

LABEL, IN PART: "Red Hearts Iron Manganese B₁ and E Tonic."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements and designs in the labeling of the article were false and misleading since the article would not be effective in imparting pep and ambition: (Display carton) "Gee! You're full of Pep—[cut showing older couple dancing] Of Course! He's taking Red Hearts"; (envelope) "Gee! You're full of Pep—[cut showing older couple dancing] If you Lack Ambition to 'Go Places and Do Things' Try Red Hearts * * * Try them and see if they do not make you feel wonderful."

DISPOSITION: May 2, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1938. Misbranding of Ortex Tablets and Kayon Tablets. U. S. v. 40 Bottles of Ortex Tablets and 62 Bottles of Kayon Tablets. Default decree of condemnation and destruction. (F. D. C. No. 19265. Sample Nos. 7278-H, 7279-H.)

LABEL FILED: March 8, 1946, Northern District of New York.

ALLEGED SHIPMENT: On or about October 26 and November 30, 1945, by the Berland Pharmacal Co., from Cleveland, Ohio.

PRODUCT: 28 20-tablet bottles and 12 100-tablet bottles of *Ortex Tablets* and 31 20-tablet bottles and 31 75-tablet bottles of *Kayon Tablets* at Binghamton, N. Y. Examination showed that the products had essentially the composition stated on their labels.

LABEL, IN PART: "Ortex * * * Each Tablet Contains: Vitamin B₁ 666 U. S. P. Units Yohimbin Hydrochloride 0.005 gm Orchic Substance 0.050 gm Calcium Glycerophosphate 0.150 gm Sodium Glycerophosphate 0.150 gm," or "Kayon Tablets Each tablet contains 1/8 grain Extract Belladonna Leaves containing 0.00156 grain Total Alkaloids of Belladonna and 1/10 grain Extract Nux Vomica containing 0.00738 grains Strychnine. Also contains Methenamine. Extract Ergot, Potassium Bicarbonate and Extract Rhus Aromatica. For Adults For the temporary relief of incontinence."

NATURE OF CHARGE: *Ortex Tablets.* Misbranding, Section 502 (c), the common or usual names of the active ingredients of the article, which are required by Section 502 (e) to appear on the label, did not appear on the label in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use, since no distinction had been made in the list of ingredients between those which were active and those which were inert, such as orchic substances.

Kayon Tablets. Misbranding, Section 502 (a), the label statement, "For the temporary relief of incontinence," was false and misleading since the article would not be effective for that purpose.

DISPOSITION: April 10, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1939. Misbranding of Prostall Capsules. U. S. v. 4 Bottles of Prostall Capsules, and 50 Leaflets. Default decree of condemnation and destruction. (F. D. C. No. 19764. Sample No. 7377-H.)

LABEL FILED: May 7, 1946, District of New Jersey.

ALLEGED SHIPMENT: From Boston, Mass., by the Douglas Laboratories, Inc. The product was shipped on or about January 2, 1946, and the leaflets were shipped during the month of December 1945.

PRODUCT: 4 100-capsule bottles of *Prostall Capsules* at Plainfield, N. J., together with 50 leaflets entitled "The Story of Prostall." Analysis showed that the product consisted essentially of glutamic acid and aminoacetic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the bottle label, and certain statements contained in the leaflet accompanying the article, were false and misleading: "Prostall 'Stalls Off Pain' * * * relieves the symptoms of prostate hypertrophy (prostitis). Relief starts in a few days and improvement continues thereafter. Prostall permanently relieves some cases. However, it is primarily a pain-reducer in time." These statements represented and suggested that the article would be effective in the relief of pain and prostate hypertrophy, whereas it would not be effective for such purposes. Further misbranding, Section 502 (e) (2), the drug was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient.