

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4764. B-amino-complex (B-amino-BAC-complex or Unitone) tablets. (Inj. No. 267.)

COMPLAINT FOR INJUNCTION FILED: 9-28-53, S. Dist. N. Y., against Barrows Chemical Co., Inc., and Unitone Corp., both of New York, N. Y., and against Joseph Barrows, president of the corporations, to enjoin the interstate shipment of an article in tablet form known by the trade names of "B-Amino-Complex," "B-Amino-BAC-Complex," and "Unitone." Amended complaint filed on or about 10-30-53.

LABEL IN PART: "B-Amino-Complex [or "B-Amino-BAC-Complex" or "Unitone"]
 * * * **VITAMINS** Daily dose of 6 tablets contains: 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 25.0 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."

CHARGE: The complaint alleged that the defendants were engaged in the business of manufacturing, distributing, and selling the above-mentioned article and that, for the purpose of explaining the uses of the article and promoting its distribution, the defendants caused the article to be accompanied by labeling consisting of leaflets entitled "Amazing Medical Discovery," "If Your Body Could Talk It Would Say," and "A Revolutionary Advance in Nutrition," placards entitled "Amazing Discovery Checks Deafness, Helps Restore Hearing, Clinically Tested—Come in For Free Booklet," "BAC," and "For the One in Five Who is Hard of Hearing," and publications entitled "Nutritional Guide Better Nutrition Better Health" and "Health and Nutrition News Spring Summer 1953."

The complaint alleged further that the defendants were violating the Act by causing the introduction and delivery for introduction into interstate commerce of the article which was misbranded as follows:

502 (a)—the label of the article and the above-mentioned accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for deafness; that it was a new and amazing discovery and a revolutionary advance as a food supplement which, when used as directed, would supply an important quantity of protein; that it was needed to activate the eyes, ears, lungs, liver, intestines, muscles, brain, heart, stomach, kidneys, and the entire body; that it would supply vitamins, proteins, and minerals in the correct proportions, and balanced amounts to stimulate the body to work as nature intended; that it would endow the user with vibrant life, health, and energy; that it would enable the liver to convert more than normal amounts of carbohydrates into energy; that it would supply increased energy to the heart, lungs, muscles, liver, and other important organs; that it would supply missing enzymes necessary to carry on body functions, such as growth, repro-

*See also No. 4761.