

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

3490. Adulteration and misbranding of Testramone, Vitramone, A-Vee, and Harvaplex. U. S. v. Harvey Laboratories, Inc., and Frederick Greenbaum. Pleas of nolo contendere. Corporation fined \$1,000 on count 1 and \$1,000 on count 2; sentence suspended on remaining counts. Individual fined \$100 on count 1 and placed on probation for 1 day on remaining counts. (F. D. C. No. 30013. Sample Nos. 12394-K, 73927-K to 73929-K, incl., 73931-K, 79342-K, 80876-K.)

INFORMATION FILED: January 9, 1951, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Frederick Greenbaum, secretary of the corporation.

ALLEGED SHIPMENT: On or about March 8 and 21 and April 5, 6, and 10, 1950, from the State of Pennsylvania into the States of New Jersey, Rhode Island, Delaware, and New York.

LABEL, IN PART: "Testramone [or "Harvaplex"] * * * Harvey Laboratories" and "Testramone [or "Vitramone" or "A-Vee"] * * * Dist. by Ardsley Labs. 999 Lexington Ave. N. Y. C."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the *Testramone* fell below that which it purported and was represented to possess since it purported and was represented to be suitable and appropriate for intramuscular injection, whereas it was not suitable and appropriate for such purpose since it was not sterile but was contaminated with viable micro-organisms; and the strength of the *Vitramone*, *A-Vee*, and *Harvaplex*, and a portion of the *Testramone*, differed from that which they purported and were represented to possess since they contained less than the labeled amount of riboflavin.

Misbranding, Section 502 (a), the statement "Intramuscular Injection" on the labels of the *Testramone* was false and misleading since the statement represented and suggested that the product would be suitable and appropriate for intramuscular injection, whereas it was not suitable and appropriate for such purpose since it was not sterile but was contaminated with viable micro-organisms; and the representations in the labeling of the *Vitramone* and *A-Vee* and a portion of the *Testramone* that each cubic centimeter of the products contained 2 milligrams of riboflavin and the representation in the labeling of the *Harvaplex* that each 2 cc. of the product contained 5 milligrams of riboflavin were false and misleading since the products contained less riboflavin than so represented.

DISPOSITION: March 28, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of \$1,000 on count 1 and \$1,000 on count 2 against the corporation and a fine of \$100 on count 1 against the individual defendant. The court suspended imposition of sentence on counts 3 to 14 with respect to the corporation and on counts 2 to 14 with respect to the individual defendant, and placed the individual on probation for 1 day.

*See also Nos. 3487, 3488.