2366. Adulteration of aminophylline and misbranding of thiamine hydrochloride. U. S. v. Medicinals, Inc. Plea of guilty. Fine, $600. (F. D. C. No. 23246. Sample Nos. 40106–H, 65268–H.)

INFORMATION FILED: January 20, 1948, Eastern District of New York, against Medicinals, Inc., Richmond Hill, N. Y.

ALLEGED SHIPMENT: On or about September 23 and 25, 1946, from the State of New York into the States of Tennessee and Pennsylvania.

LABEL, IN PART: "Aminophylline U. S. P.," or "Thiamine Hydrochloride * * * Distributed by Physicians' Drug & Supply Co. Philadelphia, Pa."

NATURE OF CHARGE: *Aminophylline.* Adulteration, Section 501 (b), the article purported to be and was represented as "Theophylline Ethylenediamine Injection [Aminophylline Ampuls]," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from, and its quality and purity fell below, the official standard; and its difference in strength, quality, and purity from the standard was not plainly stated, or stated at all, on its label. The standard provides that the drug should contain an amount of anhydrous theophylline equivalent to not less than 73 percent and not more than 83 percent of the labeled amount of theophylline ethylenediamine, and that injections which are solutions of soluble medicaments must be free of undissolved material which can be detected readily when tested in accordance with the method described in the United States Pharmacopoeia. Some ampoules of the article contained an amount of anhydrous theophylline equivalent to less than 73 percent, and other ampoules contained an amount of anhydrous theophylline equivalent to more than 83 percent of the labeled amount of theophylline ethylenediamine. Further, the article contained undissolved material which could be readily detected when tested in accordance with the prescribed method.

Thiamine hydrochloride. Misbranding, Section 502 (a), the label statement "Thiamine Hydrochloride 200 mg. per cc. (Equiv. to 66,000 units of Vitamin B_1 per cc.)" was false and misleading, since the article contained less than that amount of thiamine hydrochloride per cubic centimeter.

DISPOSITION: February 11, 1948. A plea of guilty having been entered, the court imposed a fine of $600.

2367. Adulteration of thiamine hydrochloride. U. S. v. 72 Vials * * *. (F. D. C. No. 23709. Sample No. 1001–K.)

LIBEL FILED: September 25, 1947, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 13, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 72 30-cc. size vials of thiamine hydrochloride at Miami, Fla.

LABEL, IN PART: "Thiamine Hydrochloride * * * Intramuscular-Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: July 28, 1948. Default decree of forfeiture and destruction.

2368. Adulteration of thiamine hydrochloride. U. S. v. 38 Vials * * *. (F. D. C. No. 23708. Sample No. 12901–K.)

LIBEL FILED: September 17, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 21, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 38 30-cc. vials of *thiamine hydrochloride* at Philadelphia, Pa.

LABEL, IN PART: "Thiamine Hydrochloride * * * Intramuscular-Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard, since it was contaminated with undissolved material.

DISPOSITION: December 1, 1947. Default decree of condemnation and destruction.