

**DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\***

**4215. Adulteration and misbranding of amphetamine sulfate tablets. U. S. v. Leo Henzel (Penn-Lee Products). Plea of nolo contendere. Fine, \$200. (F. D. C. No. 24220. Sample Nos. 52302-H, 53635-H.)**

**INFORMATION FILED:** July 8, 1948, Northern District of Illinois, against Leo Henzel, trading as Penn-Lee Products, Chicago, Ill.

**ALLEGED SHIPMENT:** On or about July 15 and August 31, 1946, from the State of Illinois into the States of Minnesota and Ohio.

**LABEL, IN PART:** (Bottle) "Amphetamine Sulfate Tablets 10 Mgs. [or "5 Mgs.]" per Tablet \* \* \* Penn-Lee Products Chicago Distributors Ill."

**NATURE OF CHARGE:** Adulteration, Section 501 (d) (2), desoxyephedrine hydrochloride had been substituted for amphetamine sulfate.

Misbranding, Section 502 (a), the label statement "Amphetamine Sulfate Tablets" was false and misleading since the article did not consist of amphetamine sulfate tablets but consisted of desoxyephedrine hydrochloride tablets.

**DISPOSITION:** October 15, 1953. The defendant having entered a plea of nolo contendere, the court fined him \$200.

**4216. Adulteration of estrogen tablets. U. S. v. Robin Pharmacal Corp. Plea of guilty. Fine, \$200. (F. D. C. No. 33783. Sample No. 813-L.)**

**INFORMATION FILED:** May 14, 1953, Southern District of New York, against the Robin Pharmacal Corp., New York, N. Y.

**ALLEGED SHIPMENT:** Between December 1 and 31, 1950, from the State of New York into the State of Florida.

**LABEL, IN PART:** (Bottle) "1000 Each tablet contains 1.25 mgm. of estrogens in their naturally occurring water soluble form, expressed as sodium estrone sulfate Robin Pharmacal Co. New York, N. Y. 2339."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet of the article contained less than the declared amount of 1.25 milligrams of estrogens in their naturally occurring water-soluble form expressed as sodium estrone sulfate.

**DISPOSITION:** October 8, 1953. The defendant having entered a plea of guilty, the court fined it \$200.

**4217. Adulteration and misbranding of Hep-Vi-Plex. U. S. v. 63 Vials \* \* \*. (F. D. C. No. 34659. Sample No. 66905-L.)**

**LIBEL FILED:** February 12, 1953, Eastern District of Pennsylvania; libel amended March 5, 1953.

**ALLEGED SHIPMENT:** On or about November 17, 1952, by the Gold Leaf Pharmacal Co., from New Rochelle, N. Y.

**PRODUCT:** 63 vials of *Hep-Vi-Plex* at Philadelphia, Pa. Analysis showed that the product contained approximately 25 percent of the declared amount of vitamin B<sub>12</sub> activity per 2 cc.

\*See also Nos. 4209, 4212.

**LABEL, IN PART:** (Vial) "30 cc Multiple Dose Vial Sterile Solution Hep-Vi-Plex Liver, Iron and Vitamins \* \* \* Each 2 cc represent: Liver Injection (Equivalent in Vitamin B-12 activity to 10 mcg. cyanocobalamin per cc.) . . . 100 mg."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 100 milligrams of liver injection equivalent in vitamin B<sub>12</sub> activity to 10 micrograms cyanocobalamin per cubic centimeter in each 2 cubic centimeters.

Misbranding, Section 502 (a) the label statement "Each 2 cc represent: Liver Injection (Equivalent in Vitamin B-12 activity to 10 mcg. cyanocobalamin per cc.) . . . 100 mg." was false and misleading as applied to the article, which contained less than the declared amount of vitamin B<sub>12</sub> activity.

**DISPOSITION:** October 8, 1953. Default decree of condemnation and destruction.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**4218. Misbranding of shark liver oil capsules. U. S. v. 50 Bottles, etc. (F. D. C. No. 31595. Sample No. 24464-L.)**

**LIBEL FILED:** August 6, 1951, District of New Jersey.

**ALLEGED SHIPMENT:** On or about April 26, 1951, from New York, N. Y.

**PRODUCT:** 50 50-capsule bottles and 8 250-capsule bottles of *shark liver oil capsules* at Paterson, N. J., in the possession of the Vital Food Service, together with a poster entitled "Eyes Are Rationed" which was on display in the consignee's store.

**LABEL, IN PART:** (Bottle) "Shark Liver Oil Capsules Each capsule contains refined, blended Shark Liver Oils, standardized to contain not less than 25,000 U. S. P. Units Vitamin A."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statement on the above-mentioned poster accompanying the article, namely, "Vitamin A As Vitamin Deficiency May Be the Cause of \* \* \* Sinus Trouble Kidney & Bladder Trouble Poor Resistance to infections Dry Skin Poor Teeth," was false and misleading. The statement represented and suggested that the article, when used as directed, was effective in preventing sinus trouble, kidney and bladder trouble, poor resistance to infection, dry skin, and poor teeth. The article, when used as directed, was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

The libel alleged also that quantities of Special Formula capsules and Vital Veeda capsules were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** Felicia P. Kornreich, trading as Vital Food Service, appeared as claimant and filed an answer on September 28, 1951. On October 18, 1951, the Government filed a motion to strike six separate defenses contained in the answer because some of the alleged defenses were insufficient in law and others were immaterial. The motion was denied by the court on November 26, 1951, with leave to renew the motion at the trial.

On or about March 3, 1952, the claimant filed a motion to dismiss the libel, to vacate the warrant of seizure and monition, and to restore to the claimant

\*See also Nos. 4201, 4209, 4211, 4212, 4215, 4217.