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]

426–540

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. MCNUTT, *Administrator, Federal Security Agency.*

Washington, D. C., July 29, 1942.

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[1] See pages 216, 218, 220, 221, 224, and 229 (D. D. N. J. Nos. 433, 436, 437, 439, 443, and 451) for failure to bear name and place of business of manufacturer, packer, or distributor.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

426. Adulteration and misbranding of Catawba's Nervine and Acetandyne Pain Tablets; misbranding of Black Tablets for Kidneys, Bladder, and Uretes, Catawba's Bu-Q-Ju Diuretic, Catawba's Pep-A-Man Tonic Laxative, and Nu-Vig-Or Laxative-Tonic. U. S. v. William B. Goebel (Botanical Medicine Co.). Plea of guilty. Fine, $100. (F. D. C. No. 2906. Sample Nos. 340–E, 341–E, 20232–E to 20235–E, incl.)

Catawba's Nervine would be dangerous to health when used according to directions in the labeling, and its labeling also failed to bear adequate directions for use. Adequate warning statements did not appear in the labeling of the Nervine and of the Acetandyne Pain Tablets. These two products also failed to meet their own standards of strength and quality, the Nervine was falsely labeled as a safe treatment for certain conditions, and the other products all bore false and misleading therapeutic claims.

On March 28, 1941, the United States attorney for the Middle District of North Carolina filed an information against William B. Goebel, trading as Botanical Medicine Co., Kannapolis, N. C., alleging shipment on or about June 7 and 10, 1940, from the State of North Carolina into the States of Virginia and South Carolina of a quantity of the above-named products, of which a portion were misbranded and the remainder were adulterated and misbranded.

Analysis of a sample of Catawba's Nervine showed that it contained not more than 3.97 grains of sodium bromide per ⅛ fluid ounce, not more than 3.7

grains of potassium bromide per ⅛ fluid ounce, and not less than 0.93 grain of ammonium bromide per ⅛ fluid ounce. It was alleged to be adulterated in that its strength differed from or its quality fell below that which it purported or was represented to possess since it was represented to contain 4½ grains of sodium bromide, 4½ grains of potassium bromide, and ½ grain of ammonium bromide in each ⅛ fluid ounce; whereas it contained not more than 3.97 grains of sodium bromide, not more than 3.7 grains of potassium bromide, and not less than 0.93 grain of ammonium bromide. It was alleged to be misbranded: (1) In that the statement on the label, "Each teaspoonful (⅛ oz.) Contains Sodium Bromide 4½ gr. Potassium Bromide 4½ gr. Ammonium Bromide ½ gr.," was false and misleading. (2) In that the bottle label represented and suggested that it constituted a safe and appropriate treatment for the conditions mentioned thereon; whereas it was a dangerous drug and the labeling failed to reveal the material fact that its use under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual, i. e., the use of the drug in accordance with the directions, might lead to mental derangement. (3) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Adult dose—Take one teaspoonful in half glass of water. If necessary repeat but do not take over four teaspoonfuls in any twenty-four hour period." (4) In that its labeling failed to bear adequate directions for use. (5) In that its labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users.

Analysis of a sample of Black Tablets for the Kidneys, Bladder, and Uretes showed that they contained compounds of magnesium and aluminum, cubeb, copaiba, methyl salicylate, and sugar. They were alleged to be misbranded in that the statement in the labeling, "For The Kidneys Bladder and Uretes," was false and misleading since it represented that the drug was efficacious in the treatment of disorders of the kidneys, bladder, and uretes (ureter); whereas it was not efficacious for such purposes.

Analysis of a sample of Catawba's Bu-Q-Ju Diuretic showed that it consisted essentially of extracts of plant drugs (including cubeb and peppermint), sugar, alcohol, and water. It was alleged to be misbranded in that the statement in the labeling, "aids the elimination of the toxic poisonous substances," was false and misleading since the drug was not efficacious for that purpose.

Analysis of a sample of the Acetandyne Pain Tablets showed that they contained not more than 0.99 grain of acetanilid and not less than 2.79 grains of aspirin per tablet. They were alleged to be adulterated in that their strength differed from or their quality fell below that which they purported or were represented to possess since each tablet was represented to contain 2 grains of acetanilid and 1 grain of aspirin; whereas each of the tablets contained not more than 0.99 grain of acetanilid and not less than 2.79 grains of asipirin. They were alleged to misbranded in that the statement, (carton) "Acetandyne Pain Tablets This preparation contains Acetanilid 2 gr. Aspirin 1 gr.," was false and misleading. They were alleged to be misbranded further (1) in that the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users; and (2) in that the statement in the labeling, "Pain Tablets * * * pains caused by menstrual disturbances * * * Menstrual pains," was false and misleading since it represented that the drug was efficacious in the treatment of pains caused by menstrual disturbances; whereas they were not efficacious for such purposes.

Analysis of a sample of Nu-Vig-Or showed that it contained plant material including cloves, capsicum, an emodin-bearing drug such as senna, and a bitter principle such as gentian, sulfur, sodium sulfate, magnesium carbonate, and sodium bicarbonate. It was alleged to be misbranded in that the statement in the labeling, "Nu-Vig-Or * * * Tonic Nu-Vig-Or is a tonic," was false and misleading since it represented that the drug would supply new vigor and would restore vigor; whereas it was not efficacious for such purposes.

Analysis of a sample of Catawba's Pep-A-Man Tonic Laxative showed that it contained extracts of plant drugs including a laxative drug, aloin, and strychnine sulfate. It was alleged to be misbranded in that the statement in the labeling, "Pep-A-Man Tonic," was false and misleading since it represented that the drug possessed tonic properties and the restorative, vitalizing, and invigorating

properties implied in the name "Pep-A-Man"; whereas it did not possess such properties.

On April 21, 1941, the defendant entered a plea of guilty and the court imposed a fine of $100 and placed the defendant on probation for 3 years.

427. Misbranding of Hillman's D Compound. U. S. v. David Hillman (Hillman Pharmaceutical Co.). Plea of guilty. Fine, $1 and costs. (F. D. C. No. 2866. Sample No. 4610-E.)

On November 15, 1940, the United States attorney for the Northern District of Illinois filed an information against David Hillman, trading as Hillman Pharmaceutical Co., Chicago, Ill., alleging shipment on or about February 5, 1940, from the State of Illinois into the State of Wisconsin of a quantity of Hillman's D Compound which was misbranded.

Analysis of a sample of the article showed that the capsules each contained aminopyrine (1.44 grains), a small proportion of ephedrine sulfate, and milk sugar, flavored with peppermint oil.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling; (2) in that its labeling did not bear adequate directions for use; (3) it did not bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. It was alleged to be misbranded further in that the labeling was false and misleading since it created the impression that the article constituted a safe and appropriate treatment for the conditions mentioned in the labeling; whereas it did not constitute a safe and appropriate treatment for the conditions mentioned in the labeling, but was a dangerous drug, and the labeling failed to reveal the material fact that this drug might cause serious blood disturbances. It was alleged to be misbranded further in that statements in the labeling representing that it would be efficacious in the treatment of dysmenorrhea (painful menstruation), would be efficacious in the treatment of cramps, backache, and headache which accompany menstruation, and would banish painful menstruation, were false and misleading since it would not be efficacious for such purposes.

On December 18, 1940, the defendant entered a plea of guilty and the court imposed a fine of $1 and costs.

428. Misbranding of Young's Preparation. U. S. v. Oscar Lee Brunson. Plea of guilty. Defendant placed on probation for 3 years. (F. D. C. No. 2931. Sample Nos. 537-E, 20701-E.)

This product would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, in which it was recommended for the relief of itching skin and scalp and which contained directions that it should be well shaken and applied to afflicted parts two or three times a day; that if the parts were raw, it should be diluted with water until it could be used full strength and that it was natural for the drug to sting when first applied.

On March 11, 1941, the United States attorney for the Southern District of Georgia filed an information against Oscar Lee Brunson of Waycross, Ga., alleging shipment on or about March 4 and May 31, 1940, from the State of Georgia into the State of Florida, of quantities of Young's Preparation which was misbranded for the reasons appearing above.

The article was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in Notice of Judgment No. 105 published under that act.

On June 16, 1941, a plea of guilty having been entered, the defendant was placed on probation for 3 years.

429. Adulteration and misbranding of B-D-Mint Powders. U. S. v. 55 Cards of B-D-Mint Powders. Default decree of condemnation and destruction. (F. D. C. No. 3389. Sample No. 28215-E.)

This product would be dangerous to health when used as directed in the labeling and was not labeled to indicate the consequences that might result from its use. Its labeling also bore false and misleading representations regarding its curative and therapeutic efficacy and was further objectionable as indicated below.

On or about November 20, 1940, the United States attorney for the Western District of Virginia filed a libel against 55 cards, each carrying 28 envelopes