

Phenobarbital tablets. 501 (b)—the strength of the tablets when shipped differed from, and their quality fell below, the standard set forth in the United States Pharmacopeia for phenobarbital tablets since the tablets contained less than 94 percent of the declared amount of phenobarbital, the minimum permitted by the standard, and the disintegration time of the tablets exceeded the maximum allowable time of the standard by 38 percent; and, 502 (a)—the label statement "Tablets Phenobarbital U. S. P. 1½ Grain (0.097 G. M. S.)" was false and misleading as applied to the tablets, which failed to meet the requirements of the United States Pharmacopeia for phenobarbital tablets.

DISPOSITION: 8-6-54. Default—destruction.

4547. Alpha-tocopherol and alpha-tocopheryl acetate. (F. D. C. No. 33341. S. Nos. 22-859/60 L.)

QUANTITY: 29 btl. of *alpha-tocopherol* and 29 btl. of *alpha-tocopheryl acetate* at New York, N. Y.

SHIPPED: 6-7-51, from Bloomfield, N. J., by Pharmaceutical Co. of New Jersey.

LABEL IN PART: (Btl.) "100 Grams Alpha Tocopherol Nepera (Vitamin E) U. S. P." and "100 Grams Alpha Tocopherol Nepera (Vitamin E) U. S. P. Acetate."

LBELED: On or about 7-16-52, S. Dist. N. Y.

CHARGE: 501 (d) (2)—when shipped, products essentially devoid of alpha-tocopherol and alpha-tocopheryl acetate, respectively, had been substituted for *alpha-tocopherol* and *alpha-tocopheryl acetate*, respectively; and, 502 (a)—the label statements "Alpha Tocopherol" and "Alpha Tocopherol * * * Acetate" were false and misleading.

DISPOSITION: 4-7-55. Default—destruction.

4548. Alpha-tocopheryl acetate. (F. D. C. No. 33340. S. No. 22-855 L.)

QUANTITY: 20 btl. at New York, N. Y.

SHIPPED: 6-18-51, from Bloomfield, N. J., by Pharmaceutical Co. of New Jersey.

LABEL IN PART: (Btl.) "Darrylle Chemical Co. 121 Broad St. New York 4, N. Y. 500 Grams Alpha Tocopheryl Acetate (Vitamin E Acetate)."

LBELED: On or about 7-16-52, S. Dist. N. Y.

CHARGE: 501 (d) (2)—when shipped, a product essentially devoid of alpha-tocopheryl acetate had been substituted for *alpha-tocopheryl acetate*; and, 502 (a)—the label statement "Alpha Tocopheryl Acetate" was false and misleading.

DISPOSITION: 4-7-55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4549. B-amino-complex tablets. (F. D. C. No. 30384. S. No. 77-448 K.)

QUANTITY: 21 100-tablet btl. at Peoria, Ill.

SHIPPED: 12-8-50, from New York, N. Y., by Barrows Chemical Co.

*See also Nos. 4544-4548.

LABEL IN PART: "B-Amino-Complex * * * Daily dose of 6 tablets contains: Vitamins Vitamin B₁ (Thiamine Hydrochloride) 18.0 mg. Vitamin B₂ (Riboflavin) 27.0 mg. Niacinamide 180.0 mg. Vitamin B₆ (Pyridoxine Hydrochloride) 3.0 mg. High Potency Yeast 200.0 mg. Brewer's Type Yeast 200.0 mg. Inositol 60.0 mg. Choline Hydrochloride 60.0 mg. Panthenol (Equal to Cal. Pantothenate 30 mg.) 26.1 mg. Amino Acids (Vitagenic Accelerators) as contained in Yeast Protein Enzymatic Hydrolysate 1.0 Gm. fortified with Nucleic acid 100.0 mg. Glutamic Acid 50.0 mg. Glycine 50.0 mg. Cysteine Hydrochloride 35.0 mg. Di and Tri-Valent Minerals Iron (Ferric Citro Pyrophosphate Soluble) 28.8 mg. Copper (copper sulfate) 2.1 mg. Magnesium (magnesium sulfate) 5.9 mg. Zinc (zinc sulfate) 1.4 mg. Cobalt (cobalt sulfate) 1.3 mg."

ACCOMPANYING LABELING: Leaflets entitled "Amazing New Medical Discovery" and placards bearing a picture of the head of a woman and the words "Amazing Discovery Checks Deafness Helps Restore Hearing Clinically Tested Come in for Free Booklet."

LIBELED: 1-25-51, S. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained statements which represented that the article was an adequate and effective treatment for deafness, whereas the article was not an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 3-20-51 directing the removal of the libel action to the Eastern District of New York. On 7-11-51, the Unitone Corp., New York, N. Y., as claimant, filed an answer to the libel. Thereafter, interrogatories were served upon and answered by each party. An order to compel the claimant to make further answers to the interrogatories was entered on 3-16-54, and was complied with by the claimant. On 2-4-55, with the consent of the claimant, a decree of condemnation and destruction was entered.

4550. B-amino-complex tablets. (F. D. C. No. 35696. S. No. 59-473 L.)

QUANTITY: 34 100-tablet btls. at Atlanta, Ga.

SHIPPED: 4-7-52, from New York, N. Y., by Sherman Foods, Inc.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label previously described in notice of judgment No. 4549.

ACCOMPANYING LABELING: Circulars entitled "A Revolutionary Advance in Nutrition Now B-Amino-Complex instead of B-Complex."

LIBELED: 10-7-53, N. Dist. Ga.

CHARGE: 502 (a)—the accompanying labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 11-25-53 directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimant, Unitone Corp., New York, N. Y., a decree of condemnation and destruction was entered.

4551. B-amino-complex tablets. (F. D. C. No. 35697. S. No. 55-913 L.)

QUANTITY: 5 100-tablet btls. at Pittsburgh, Pa.

SHIPPED: 3-13-53, from New York, N. Y., by Balanced Foods, Inc.