

8999. Adulteration and misbranding of Decalbex Capsules. U. S. v. 9 Drums of Decalbex Capsules. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 15345. Sample No. 902-H.)

LIBEL FILED: March 3, 1945, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 18, 1944, by the Standard Pharmacal Co., from Chicago, Ill.

PRODUCT: 9 drums containing about 472,800 Decalbex Capsules at Miami, Fla. Examination showed that the article was 28 percent deficient in vitamin C.

LABEL, IN PART: "Capsules Decalbex * * Capsules Calcium Phosphate and Iron with Vitamins."

NATURE OF CHARGE: Adulteration, Section 402 (b) (1), a valuable constituent, vitamin C, had been in part omitted from the article.

Misbranding, Section 403 (a), the label statements, "Eight Capsules Represent * * * Ascorbic Acid (Vitamin C) 30 mg. * * * Two capsules four times daily will supply the minimum daily requirements for an adult of * * * ascorbic acid * * * Each capsule contains * * * Ascorbic Acid (vitamin C—75 U. S. P. units) 3.75 mg.," were false and misleading as applied to an article which did not supply or contain the stated amount of vitamin C.

DISPOSITION: April 6, 1945. The Hart Drug Corporation, Miami, Fla., claimant, having admitted the material allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling in compliance with the law, under the supervision of the Food and Drug Administration.

9000. Adulteration and misbranding of Monarch Vitamins. U. S. v. 3,453 Bottles of Monarch Vitamins. Default decree of condemnation and destruction. (F. D. C. No. 13413. Sample No. 54632-F.)

LIBEL FILED: September 19, 1944, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 24, 1944, by the Cerophyl Laboratories, Inc., from Kansas City, Mo.

PRODUCT: 3,453 bottles, each containing 225 tablets, of Monarch Vitamins at Chicago, Ill. Examination showed that the product contained not more than 50 milligrams of vitamin C per 10 grams (20 tablets).

NATURE OF CHARGE: Adulteration, Section 402 (b) (1), a valuable constituent, vitamin C, had been in whole or in part omitted or abstracted from the article.

Misbranding, Section 403 (a), the following label statements were false and misleading since the article did not contain the declared amounts of vitamin C: "Vitamin Content of Monarch Vitamins per 10 Grams * * * C (Ascorbic Acid) . . 75 mg. (1500 U. S. P. Units) 900 units more than adult minimum daily requirement * * * 2 tablets twice daily (with meals)—(2 grams) * * * supplies at least 25% of the full minimum daily requirements of * * * C." The label statements, "10 Vitamins * * * 11 Natural Minerals * * * Whole 'B' Complex," appearing in large and conspicuous type on the main display panel, were misleading in that the article was not of dietary significance by reason of the 10 vitamins, the 11 minerals, and the whole B complex, since the article would supply nutritionally significant amounts of only 6 vitamins and 1 mineral. Certain statements in the circular entitled "To Users of Monarch Vitamins," enclosed in the retail package containing the article, created the false and misleading impression that the article would be effective in the prevention or correction of poor appetite, nervousness, irritability, colds, and chronic constipation; that it would be a substitute for large quantities of fruits and vegetables as a source of vitamins and minerals; and that it was an ideal supplement such as recommended by the Food and Nutrition Board of the National Research Council.

Further misbranding, Section 403 (f), the information concerning the vitamin, mineral, and other dietary properties of the article, required by Section 403 (j) to appear on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices on the label) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use since the information appeared on the back portion of the label; and, Section 403 (i) (2), the label of the article failed to bear a list of the ingredients by their common or usual names.

The article was also alleged to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 1588.

DISPOSITION: November 8, 1944. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.