

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. Biphedamine-T 12½ and Biphedamine-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: "Biphedamine T-12½ [or "T-20"] * * * Strassenburgh Laboratories Division Wallace & Tiernan, Inc., Rochester, N.Y."

ACCOMPANYING LABELING: File card entitled "Biphedamine-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 "Biphedamine-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 "Biphedamine-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

(b) in the brochure entitled "The Clinical Importance of Weight Reduction in Exogenous Obesity" the drug was offered for diabetes, arteriosclerotic heart disease, hypertension, and ulcers;

which labeling representations differed materially from the labeling claims permitted by the effective new drug application.

DISPOSITION: 10-13-61. Default—destruction.

DRUG FOR VETERINARY USE

6744. *Iro-Jex* injectable. (F.D.C. No. 45628. S. Nos. 61-044/45 R.)

QUANTITY: 226 30-cc. btl. and 607 100-cc. btl. at Kansas City, Mo.

SHIPPED: 2-7-61 and 3-22-61, from Los Angeles, Calif.

LABEL IN PART: "Iro-Jex Injectable Iron-Arsenic Solution each 2 cc contains: Ferric Cacodylate 1 Gr. Copper Sulfate 1/100 Gr. * * * Suggested dosage: 2 cc given intramuscularly or intravenously—distributed by the National Laboratories Corp. Kansas City."

RESULTS OF INVESTIGATION: When shipped, the labeling offered the drug for human use. The dealer relabeled the article for veterinary use.

LIBELED: On or about 4-17-61, W. Dist. Mo.; amended libel on or about 5-17-61.

CHARGE: 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 7-12-61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6745. *Vigo Forte* tablets, *Altocaps* capsules, and vitamin B₁₂ and B₁ injection. (F.D.C. No. 45900. S. Nos. 32-274/77 R.)

QUANTITY: 19 50-tablet btl. of *Vigo Forte* tablets; 18 20-capsule btl. of 50-mg. *Altocaps* capsules; 20 20-capsule btl. of 100-mg. *Altocaps* capsules; and 79 10-cc. vials of *vitamin B₁₂ and B₁ injection*, at San Juan, P.R.

SHIPPED: Between 10-1-60 and 11-17-60, from Newark, N.J., by Benson Pharmacal Corp.

LABEL IN PART: (Btl.) "Vigo Forte * * * Testosterona 2 mgm. Vitamin E 10 mgm. Extracto de damiana 60 mgm. Extracto de nucz vomica 5 mgm. Clorhidrato de yohimbine 5 mgm. Puerto Rico Drug * * * San Juan, P.R.—Distributors"; "Benson Altocaps 50 Mg. [or "100 Mg."] Each capsule contains * * * Vitamin E (from d-alpha Tocopheryl Acetate Concentrate, N.F.) Directions: One to six capsules daily * * * Benson Pharmacal Co., Inc., New York, N.Y."; and (vial) "Multiples Dosis 10 cc Frasco Vitaminas B₁₂ y B₁ Cada cc contiene vitamina B₁₂ 1000 mcgm. Vitamina B₁ 100 mg. * * * intramuscular Benson Pharmacal Corp., Newark, N.J."

LIBELED: 5-29-61, Dist. P.R.

CHARGE: *Altocaps* capsules, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for habitual abortion, ovarian failure, muscular dystrophy, and amyotrophic lateral sclerosis.