United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

27351–27400

[Approved by the Acting Secretary of Agriculture, Washington, D. C., October 23, 1937]

27351. Misbranding of Apco No. 20. U. S. v. Ampere Products Co. Plea of guilty. Fine, $25. Payment suspended and defendant placed on probation for 1 year. (F. & D. no. 37931. Sample no. 43734–B.)

The labeling of this product bore false and fraudulent curative and therapeutic claims.

On August 26, 1936, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Ampere Products Co., a corporation, West Orange, N. J., alleging shipment by said company in violation of the Food and Drugs Act as amended, on or about April 17, 1935, from the State of New Jersey into the State of Massachusetts of a quantity of Apco No. 20 that was misbranded.

Analysis showed that the article consisted of sodium hypochlorite, sodium chloride, sodium carbonate, and water (93.10 percent).

It was alleged to be misbranded in that certain statements borne on the jug label and contained in an accompanying circular falsely and fraudulently represented that it was effective as a treatment, cure, and preventive of disease in poultry and livestock; as a treatment and remedy for abortion, cowpox, garget, scours, barrenness, retention of afterbirth, and many other diseases in cattle; as a treatment for diseases of swine and as a preventive of cholera in swine; as a treatment and remedy for coccidiosis, cholera, white diarrhoea, and roup in poultry, and as a preventive of blackhead in poultry.

The information also charged misbranding of this product and several other products in violation of the Insecticide Act of 1910 reported in Notice of Judgment No. 1556 published under that date.

On June 25, 1937, the defendant entered a plea of guilty to all charges and the court imposed a fine of $25 on each count of the information. Payment of fine was suspended on certain counts, which included the count charging violation of the Food and Drugs Act, and the defendant was placed on probation for a period of 1 year.

M. L. WILSON, *Acting Secretary of Agriculture.*

27352. Adulteration of morphine sulphate tablets, morphine sulphate and atropine sulphate tablets, nitroglycerin tablets, elixir of barbital, arsenous acid tablets, strychnine sulphate tablets, powdered extract of belladonna leaves, belladonna ointment, santal oil capsules, and powdered extract of stramonium; misbranding of strychnine sulphate tablets, corrosive sublimate tablets, fluidextract of ephedra, and nitroglycerin tablets. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, $500 and costs. (F. & D. no. 36090. Sample nos. 4577–B, 14190–B, 14191–B, 14192–B, 35978–B, 35984–B, 41782–B, 41785–B, 41788–B, 45473–B, 45475–B, 45476–B, 45481–B, 45482–B, 45485–B, 45486–B, 61429–B, 61438–B, 61440–B, 61445–B, 64005–B, 70151–B, 72663–B, 72664–B.)

This case involved the following drugs: Powdered extract of belladonna leaves, belladonna ointment, and powdered extract of stramonium, products recognized in the United States Pharmacopoeia, but which differed from the pharmacopoeial standard; one lot each of strychnine sulphate tablets and corrosive sublimate tablets, two lots of nitroglycerin tablets, and one lot of

fluidextract of ephedra which contained the labeled drugs in excess of the amount declared; and certain lots of strychnine sulphate tablets, nitroglycerin tablets, and various other drugs that contained smaller quantities of the drugs than declared on the labels.

On April 16, 1937, the United States attorney for the District of Maryland, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Standard Pharmaceutical Corporation, Baltimore, Md., alleging shipment by said company in violation of the Food and Drugs Act between the dates of January 9, 1935, and May 13, 1936, from the State of Maryland into the District of Columbia and the States of Alabama, Georgia, North Carolina, and New York of quantities of the above-named drugs a part of which were adulterated and the remainder of which were misbranded. The articles were labeled variously: "Tablets * * * Morphine Sulphate ½ Grain [or "¼ Grain"]"; "Tablets * * * Morphine Sulphate ¼ gr. Atropine Sulphate 1/150 gr."; "Tablets Strychnine Sulphate 1/40 Grain [or "1 Grain", "½ Grain", or "1/200"]"; "Tablets Nitroglycerin 1/100 Grain [or "1/150 Grain" or "1/200"]"; "Elixir Barbital * * * Each fluidounce contains Barbital 16 Grains"; "Tablets Arsenous Acid * * * 1 Grain [or "½ Grain"]"; "Tablets Corrosive Sublimate 1 Grain"; "Powdered Extract Belladonna Leaves U. S. P. Standard:—1.25% Alkaloids"; "Ointment Belladonna (Unguentum Belladonnae) U. S. P."; "Powdered Extract Stramonium (Ext. Stramonii) U. S. P. * * * Standard Pharmaceutical Corp. Baltimore, Md."; "Fluid Extract Ephedra * * * Each 100 cc yields 0.5 Gm. of the Alkaloids of Ephedra * * * Prepared For Standard Pharmaceutical Corp."; "Capsules * * * Santal Oil * * * 5 Minims Manufactured For Standard Pharmacentical Corp."

Certain of the products were alleged to be adulterated in that they were sold under names recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the test laid down in said pharmacopoeia official at the time of investigation and their standards of strength, quality, and purity were not declared on the containers, viz: The powdered extract belladonna leaves yielded not more than 1.1 percent of the alkaloids of belladonna leaves, whereas the pharmacopoeia provided that extract of belladonna leaves should yield not less than 1.18 percent of the alkaloids of belladonna leaves; the belladonna ointment contained not more than 9 grams of pilular extract of belladonna per 100 grams, whereas the pharmacopoeia provided that belladonna ointment should contain not less than 10 grams of pilular extract of belladonna per 100 grams; the powdered extract stramonium yielded not more than 0.347 percent of the alkaloids of stramonium, whereas the pharmacopoeia provided that extract of stramonium should yield not less than 0.9 percent of the alkaloids of stramonium.

Adulteration of the above products and of certain of the others was charged in that their strength and purity fell below the professed standard and quality under which they were sold in the following respects: The powdered extract belladonna leaves, the belladonna ointment, and the powdered extract stramonium were represented to conform to the standard laid down in the United States Pharmacopoeia, and the powdered extract belladonna leaves was further labeled as containing 1.25 percent of the alkaloids of belladonna leaves, whereas the products did not conform to said standard and the powdered extract belladonna leaves contained less than 1.25 percent, namely, not more than 1.1 percent of the alkaloids of belladonna leaves; two of the lots of morphine sulphate tablets were represented to contain one-half grain of morphine sulphate each and one lot was represented to contain one-fourth grain of morphine sulphate per tablet, whereas samples of the former contained 0.37 grain and 0.39 grain of morphine sulphate per tablet and samples from the latter contained not more than 0.18 grain (approximately one-fifth grain) of morphine sulphate; two lots of the strychnine sulphate tablets were represented to contain 1 grain or one-half grain of strychnine sulphate per tablet, whereas the former contained not more than 0.78 grain, and the latter not more than 0.414 grain of strychnine sulphate per tablet; certain lots of the nitroglycerin tablets were represented to contain one one-hundredth of a grain of nitroglycerin per tablet, whereas samples from three of the four lots were found to contain 0.005, 0.0056, 0.0055 grain, respectively (approximately one two-hundredth of a grain), of nitrogylcerin and samples from the fourth lot contained 0.0074 (approximately one one-hundred thirty-fifth grain of nitroglycerin; the arsenous acid tablets were represented to contain 1 grain or one-half grain of arsenous acid, whereas the former contained not more than 0.87 (seven-eighths) grain and

the latter contained not more than 0.375 (three-eighths) grain of arsenous acid per tablet; the morphine sulphate and atropine sulphate tablets were each represented to contain one-fourth grain of morphine sulphate, whereas they contained not more than 0.215 (approximately one-fifth) grain of morphine sulphate; the elixir barbital was represented to contain 16 grains of barbital per fluid ounce, whereas each fluid ounce contained less than represented, namely, not more than 11.6 grains of barbital; and the santal oil capsules were each represented to contain 5 minims of santal oil, whereas they contained less than represented, namely, not more than 4.28 minims of santal oil.

The remaining products were alleged to be misbranded in that certain statements on the labels were false and misleading in the following respects: One lot of strychnine tablets were labeled: "Tablets * * * Strychnine Sulphate 1/40 Grain", whereas the tablets contained more than declared, namely, not less than 0.029 approximately (one thirty-fifth) grain of strychnine sulphate; the fluidextract of ephedra was labeled "Fluid Extract Ephedra * * * Standard: Each 10 cc yields 0.5 Gm. of the Alkaloids of Ephedra", whereas each cubic centimeter yielded more than declared, namely, not less than 0.657 gram of ephedra; the corrosive sublimate tablets were labeled "Tablets Corrosive Sublimate 1 Grain", whereas the tablets contained more than declared, namely, not less than 1.125 grain of corrosive sublimate; two of the lots of nitroglycerin tablets were labeled, "Tablet * * * Nitroglycerin 1/150 [or "1/200"] Grain", whereas the tablets contained more than declared, the former containing not less than 0.012 (approximately one-eightieth) grain and the latter containing not less than 0.0083 (one one-hundred and twentieth) grain of nitroglycerin.

On May 20, 1937, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $500 and costs.

M. L. WILSON, *Acting Secretary of Agriculture.*

27353. Adulteration and misbranding of Geba. U. S. v. Vitamin Products Research Foundation, Inc. Plea of guilty. Fine, $25 and costs. (F. & D. no. 37946. Sample no. 48064–B.)

The labeling of this product contained misrepresentations regarding its value as a source of vitamin A, and false and fraudulent claims regarding its curative and therapeutic effects.

On September 29, 1936, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Vitamin Products Research Foundation, Inc., trading at Chicago, Ill., alleging shipment by said company in violation of the Food and Drugs Act as amended, on or about July 19, 1935, from the State of Illinois into the State of Wisconsin of a quantity of Geba which was adulterated and misbranded. The article was labeled in part: "Geba * * * Vitamin Products Research Foundation, Inc. * * * Chicago, Ill."

Microscopic examination showed that it consisted essentially of cereal starch, bran, and germ (embryo) tissues, apparently from wheat; analysis showed that it contained protein, starch, sugars, and compounds of calcium and magnesium, phosphates, and carbonates. Vitamin determination showed that it contained approximately 2 U. S. P. units of vitamin A per tablet.

The article was alleged to be adulterated in that its strength and purity fell below the professed standard and quality under which it was sold, since it was represented to be a good and excellent source of vitamin A; whereas it contained little, if any, vitamin A.

It was alleged to be misbranded in that the statements (circular) "A Vitamin Concentrate", "Geba * * * is an excellent source of Vitamin A", "Vitamin A * * * Geba Tablets are an excellent source of Vitamin A", and (jar) "A good source of vitamin A", were false and misleading since they represented that it was a good and excellent source of vitamin A, and that it was a vitamin concentrate; whereas it was not a good and excellent source of vitamin A and was not a vitamin concentrate since it contained little, if any, vitamin A. The article was alleged to be misbranded further in that certain statements, designs, and devices regarding its therapeutic and curative effects, contained in the circular shipped with it, falsely and fraudulently represented that it was effective to promote health, to help attain vigorous, robust mind and body, to provide elements vital to vigorous normal health, to build resistance to disease, to supply vitamin strength; effective to protect the system against bacterial infections such as common colds, infections of the eyes, ears, sinuses,