FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1201–1250

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *April 30, 1945.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1201. Adulteration and misbranding of Nelson's Antacid Powder and misbranding of B-M Cold Caps. U. S. v. The Cleveland Druggists Specialties Co. (Great Lakes Laboratories), and Bernard A. Saltzman. Pleas of guilty. Fine of $450 plus costs against each defendant. Payment of fine and costs of corporate defendant suspended. (F. D. C. No. 10541. Sample Nos. 6597–F to 6599–F, incl.)

On September 16, 1943, the United States attorney for the Northern District of Ohio filed an information against the Cleveland Druggists Specialties Co., a corporation trading under the name of Great Lakes Laboratories, Cleveland, Ohio, and against Bernard A. Saltzman, president of the corporation, alleging shipment from the State of Ohio into the State of Missouri of a quantity of B-M Cold Caps, on or about January 2, 1943, and a quantity of Nelson's Antacid Powder, on or about May 25, 1942.

Analysis of the Cold Caps disclosed that the article was in the form of capsules which contained acetanilid, aspirin, caffeine, extracts of plant drugs, including a laxative drug and an alkaloid-bearing drug, and capsicum.

The article was alleged to be misbranded (1) in that each capsule contained 1.72 grains of acetanilid and would be dangerous to health when used in the dosage

*For omission of, or unsatisfactory, ingredients statements, see Nos. 1201, 1202, 1204, 1234, 1235, 1239; failure to bear adequate statements of quantity of contents, Nos. 1229, 1238, 1240, 1248; cosmetics, subject to the drug provisions of the Act, Nos. 1239, 1240.

or with the frequency prescribed, recommended, or suggested in the directions borne on the label, "One capsule every 2 or 3 hours with a glassful or more of water"; (2) in that the statement "For Temporary Relief of Minor Colds, Flu," borne on the label, was false and misleading since the article would not be efficacious as a temporary relief of minor colds and flu; (3) in that the article was fabricated from two or more ingredients and contained the alkaloids of atropine, hyoscine, and hyoscyamine, as constituents of belladonna, and its label did not bear the name and quantity or proportion of the said alkaloids or, in lieu thereof, the quantity or proportion of total alkaloids contained in the article as constituents of belladonna; (4) in that its labeling failed to bear adequate directions for use since the directions on the label provided for the administration of excessive amounts of acetanilid; and (5) in that its labeling failed to bear adequate warnings against use or against unsafe dosage or duration of administration, since its labeling did not bear warning that it might cause serious blood disturbances, anemia, collapse, or dependence on the drug; that it should not be used frequently or continuously; that it should be used cautiously if dryness of the throat occurred; that its use should be discontinued if rapid pulse or blurring of vision occurred; and that continued use of the article, which was a laxative, might result in the dependence of the user upon laxatives to move the bowels.

Analysis of Nelson's Antacid Powder disclosed that the article consisted essentially of compounds of sodium, calcium, magnesium, and carbonate, and that it contained no bismuth salts.

The article was alleged to be adulterated in that its strength differed from that which it purported to possess since it purported to contain bismuth salts, whereas it contained no bismuth salts. It was alleged to be misbranded in that the statement "Bismuth Salts in the form of Carbonates Subnitrates," borne on the label, was false and misleading. It was alleged to be misbranded further because of false and misleading statements in its labeling which represented and suggested that the article would be efficacious in the treatment of gastric ulcers, gastralgia, gastritis, and acidosis; that it would form a soothing, protecting coating over the highly inflamed mucous membranes of the stomach; that it was mildly astringent and sedative; that it would convert all protein foods such as meats and albumens into soluble and readily absorbed peptones; that it would convert all starchy foods into soluble dextrins and sugars; that it would be efficacious in treatment of functional stomach disorders and indigestion; that it was a strictly scientific preparation which offered a rational and effective method of reestablishing the normal alkalinity of the body fluids without danger of systemic disturbance; that it would instantly neutralize all stomach acids; and that it would be efficacious as an instant relief from acidity and gas pressure. It was alleged to be further misbranded in that its label failed to bear an accurate statement of the quantity of contents.

On October 25, 1943, pleas of guilty having been entered, the court imposed a fine of $150 on each of 3 counts, a total fine of $450 plus costs, against each defendant. Payment of the fine and costs against the corporate defendant was suspended.

1202. Misbranding of Grover Graham Remedy. U. S. v. 22 Bottles and 22 Bottles of Grover Graham Remedy (and 4 other seizure actions against the same product). Default decrees of condemnation and destruction. (F. D. C. Nos. 11750, 11816, 11867, 11868, 11977. Sample Nos. 47774–F, 50750–F, 51636–F, 65932–F, 76308–F.)

Between February 5 and March 10, 1944, the United States attorneys for the Eastern District of Missouri, the District of New Jersey, the District of Massachusetts, and the Middle District of Pennsylvania filed libels against the following quantities of the above-named product, contained in 6-ounce and 12-ounce size bottles: 44 bottles at St. Louis, Mo., 65 bottles at Newark, N. J., 60 bottles at Boston, Mass., 82 bottles at Hackensack, N. J., and 18 bottles at Northumberland, Pa., alleging that the article had been shipped on or about December 6 and 21, 1943, and January 24, 1944, from Newburgh, N. Y., by the Grover Graham Co., Inc.; and charging that it was misbranded.

Examination of samples disclosed that the article consisted essentially of magnesia, sodium bicarbonate, sodium bromide, equivalent to 8¼ grains or 8.4 grains per tablespoonful, alcohol, chloroform, oil of peppermint, and coloring matter.

The article was alleged to be misbranded in that the statements on its label which represented and suggested that it would be efficacious in the treatment