underweight, lack of ambition and sparkle, powers weakened, digestive disturbances, vague pains, bad breath, weakness, heartburn, numbness, paleness, stomach gas, tiredness, listlessness, and irritability. The article was not an adequate and effective treatment for such conditions. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

The portion of the article at Monroe, Wis., consisting of a lot of 140 bottles, was alleged to be misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Between March 6 and September 5, 1952. Default decrees of condemnation. The courts ordered that the Wisconsin and Pennsylvania lots of the product be delivered to local hospitals and that the other lots of the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

✓ 3907. Adulteration of dl-desoxyephedrine hydrochloride tablets. U. S. v. 1 drum, etc. (F. D. C. No. 32981. Sample No. 13009-L.)

LIBEL FILED: April 30, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about May 8, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

*See also No. 3905.

PRODUCT: 1 drum of *dl-desoxyephedrine hydrochloride tablets*, together with a number of bottles containing tablets which had been removed from the drum and repacked at Big Spring, Tex.

Examination showed that the product contained no *dl-desoxyephedrine hydrochloride* or *dextro-N-methyl amphetamine hydrochloride* but did contain approximately 5 milligrams of *dextro-amphetamine hydrochloride* per tablet.

RESULTS OF INVESTIGATION: The tablets had been removed from the drum and repacked into the bottles by the Southern Pharmacal Co. (Leonards Rx Pharmacy), Big Spring, Tex.

LABEL, IN PART: (Drum) "Lot No. 8986 Count 100,000 Date 5-3-51 Compressed Tablets *dl-Desoxyephedrine Hydrochloride* 5 Mg.", (bottle) "5 mg. *Dextro-N-Methyl Amphetamine Hcl.* Each tablet contains . . . 5 mg."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), *dextro-amphetamine hydrochloride* had been substituted for *dl-desoxyephedrine hydrochloride* in the drum and *dextro-N-methyl amphetamine hydrochloride* had been substituted for *dl-desoxyephedrine hydrochloride* in the bottles. The article was adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: July 16, 1952. Default decree of condemnation. The court ordered that the product be delivered to a Government hospital for its use.

3908. Adulteration and misbranding of Livo B-12 injection. U. S. v. 41 Bottles * * *. (F. D. C. No. 33602. Sample No. 27210-L.)

LIBEL FILED: July 31, 1952, Northern District of California.

ALLEGED SHIPMENT: On or about May 5, 1952, by the Central Pharmacal Co., from Seymour, Ind.

PRODUCT: 41 bottles of *Livo B-12 injection* at Palo Alto, Calif. Analysis showed that the article contained 33 percent of the declared amount of vitamin B₁₂.

LABEL, IN PART: (Bottle) "10 CC Vial * * * Livo B-12."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each CC Contains * * * Vitamin B-12 50 MG."

Misbranding, Section 502 (a), the label statement "Each CC Contains * * * Vitamin B-12 50 MG" was false and misleading as applied to the article, which contained less than the declared amount of vitamin B₁₂; and the label statement "Liver Injection 10 U. S. P. Units" was false and misleading since no U. S. P. units of liver injection is recognized in the United States Pharmacopeia.

DISPOSITION: On October 8, 1952, a default decree of condemnation was entered, and the court ordered that the product be destroyed. On October 16, 1952, the decree was amended to provide for the delivery of the product to the Food and Drug Administration.

3909. Adulteration and misbranding of liver-folic acid—B₁₂ injection. U. S. v. 7 Vials * * *. (F. D. C. No. 33505. Sample No. 6469-L.)

LIBEL FILED: August 1, 1952, District of Massachusetts.

ALLEGED SHIPMENT: On or about June 16, 1952, by the Addison Laboratories, from Philadelphia, Pa.