

17249. Adulteration and misbranding of Pro-Dyne oral tablets, Pro-Dyne oral capsules, Red-Zyne tablets, and Red-Zyne capsules. U. S. v. 89,380 Tablets, etc. (F. D. C. No. 29796. Sample Nos. 69429-K, 69430-K.)

LIBEL FILED: October 9, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 2, June 24, and August 16, 1950, by Food Essentials, Inc., from Chicago, Ill.

PRODUCT: 89,380 Pro-Dyne oral tablets; 5 dozen 60-tablet bottles, 5½ dozen 120-tablet bottles, and 5 dozen 240-tablet bottles of Red-Zyne tablets; 60,380 Pro-Dyne oral capsules; 6½ dozen 30-capsule bottles, 3½ dozen 60-capsule bottles, and 2 dozen 120-capsule bottles of Red-Zyne capsules at Duquesne, Pa., in possession of the Royal Pharmacal Corp.

RESULTS OF INVESTIGATION: The products were shipped in drums under the names of Pro-Dyne oral tablets and Pro-Dyne oral capsules, and portions had been repackaged after shipment under the names of Red-Zyne tablets and Red-Zyne capsules.

LABEL, IN PART: (Drums, when shipped) "Pro-Dyne Oral Tablets A Dietary Supplement Containing B₁₂ with other A. P. F. Factors from fermentation products B-Complex Vitamins and Minerals * * * Directions: As a dietary supplement Two Tablets 3 times a day * * * Each Pro-Dyne Tablet Supplies: * * * .2 mg. Boron (from Sod. Borate)" and "Pro-Dyne Oral Capsules A Dietary Supplement Containing B₁₂ with other A. P. F. Factors from fermentation products B-Complex Vitamins and Minerals * * * Directions: As a dietary supplement One Capsule 3 times a day * * * Each Pro-Dyne Capsule Supplies * * * .4 mg. Boron (from Sod. Borate)."

(Bottles, repackaged from drums) "Red-Zyne Tablets A Dietary Supplement Containing the New Red Vitamin B₁₂ with other A. P. F. Factors B-Complex Vitamins and Essential Minerals * * * Directions: Two Tablets 3 times a days * * * Each Red-Zyne Tablet Supplies: * * * .2 mg. Boron (from Sod. Borate)" and "Red-Zyne Capsules A Dietary Supplement Containing the New Red Vitamin B₁₂ with other A. P. F. Factors B-Complex Vitamins and Essential Minerals * * * Directions: As a dietary supplement One Capsule Three times a day * * * Each Red-Zyne Capsule Supplies: * * * .4 mg. Boron (from Sod. Borate)."

NATURE OF CHARGE: Adulteration, Section 402 (a) (2), the articles contained an added poisonous and deleterious substance, sodium borate, which was unsafe within the meaning of the law since it is a substance not required in the production of the articles and could have been avoided by good manufacturing practice.

Misbranding, Section 403 (a), certain statements on the labels of the drums and bottles were misleading. These statements represented and suggested that the articles were of special dietary value primarily by reason of their vitamin B₁₂ content, and that other constituents enumerated on the labels were likely to be of some nutritional value, whereas the special dietary value of the articles was due primarily to ingredients other than vitamin B₁₂, and the other constituents enumerated on the labels were of no nutritional value.

The articles were adulterated and misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

The articles were alleged also to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices.

DISPOSITION: January 31, 1951. Default decree of condemnation and destruction.

17250. Adulteration and misbranding of filled milk. U. S. v. 236 Cases * * *
(F. D. C. No. 29732. Sample No. 77780-K.)

LABEL FILED: On or about September 21, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 11, 1950, by the Ashley Milk Co., from Nashville, Ill.

PRODUCT: 236 cases, each containing 48 14½-ounce cans, of filled milk at Linn, Mo.

LABEL, IN PART: "Rich-Whip * * * Wholesome Food Product Composition Milk Solids 20% Fat 6% * * * Approximate Analysis * * * Fat 6.00% Vitamin Content 2,000 U. S. P. units of Vitamin A, 400 U. S. P. units of Vitamin D Some Vitamins B and G" and "Hum * * * A Mixture of evaporated skimmed milk and Hydrogenated Vegetable Oils * * * Composition Milk Solids 20%, Fat 6% * * * Approximate Analysis 2,000 U. S. P. units of Vitamin A, 400 U. S. P. units of Vitamin D Some Vitamins B and G."

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

Misbranding, Section 403 (a), the label statements "Fat 6% * * * This product complies in all respects with the Federal Food and Drugs Act of June 25, 1939, and is neither adulterated nor misbranded under the provisions thereof" were false and misleading as applied to an article which contained less than 6 percent fat and was both adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act; Section 403 (i) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each such ingredient since it failed to reveal the source of the added vitamins A and D; and, Section 403 (j), the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content, and its label failed to bear as required by regulations a statement of the proportion of the minimum daily requirement of vitamins A, B, D, and G furnished by a specific quantity of the product when consumed during a period of one day.

DISPOSITION: November 15, 1950. Default decree of destruction.

INDEX TO NOTICES OF JUDGMENT F. N. J. NOS. 17201 TO 17250

PRODUCTS

	N. J. No.		N. J. No.
Alfa-Zyme feed	¹ 17221	Bread	17207
Almonds, unshelled	17243	Brewers rice	17212, 17213
Bakery products	17207, 17208	Butter	17216, 17217
Beans, kidney, canned	17229	Calvital capsules	17248
Beer	17201	Candy	17204, 17205
Beverages and beverage materials	17201-17203, 17238	Carrots and peas, canned	17230
Black-eyed peas, canned	17231	Catsup, tomato	17237
dried	17232	Cereals and cereal products	17207-17215
Boysenberries, canned	17226	Cheese, Primost	17218
Brazil nuts	17241, 17242	Chili powder	17245

¹ (17221) Prosecution contested.