

27049. Vitamin tablets. (F.D.C. No. 42435. S. No. 30-961 P.)

INFORMATION FILED: 4-30-59, Dist. Mass., against Cowley Pharmaceuticals, Inc., and Benjamin (Ben) C. Cowley, president, Auburn, Mass.

SHIPPED: 10-29-57, from Massachusetts to New York.

LABEL IN PART: "Tablets METAVITES."

CHARGE: 403(a)—the label statements, "Each tablet contains: Vitamin A 10,000 units, Vitamin D 1,000 units, Vitamin B-1 (Thiamin HCl) 6 mg., * * * Vitamin C (Ascorbic Acid) 50 mg., Niacinamide 10 mg. * * * Vitamin B-12 * * * 3 mcg." were false and misleading since each tablet of the article contained less than those amounts of vitamin A, vitamin D, vitamin B-1, vitamin C, niacinamide, and vitamin B-12.

The information also alleged that 4 other products, namely, Cowlserpa (reserpine) tablets, atropine sulfate tablets, digitalis tablets, and Salamin tablets, were misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6215.

PLEA: Guilty.

DISPOSITION: 5-23-60. Corporation—\$500 fine. Cowley—\$1,000 fine, \$500 of which was suspended, and probation for 1 year.

27050. Yeast culture wafers. (F.D.C. No. 44605. S. No. 43-668 R.)

QUANTITY: 230 cases, each containing 72 60-wafer btl. at Seattle, Wash., in possession of Genius, Inc.

SHIPPED: Between 3-1-60 and 4-5-60, from Chillicothe, Ill., by Newhaven Laboratories.

LABEL IN PART: (Btl.) "Western Yeast Culture A Food Supplement with Vitamin B Complex and Vitamins A and D * * * Each Wafer contains * * * with Vitamin B Complex and Vitamin A and D additions to Vitamins as listed below Vitamin B₁ (Thiamin Mononitrate) 2 mg. Vitamin B-2 (Riboflavin) 2.4 mg. Vitamin B-6 (Pyridoxine Hydrochloride) 1 mg. Vitamin B-12 Cobalamin Concentrate NF) 1 microg. Calcium Pantothenate 2 mg. Acid Nicotinic 10 mg. Folic Acid 0.25 mg. Vitamin A (Acetate) 4000 Units Vitamin D (Irradiated Yeast) 600 Units Powdered Sugar Excipient added * * * The need for Folic Acid, Pyridoxine Hydrochloride, Calcium Pantothenate and Vitamin B-12 has been established * * * Distributed by Western Products South 5th and Broadway, Tacoma 2, Washington."

ACCOMPANYING LABELING: Leaflets entitled "The Western Yeast Story," "S-1 Direct Retail Buyer," "S-2 Wholesale Buyer" and "S-3 Retailer"; placards entitled "As Advertised by Bob Hale"; and cards reading in part "I'll Send You \$2.50 for this card."

RESULTS OF INVESTIGATION: The circulars and placards were designed and printed by Genius, Inc., and were used in promoting sales of the article.

LIBELED: 6-10-60, W. Dist. Wash.

CHARGE: 403(a)—when shipped and while held for sale, the label statement "Western Yeast Culture A Food Supplement" was false and misleading since it suggested and implied that the vitamin content of the article was primarily due to the yeast, whereas the yeast was only a vehicle for the added vitamins which were the primary source of the vitamin content; the labeling statement that the product had been found to aid in more rapid and thorough assimilation, represented that the article was better than other similar food supple-

ments, which representation was false and misleading since it was contrary to fact; and the label statement "The need for Calcium Pantothenate * * * has been established" was false and misleading since such need had not been established; and 403(j)—the article was represented as a food for special dietary uses by reason of its vitamin content and its label failed to bear such information concerning its vitamin properties as the Secretary has determined to be, and by regulation, prescribed as, necessary in order to fully inform purchasers as to its value for such uses, since its label failed to bear the statement "The need for calcium pantothenate in human nutrition has not been established."

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 6230.

DISPOSITION: 6-17-60. Consent—claimed by Genius, Inc., of Seattle, Wash., and relabeled.

INDEX TO NOTICES OF JUDGMENT F.N.J. NOS. 27001 TO 27050

PRODUCTS

	N.J. No.		N.J. No.
Abundagreen	27041	LifAnu Food Supplement	27043
Abundavita mineral tablets	27041	Lima beans, dried	27030
vitamin tablets	27041	Multiple-vitamin capsules	27045
Beans, green, canned	27029	Nuts	27032-27038
lima, dried	27030	Peanuts, unshelled	27033
Beverages and beverage ma-		Poultry	27039, 27040
terials	27001-27005	Poundron vitamin tablets	27048
Cereals and cereal products		Protein wafers	27046
	27006-27018	Prunes, dried	27024
Cherries, frozen	27027	Raisins, seedless	27025, 27026
Chickens. <i>See</i> Poultry.		Rice	27014-27018
Coconuts	27035-27038	Soybeans	27031
Coffee beans, green	27001-27003	Strawberries, frozen	27028
Cornmeal	27010-27012	Toddets vitamin tablets	27048
Eggs, frozen	27019-27023	Vegetables. <i>See</i> Fruits and	
Filberts, unshelled	27032	vegetables.	
Flour	27006-27009	Victorvita Food Supplement	27044
Food supplement tablets	27042	Vitamin, mineral, and other prod-	
Fruits and vegetables	27024-27031	ucts of special dietary sig-	
fruit, dried	27024-27026	nificance	27041-27050
frozen	27027, 27028	Vodka	27004
vegetables and vegetable		Wafers, protein	27046
products	27029-27031	yeast culture	27050
Lecithin granules	27047	Walnuts, shelled	27034
Lederplex Vitamin B Complex		Whiskey	27005
Liquid	27048	Yeast culture wafers	27050