

United States Department of Agriculture,

OFFICE OF THE SECRETARY.

NOTICE OF JUDGMENT NO. 942, FOOD AND DRUGS ACT.

MISBRANDING OF A DRUG PRODUCT—"AMMON PHENYL."

On or about March 25, 1910, Salvadore Penny, trading as The International Chemical Company, Palisades Park, N. J., shipped from the State of New Jersey into the State of Massachusetts a quantity of a drug product labeled as follows: "Ammon Phenyl, Trade Mark, Antipyretic Antiseptic, Antineuralgic, Antiseptic Puritas et Potentia. Non Plus Ultra Stimulant, Laxative, International Chemical Company, New York, U. S. A. Keep well corked and beware of substitutes. * * * For Physicians' Prescriptions only. 1 oz. 5-grain Tablets Ammon Phenyl. Ammoniated Pheno Acetyl, $C_6H_5NH_2$, Stimulant, Antipyretic, Analgesic, Antineuralgic, Antiseptic, Antirheumatic, Antispasmodic, Expectorant, Antacid, Sedative, Hypnotic, etc. Dose.—Five to fifteen grains, according to age. (0.33—1 gr.) Manufactured only by the International Chemical Co., New York, U. S. A., London, Paris, Vienna, Berlin, Amsterdam, Brussels, Milan, St. Petersburg, Montreal, Madrid, Mexico, Geneva, Melbourne, Buenos Ayres, Lisbon, Stockholm, Calcutta, Rio Janeiro." Packed with the product was a circular which contained the following statements: "Ammon Phenyl is one of the acetyl derivatives of aniline of the Amido-Benzene Series whose base is $C_6H_5NH_2$, combined by our own special chemical process with ammonia. The presence of ammonia tends to overcome the depressing effects usually observed in the other Coal Tar derivatives, such as Antipyrine, Phenacetine, Acetanilide, etc., and it can be used in conditions of vital depression where these drugs would be contraindicated. Cyanosis and Collapse never appear after its use. Uses. In Pneumonia, Phthisis, Influenza, Typhoid Fever, Epilepsy, Erysipelas, Opium Habit, Convulsion of Infants, Rheumatism (Acute or Chronic), Senile Gangrene, Scarlatina, Diphtheria, Angina Pectoris, in weak, Irritable or Dilated Heart. In Croupous Pneumonia it has been observed that it not only reduces the temperature, but has a favorable influence on the pathological process in the lung, while the ammonia as is well known,

has a tendency to prevent blood clot in the ventricle, a very frequent cause of death in this disease." A sample from this shipment was procured and analyzed by the Bureau of Chemistry, United States Department of Agriculture, and it was found to contain acetanilid, sodium bicarbonate, and ammonium carbonate. As the findings of the analyst and report thereon indicated that the product was misbranded within the meaning of the Food and Drugs Act of June 30, 1906, the said Salvadore Penny and the party from whom the sample was procured were afforded opportunities for hearings. As it appeared after hearings held that the above shipment was made in violation of the act, the Secretary of Agriculture reported the facts to the Attorney-General, with a statement of the evidence upon which to base a prosecution.

On November 4, 1910, a criminal information was filed in the District Court of the United States for the District of New Jersey against the said Salvadore Penny, charging the above shipment, and alleging that the product so shipped was misbranded because the statement appearing in the label and circular that the product was "one of the acetyl derivatives of aniline of the Amido-benzene series, whose base is $C_6H_5NH_2$, combined by our own special process with ammonia", obscured the real origin and nature of the product, in fact but a mixture of acetanilid, sodium bicarbonate, and ammonium carbonate, and not a chemical compound; in that the statement "The presence of ammonia tends to overcome the depressing effects usually observed in other coal tar derivatives, such as Antipyrine, Phenacetine, Acetanilid, etc.", was false and misleading, as the preparation does possess the depressing effects of acetanilid; and in that the statements following the word "Uses", in the circular above referred to as the therapeutic properties of the preparation, were false and misleading, as the product is not capable of effecting the beneficial physiological results therein claimed for it, but would in many of the disorders enumerated prove harmful, and its use would be contraindicated.

On February 15, 1911, the defendant entered a plea of non vult to the above information, whereupon the court imposed a fine of \$25.

This notice is given pursuant to section 4 of the Food and Drugs Act of June 30, 1906.

JAMES WILSON,
Secretary of Agriculture.

WASHINGTON, D. C., *June 10, 1911.*