

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

2015. Misbranding of Procon Tablets and Orimbo Tablets; adulteration and misbranding of Hi-Test Vegetable Compound. U. S. v. The Allied Pharmacal Company and Samuel A. Salzman. Pleas of guilty. Fine, \$1,000 and costs against each defendant; fine against partnership suspended. (F. D. C. No. 20105. Sample Nos. 20253-H, 20255-H, 22454-H.)

INFORMATION FILED: August 1, 1946, Northern District of Ohio, against the Allied Pharmacal Company, a partnership, Cleveland, Ohio, and Samuel A. Salzman, a partner.

ALLEGED SHIPMENT: Between the approximate dates of October 25, 1944, and March 3, 1945, from the State of Ohio into the States of Kansas and Missouri.

PRODUCT: Analysis of the *Procon Tablets* showed that the article contained methenamine, potassium bicarbonate, and plant material, including alkaloid-bearing drugs, such as belladonna and nux vomica. Analysis of the *Orimbo Tablets* showed that the article contained glandular substances, nux vomica and phosphate. Analysis of the *Hi-Test Vegetable Compound* showed that the article contained little or no vitamin B₁.

LABEL, IN PART: "Procon Tablets * * * Distributed by Erie Laboratories Cleveland, Ohio," "Orimbo Tablets * * * Distributed by The Allied Pharmacal Co. Cleveland, Ohio, U. S. A." and "Hi-Test Vegetable Compound With Thiamin Chloride B-1 * * * Distributed by Hi-Test Pharmacal Co. Cleveland, Ohio."

NATURE OF CHARGE: *Procon Tablets*, misbranding, Section 502 (a), the name "Procon" and the label statements, "For the temporary relief of incontinence" and "If incontinence persists, consult your physician," were false and misleading. The name and the label statements represented and suggested that the article would be effective for the relief of incontinence. The article would not be effective for such purpose.

Orimbo Tablets, misbranding, Section 502 (a), the labeling of the article failed to reveal the fact that orchic substance is of no therapeutic value when taken by mouth, which fact was material in the light of the representations displayed upon the bottles of the article, "Orchic," "Orchic Substance . . . 0.05 gr." and "Dosage: 2 to 3 tablets."

Hi-Test Vegetable Compound, adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to contain 250 units of vitamin B₁ to each ounce, but it contained little or no vitamin B₁. Misbranding, Section 502 (a), the following statements on the label were false and misleading: "Vegetable Compound with Thiamin Chloride B-1 * * * Active Ingredients Crystalline Vitamin B-1" and "Each ounce contains 250 units of B-1. The daily average dose of 3 tablespoonsful supply the full daily requirement of B-1." These statements represented and suggested that vitamin B₁ was an active ingredient of the article; that 250 units of vitamin B₁ were contained in each ounce of the article; and that 3 tablespoonsful of the article would supply the full daily requirement of vitamin B₁. Vitamin B₁ was not an active ingredient of the article, 250 units of vitamin B₁ was not contained in each ounce of the article, and 3 tablespoonsful of the article would not supply the full daily requirement of vitamin B₁, because the article contained little or no vitamin B₁.

DISPOSITION: October 22, 1946. Pleas of guilty having been entered on behalf of both defendants, the court imposed a fine of \$1,000, plus costs, against each defendant. The fine against the partnership defendant was suspended.

2016. Adulteration and misbranding of Syrup Tolu & Lobelia Compound, and Syrup Tolesol. U. S. v. The P. J. Noyes Co. Plea of nolo contendere. Fine, \$200. (F. D. C. No. 20920. Sample Nos. 12459-H, 12784-H, 12790-H.)

INFORMATION FILED: September 26, 1946, District of New Hampshire, against the P. J. Noyes Co., a corporation, Lancaster, N. H.

ALLEGED SHIPMENT: On or about September 13, 1945, and February 4, 1946, from the State of New Hampshire into the States of Maine and Massachusetts.

LABEL, IN PART: "Syrup 3 Fl. Ozs. Tolu & Lobelia Compound With Morphine 5% Alcohol. Each Fluidounce Contains: Morphine Sulfate, 1-4 Gr.," or "Syrup 4 Fl. Ozs. Tolesol 5% Alcohol Each Fluidounce Contains: Morphine Sulfate, 1-4 Gr."