

(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. btls. and 607 100-cc. btls. 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 btls. of *Vigo Forte* tablets; 18 20-capsule btls. of 50-mg. *Altocaps* capsules; 20 20-capsule btls. 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.