

6742. Armatinic liquid. (F.D.C. No. 45807. S. Nos. 32-281/82 R.)

QUANTITY: 180 4-oz. btls. and 127 8-oz. btls. at Santurce, P.R.

SHIPPED: 12-31-60 and 2-8-61, from Kankakee, Ill., by Armour Pharmaceutical Co.

LABEL IN PART: (Btl.) "Armatinic Liquido—Cada 29.57 ML Contiene—Acido Folic 2 mg.—Armour Pharmaceutical Company Kankakee, Illinois."

LIBELED: 5-25-61, Dist. P.R.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling, since, under the label directions for use, 2 tablespoonfuls twice a day (1 lot) and 2 teaspoonfuls twice a day (second lot), the article would supply 4 mg. and 1.3 mg. of folic acid daily respectively.

DISPOSITION: 7-20-61. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6743. Biphettamine-T 12½ and Biphettamine-T 20. (F.D.C. Nos. 46260, 46264. S. Nos. 97-215 R, 97-217/18 R.)

QUANTITY: 33 50-capsule btls. of 12½-mg. capsules; 49 50-capsule btls. of 20-mg. capsules; 5 cases, each containing 12 50-capsule btls. of 12½-mg. capsules; and 4 cases, each containing 12 50-capsule btls. of 20-mg. capsules, at Pittsburgh, Pa.

SHIPPED: Between 4-14-61 and 6-30-61, from Rochester, N.Y., by Strassenburgh Laboratories, Div. of Wallace & Tiernan, Inc.

LABEL IN PART: "Biphettamine T-12½ [or "T-20"] * * * Strassenburgh Laboratories Division Wallace & Tiernan, Inc., Rochester, N.Y."

ACCOMPANYING LABELING: File card entitled "Biphettamine-T" and a brochure entitled "The Clinical Importance of Weight Reduction in Exogenous Obesity."

LIBELED: 8-23-61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the drug, namely, the file card entitled "Biphettamine-T," contained false and misleading representations that the article reduced the insulin requirement in diabetes, reduced the nitroglycerin requirement in arteriosclerosis, and reduced the blood pressure in hypertension; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from the requirement that the article bear such directions for use, since the promotional material for the new drug was not the same as, or substantially the same as, the labeling authorized by the effective new drug application; 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since the effective new drug application filed with respect to the article did not apply to the conditions for which the article was promoted to the medical profession, namely, (a) in the physician's file card entitled "Biphettamine-T," distributed to physicians, the drug was represented as being capable of reducing the insulin requirement in diabetes, of reducing the nitroglycerine requirement in arteriosclerosis, and of reducing blood pressure in hypertension; and