

**4164. Misbranding of Taboyster tablets. U. S. v. 21 Bottles \* \* \*. (F. D. C. No. 35290. Sample No. 57067-L.)**

**LABEL FILED:** June 4, 1953, Northern District of Ohio.

**ALLEGED SHIPMENT:** On or about March 17 and 19, 1953, by the Hollister Pharmacal Co., from Chicago, Ill.

**PRODUCT:** 21 bottles of *Taboyster tablets* at Toledo, Ohio.

**LABEL, IN PART:** (Bottle) "Hollister's Taboyster Tablets Contents 48 Tablets \* \* \* Ingredients Tricalcium Phosphate Sodium Chloride Potassium Chloride Magnesium Phosphate Ferrous Sulfate Manganese Glycerophosphate Potassium Iodide Cupric Sulfate Crystalline Vit. A Acetate (Vitamin A) Thiamin HCL (Vitamin B-1) Riboflavin (Vitamin B-2) (G) Ascorbic Acid (Vitamin C) In especially prepared base containing vegetable protein and vegetable oil."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in rejuvenating strength and restoring sexual vigor, which were the conditions for which the article was offered in advertising sponsored by the distributor, the Hollister Pharmacal Co.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** August 6, 1953. Default decree of condemnation and destruction.

**4165. Misbranding of vaginal diaphragms. U. S. v. 21 Diaphragms \* \* \*. (F. D. C. No. 35260. Sample No. 54779-L.)**

**LABEL FILED:** May 20, 1953, Eastern District of Michigan.

**ALLEGED SHIPMENT:** On or about March 23, 1953, by the Diaphragm & Chemical Co., from Chicago, Ill.

**PRODUCT:** 21 *vaginal diaphragms* in individual plastic boxes at Detroit, Mich.

**LABEL, IN PART:** (Box) "Molded D & C Narrow Rim"; (molded in diaphragm) "Molded D & C Long Life"; (glassine insert) "This Is The New Safety Seal D & C Diaphragm \* \* \* Sold Only Through Accredited Surgical Supply Dealers."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** July 17, 1953. Default decree of condemnation and destruction.

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

**4166. Adulteration and misbranding of liver injection. U. S. v. 500 Vials \* \* \*. (F. D. C. No. 35210. Sample No. 26462-L.)**

**LABEL FILED:** On or about May 4, 1953, District of New Jersey.

**ALLEGED SHIPMENT:** On or about February 26, 1953, from Baltimore, Md.

**PRODUCT:** 500 vials of *liver injection* at Camden, N. J. Analysis showed that the vitamin B<sub>12</sub> activity of the product was equivalent to 0.5 microgram of cyanocobalamin per cubic centimeter.

**LABEL, IN PART:** (Vial) "Multiple Dose Vial 30 cc. Liver Injection, Crude, U. S. P. Each cc. has a Vitamin B<sub>12</sub> activity equivalent to 2 micrograms of cyanocobalamin."

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be and was represented as "Liver Injection Crude," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since each cubic centimeter of the article possessed a vitamin B<sub>12</sub> activity equivalent to less than 2 micrograms of cyanocobalamin.

Misbranding, Section 502 (a), the label statements "Liver Injection, Crude, U. S. P. Each cc. has a Vitamin B<sub>12</sub> activity equivalent to 2 micrograms of cyanocobalamin" were false and misleading as applied to the article, which did not conform to the specifications of the United States Pharmacopeia for liver injection crude and the vitamin B<sub>12</sub> activity of which was equivalent to less than 2 micrograms of cyanocobalamin per cubic centimeter.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** July 1, 1953. Default decree of condemnation and destruction.

**4167. Adulteration and misbranding of AAC Compound tablets and Compressed tablets. U. S. v. 22 Bottles, etc. (F. D. C. No. 34981. Sample Nos. 62045-L, 62047-L.)**

**LIBEL FILED:** April 24, 1953, Southern District of Illinois.

**ALLEGED SHIPMENT:** On or about September 2, 1952, by Dumas-Wilson & Co., from St. Louis, Mo.

**PRODUCT:** 22 1,000-tablet bottles and 6 3,000-tablet bottles of *AAC Compound tablets* and 4 5,000-tablet bottles and 3 1,000-tablet bottles of *Compressed tablets* at Decatur, Ill.

Analysis showed that each *AAC Compound tablet* contained approximately 1.4 grains of acetophenetidin and that each *Compressed tablet* contained approximately  $\frac{1}{11}$  grain of kermes mineral (antimony sulfide, golden).

**RESULTS OF INVESTIGATION:** The drugs involved, when shipped in interstate commerce, were packaged in bulk containers, and upon their receipt by the consignee, were repacked into bottles and relabeled by the consignee.

**LABEL, IN PART:** *AAC Compound tablets.* (Bottle) "Acetophenetidin 2½ grs. (Derivative of Acetanilid) Acetylsalicylic Acid 3½ grs. Caffeine Alkaloid ½ gr. \* \* \* Distributed by Sly and Company \* \* \* Decatur, Illinois"; (bulk container) "Contains 50,850 Specifications Compressed Tablets Mottled Each tablet contains: Aspirin 3.5 grs. Acetophenetidin 2.5 grs. Caffeine Alk. 0.5 gr."

*Compressed tablets.* (Bottle) "Each tablet contains: Kermes Mineral  $\frac{1}{6}$  gr. Powdered Ipecac  $\frac{1}{12}$  gr. \* \* \* Sly and Company \* \* \* Decatur, Illinois"; (bulk container) "Contains 50,100 Specifications Compressed Tablets Each tablet contains: Kermes Mineral  $\frac{1}{6}$  gr. (Antimony Sulfide, Golden) Powdered Ipecac  $\frac{1}{12}$  gr."

**NATURE OF CHARGE:** *AAC Compound tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 2.5 grains of acetophenetidin per tablet. Misbranding, Section 502 (a), the label statements (bulk container) "Acetophenetidin 2.5 grs." and (relabeled bottle) "Acetophenetidin 2½ grs." were false and misleading as applied to a product which contained less than 2.5 grains of acetophenetidin per tablet.

*Compressed tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.