

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**DRUGS FOR HUMAN USE***

3006. Misbranding of Nelson's Hygienic Powder. U. S. v. Great Lakes Pharmacal Corp. and Paul M. Hiller. Motion to remand case to Administrator denied. Plea of guilty on behalf of corporation; plea of not guilty by individual. Tried to the court. Fine of \$500 against corporation; case against individual dismissed. (F. D. C. No. 25625. Sample No. 41626-K.)

INFORMATION FILED: April 1, 1949, Northern District of Ohio, against the Great Lakes Pharmacal Corp., Cleveland, Ohio, and Paul M. Hiller, president of the corporation.

ALLEGED SHIPMENT: On or about March 3, 1948, from the State of Ohio into the State of Michigan.

PRODUCT: Analysis showed that the product was a white, aromatic powder containing 74% boric acid, 22.7% zinc sulfate, 0.36% phenol, 2.11% oxyquinoline sulfate, and aluminum compounds.

LABEL, IN PART: "Nelson's Hygienic Powder * * * Great Lakes Laboratories Cleveland, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of leucorrhoea, vaginitis, all inflamed conditions, catarrh, all inflamed mucous membranes, wounds, ulcers, abscesses, and sores. The article would not be efficacious for such purposes.

DISPOSITION: A motion was filed on behalf of the defendants, requesting that the case be remanded to the Federal Security Administrator for review and reconsideration of the charges, on the ground that the matter was a minor violation that could be disposed of under Section 306 of the Act. This motion was heard by the court on October 11, 1949, and was overruled. A plea of guilty was entered on behalf of the corporation and a plea of not guilty was entered by the individual.

The case came on for hearing before the court on October 12, 1949, on the question of the responsibility of Mr. Hiller for the violation. At the conclusion of the testimony on such question, the court, on October 12, 1949, dismissed the case against the individual and imposed a fine of \$1,000 against the corporation. A motion for a new trial was filed on behalf of the corporate defendant but was overruled by the court; however, the fine imposed against this defendant was reduced to \$500.

3007. Misbranding of Patrick's Lung Remedy. U. S. v. Lewis Patrick. Plea of not guilty. Tried to the jury. Verdict of guilty. Defendant sentenced to serve 8 months in Federal institution. (F. D. C. No. 25589. Sample No. 14124-K.)

INFORMATION FILED: February 23, 1949, Southern District of West Virginia, against Lewis Patrick, residing at Stone, Ky., and doing business at William-son, W. Va.

*See also No. 3004.

ALLEGED SHIPMENT: On or about May '18, 1948, from the State of West Virginia into the State of Indiana.

PRODUCT: Analysis showed that the product was a viscous, aqueous liquid with an aromatic odor and sweet taste, and that it contained chiefly sugar, with a small amount of plant extractives, including a trace of unidentified alkaloids.

LABEL, IN PART: "The Patrick's Lung Remedy Herb Compound * * * Contains: Yellow Dock, Bur Dock, Wild Cherry, Sarsaparilla, Hoarhound, Elecampane, Golden Seal, Syrup."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Patrick's Lung Remedy" and the statement "For Treatment of Weak Lung Condition," borne on the label of the article, were false and misleading. The name and statement represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of lung ailments, and in the treatment of a weak lung condition, whereas the article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Attention! Patrick's Lung Remedy" and in an undated letter beginning with the words "Dear Friend: Your order has been mailed this date" were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of tuberculosis, whereas the article would not be efficacious for such purposes.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court and jury, and at its conclusion the jury returned a verdict of guilty. On December 16, 1949, the court sentenced the defendant to serve 8 months in the Federal institution at Mill Point, W. Va.

3008. Misbranding of Se-Bex Tablets, D-E Plex Capsules, and vitamin A capsules. 1 Drum, etc. (F. D. C. No. 27792. Sample Nos. 20067-K to 20069-K, incl., 20098-K, 20099-K.)

LABEL FILED: September 1, 1949, District of Nebraska.

ALLEGED SHIPMENT: On or about August 26, 1948, and May 4 and 11, 1949, from Chicago, Ill., and Detroit, Mich.

PRODUCT: 1 drum containing 50,750 *Se-Bex Tablets*; 2 drums each containing 52,800 *D-E Plex Capsules*; 23 combination cartons labeled *A-D-E Plex Capsules*, each containing 1 100-tablet bottle of *D-E Plex Capsules* and 1 100-tablet bottle of *vitamin A capsules*; and 2 price lists entitled "Guardian Vitamins," in possession of Vitamin Industries, Inc., at Omaha, Nebr.; also 8 100-tablet bottles of *Se-Bex Tablets*; 7 combination cartons labeled *A-D-E Plex Capsules*, which were packaged in the same manner as the capsules in the 23-carton lot; 1 placard headed "Arthritis Sufferers! Famous A-D-E Plex"; and 1 placard headed "Hay Fever Sufferers. Try Se-Bex," in possession of The Vitamin Store, Omaha, Nebr.

LABEL, IN PART: (Bottle) "Tablets Se-Bex Vitamin C with B Complex"; (carton) "Guardian 200 Capsules A-D-E Plex" and "Guardian 100 Capsules D-E Plex Each D-E Plex Capsule contains: Vitamin D 25,000 U. S. P. units * * * Vitamin B₁ 3 Mgm., Vitamin B₂ 2 Mgm., Vitamin C 37.5 Mgm., Niacinamide 20 Mgm., Calcium Pantothenate 1 Mgm., Vitamin B₆ 100 Mgm., Alpha Tocopherol 10 Mgm. * * * Each amber capsule contains: Vitamin A 5,000 U. S. P. units."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the price lists and placards accompanying the articles were false and misleading. These statements represented and suggested that the *Se-Bex Tablets* were ef-