

CHARGE: 501(b)—when shipped, the article purported to be a drug, *secobarbital sodium capsules*, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 10-7-60. Default—destruction.

6428. Higadoce Forte injection. (F.D.C. No. 44734. S. No. 6-360 R.)

QUANTITY: 8 10-cc. vials at Wakefield, R.I.

SHIPPED: 3-9-60, from Worcester, Mass.

LABEL IN PART: (Vial) "HIGADOCE Forte 10 cc. Each cc. contains: Vitamins B₁₂ Crystalline 60 mcg. Liver injection Crude (2 U.S.P. Units per cc.) For intramuscular use."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 76 percent of the declared amount of vitamin B₁₂.

LIBELED: 7-22-60, Dist. R.I.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Vitamins B₁₂ Crystalline 60 mcg." was false and misleading.

DISPOSITION: 8-16-60. Default—destruction.

6429. Rubber prophylactics. (F.D.C. No. 44865. S. Nos. 45-469/70 R.)

QUANTITY: 253 gross, in bulk in polyethylene bags, within cardboard boxes, and 900 gross, packed in 36 25-gross ctns., each containing 72 2-unit pkgs., at Durham, N.C., in possession of Barnett Coin Machine & Distributing Co.

SHIPPED: 6-30-60, from Akron, Ohio.

LABEL IN PART: (Box) "T-S-R 50 Gr. OP UN 2-24-6 O-N-E L/26" and (2-unit pkg.) "Safe-Tex * * * Prophylactics."

RESULTS OF INVESTIGATION: Investigation revealed that the dealer had repacked and relabeled the 2-unit packages from the bulk lot described above. Examination of both lots showed that 1.1 percent of the units examined were defective in that they contained holes.

LIBELED: 8-22-60, M. Dist. N.C.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; 502(a)—the label statement "Sold and Intended to be Used as a Preventive of Disease" was false and misleading as applied to a product which contained holes.

DISPOSITION: 9-23-60. Default—destruction.

6430. Rubber prophylactics. (F.D.C. No. 44849. S. No. 2-964 R.)

QUANTITY: 250 ctns., each containing 48 3-unit plastic vials, at Durham, N.C., in possession of Barnett Coin Machine & Distributing Co.

SHIPPED: 1-16-60, from Akron, Ohio.

LABEL IN PART: (Vial) "Triple 'A' Brand Nipple End Prophylactics."

RESULTS OF INVESTIGATION: The article was repacked into vials from bulk lots and labeled as described, by the Barnett Coin Machine & Distributing Co. Examination revealed that 3 out of 126 of the articles were defective in that they contained holes.

LIBELED: 8-9-60, M. Dist. N.C.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "To Be Used As A Preventive of Disease" was false and misleading as applied to a product which contained holes.

DISPOSITION: 9-23-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6431. Ulcertrol. (F.D.C. No. 42661. S. No. 47-135 P.)

QUANTITY: 42 12-oz. ctnd. btls. at White Pigeon, Mich., in possession of Ulcertrol, Inc.

SHIPPED: Two ingredients of the article, grapefruit juice and lemon juice, had been shipped on unknown dates from New York, N.Y., Davenport, Fla., and Ontario, Calif.

LABEL IN PART: "Ulcertrol A Completely New Ulcer Treatment * * * Made * * * of the following: Potatoe water, orange, lemon & grapefruit juices * * * Ulcertrol, Inc., White Pigeon, Michigan."

ACCOMPANYING LABELING: Leaflet enclosed in each carton entitled "*Ulcertrol*."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer at White Pigeon, Mich., using, among other ingredients, those ingredients which had been shipped in interstate commerce as described above.

LIBELED: 1-19-59, W. Dist. Mich.; amended 12-31-59.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers.

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: Ulcertrol, Inc., appeared as claimant and filed an answer. Thereafter, the Government served written interrogatories upon the claimant and, on 9-16-59, the claimant made certain replies to the interrogatories. Subsequently, motions were filed by the Government and granted by the court to compel further and complete answers to the interrogatories. Such answers were furnished by the claimant. On 9-8-60, a motion for summary judgment was filed by the Government. Such motion was not opposed by the claimant and, on 2-7-61, the court entered a decree of condemnation and destruction.

6432. Vita-Lea tablets, Pro-Lecin tablets, and Pro-Vita tablets. (F.D.C. No. 44680. S. Nos. 18-743/4 R, 19-071 R.)

QUANTITY: 21 180-tablet btls. of Vita-Lea; 15 180-tablet btls. and 12 360-tablet btls. of Pro-Lecin; and 5 pkgs. of 2 360-tablet btls. each, of Pro-Vita, at Delta, Colo.

SHIPPED: 5-1-60 and 6-10-60, from Oakland, Calif., by Shaklee Products.

LABEL IN PART: (Btl.) "Shaklee * * * Food Supplement With Digestive Enzymes * * * Vita-Lea;" "Shaklee * * * Pro-Lecin;" and (pkg.) "Shaklee Twin Pack Pro-Vita * * * Protein Vitamins Lecithin Minerals * * * Distributed by Shaklee Products, Oakland, Calif."

*See also Nos. 6421, 6422, 6425, 6426, 6428-6430.