

was taken under the Federal Trade Commission Act; (4) that plaintiff's counsel, after the entry of a decree of condemnation in 1946 and during the pendency of an appeal therefrom, discovered an irregularity in the labeling of the drug, and thereupon the plaintiff revised the said labeling and literature; (5) that the plaintiff advised Defendant Dunbar, on April 8, 1947, of the revisions made and sought his advice and comment, but that defendant refused to discuss the said revisions with plaintiff's attorneys, giving as his reason that the Food and Drug Administration could not enter into such discussions so long as litigation respecting the product was in progress; and (6) that, on August 4, 1947, the Food and Drug authorities made a further seizure of plaintiff's product, which was stored in a warehouse and was not for sale, though technically misbranded.

PRAYER FOR RELIEF: That the defendants be ordered to come forward and state any and all objections they might have to plaintiff's product, its labeling, or literature, and that the court determine the merits of such objections that might be made; and that the defendants be restrained from taking further administrative or enforcement action under the Federal Food, Drug, and Cosmetic Act, or, in the alternative, that a judicial declaration be issued as to plaintiff's rights with respect to the distribution of its product.

DISPOSITION: A motion for dismissal of the complaint was filed on behalf of the Government, and, on December 18, 1947, the court handed down the following opinion in favor of the motion:

McGUIRE, Associate Justice: "There is no justiciable controversy here. *Aetna Life Insurance Company v. Haworth et al.*, 300 U. S. 227-240, 241. *Helco v. McNutt*, 137 F. 2d 681, 683, 687.

"*Currin v. Wallace* (306 U. S. 1) can be distinguished. There, there was an actual controversy of a real and substantial character going to the constitutionality of the Tobacco Inspection Act (Aug. 13, 1935) as the Circuit Court held, which view the Supreme Court adopted.

"Here, however, no such definitiveness exists. The declaratory judgment is not a substitute for a new trial or for an appeal from a former judgment deciding identical issues or issues which the court believes were necessarily passed upon. Borchard: *Declaratory Judgments*, 355. Nor can the Federal Security Agency under guise of this remedy be compelled to give an advisory opinion in futuro or to place its nihil obstat on some contemplated labeling of the plaintiff's product—that is neither its established purpose or function.

"Again, infraction of Title 21, § 331 USCA is a criminal act (§ 333) and what the plaintiff here is actually seeking is an advisory opinion *in limine* as to the criminality or lack of criminality of its prospective sales activities.

"Motion to dismiss granted. Counsel will prepare proper order."

Pursuant to the above opinion, an order was entered on January 8, 1948, dismissing the complaint. Research Laboratories, Inc., as plaintiff, thereafter filed a motion to vacate the order of dismissal; and, on October 26, 1948, after consideration of the arguments of counsel, the court denied the motion.

4133. Misbranding of inorganic nutrient tablets, soya lecithin, dicalcium phosphate tablets, and calcium phytate tablets. U. S. v. Inorganic Bioelements, Inc., and John F. Wischhusen. Pleas of nolo contendere. Fine of \$300 against each defendant. (F. D. C. No. 33751. Sample Nos. 7852-L, 7853-L, 18773-L, 18775-L.)

INFORMATION FILED: January 13, 1953, Northern District of Ohio, against Inorganic Bioelements, Inc., Cleveland, Ohio, and John F. Wischhusen, a director of the corporation.

ALLEGED SHIPMENT: On or about November 8, 1950, and February 23 and March 13, 1951, from the State of Ohio into the States of Pennsylvania, Illinois, and Iowa.

LABEL, IN PART: "Each Tablet Contains: Manganese Sulfate----- 170 mg. Iron Sulfate ----- 10 mg. Cobalt Sulfate----- 3 mg. Copper Sulfate----- 1 mg. Zinc Sulfate----- 1 mg. In combination with Lecithin Inorganic IBI Nutrient Tablets Designed to Complement the Diet With Essential Trace Elements Known to be Deficient in Several Major Diseases"; "IBI Soya Lecithin, Refined Edible, Oil Free"; "IBI Tablets Each Tablet Contains 7½ Grains Dicalcium Phosphate, Flavored (Calcium Phosphate Dibasic)"; and "Calcium IBI Phytate Calcium-Inositol-Hexaphosphate * * * Designed to Correct and Prevent Relative Deficiencies and their Consequences Each Tablet Contains 7½ Grains Calcium Phytate, Flavored."

NATURE OF CHARGE: *Inorganic nutrient tablets.* Misbranding, Section 502 (a), certain statements in the following labeling of the article, which accompanied the article, were false and misleading: a leaflet entitled "The Miracle of the Ozarks," a pamphlet entitled "Health vs Disease," a booklet entitled "Notes on Inorganic Bioelements, volume 1, number 1," a folder entitled "Bang's Disease and Undulant fever are due to Nutritional Deficiencies," a leaflet entitled "Good-by Bang's Disease," a leaflet entitled "What About Trace Minerals," a folder entitled "The Role of Manganese and Other Essential Elements in Life Processes," a leaflet entitled "Retail Price List," a copy of a letter of March 16, 1950, from Dr. Fred Loe to Dr. Ira Allison, a copy of a letter of October 19, 1950, from Dr. Leonard W. Kuttler to Dr. Ira Allison, copies of letters of November 29, 1950, and January 2, 1951, from Edward F. (Frank) Slavik, M. D., to Mr. J. F. Wischhusen, a copy of a letter of December 21, 1950, from Guerin Buonpane to Mr. J. F. Wischhusen, a letter of February 28, 1951, from J. F. Wischhusen to B. R. Reuscher, and an invoice No. 470 dated February 23, 1951, from Inorganic Bioelements, Inc., to B. R. Reuscher, bearing reference to "your order No. letter 20th F." The statements in the labeling represented and suggested that manganese, cobalt, and zinc are essential in human nutrition; that they are known to be deficient in several major diseases and are a first requisite for normal body functioning; that the article would correct and prevent deficiencies of manganese, cobalt, and zinc, and the consequences of such deficiencies; that manganese, cobalt, and zinc, as supplied by the article, are associated with gland secretions and enzyme activities and are concerned with growth, reproduction, and health; that cobalt, as supplied by the article, is required to regenerate and mature red blood cells, prevent anemia, and increase hemoglobin; that the article would form within the body antibiotics destructive to Brucella organisms of all types; and that the article would be an adequate and effective treatment for diabetes, brucellosis, Malta fever, undulant fever, tularemia, disorders resulting from abortion, allergies, splenic enlargements, vertigo, "much chronic illness," arthritis, asthma, hay fever, allergic dermatitis of the hands, heart diseases, fatigue, weakness, backache, joint and muscle pain, irritability, nervousness, insomnia, severe mental depression, gastric ulcers and other stomach troubles, repeated attacks of chills and fever, malaise, mastitis, caked breast, diabetes (mellitus and insipidus), Buerger's disease, arthritic conditions, sciatica, lumbago, bone fractures, Paget's disease, sterility, and all cases of malnutrition; that the article would depress pathogens responsible for various disorders; that the article would

be an adequate and effective treatment for headaches, pains behind the knees, loss of weight, loss of strength, anemia, intolerance to light, rheumatism, and influenza; that the article would prevent susceptibility to colds and sore throats and prevent easy tiring, chronic muscular ailments, mental depression, and discomforts of pregnancy; that its use by the pregnant woman would render delivery easy, the milk supply abundant, and the baby exceptionally alert, healthy, and energetic; and that the article would fill the user with "pep" and would supply the difference between disease and health. The statements were false and misleading since the need in human nutrition for manganese, cobalt, and zinc has not been established; manganese, cobalt, and zinc are not known to be deficient in several major diseases and are not a first requisite for normal body functioning; manganese, cobalt, and zinc, as supplied by the article, are not associated with gland secretions and enzyme activities concerned with growth, reproduction, and health; cobalt, as supplied by the article, is not required to regenerate and mature red blood cells, to prevent anemia, and to increase hemoglobin; and the article would not be effective for the diseases and conditions stated and implied, and it would not fulfill the promises of benefit stated and implied.

Soya lecithin. Misbranding, Section 502 (a), certain statements in a letter dated February 28, 1951, from John F. Wischhusen to B. R. Reuscher, and in a leaflet entitled "Retail Price List" and in a circular entitled "Oil Free Soybean Lecithin Edible," accompanying the article, were false and misleading. The statements represented and suggested that the article was a tonic; that it was an adequate and effective treatment for calcination of the spine and other parts of the skeleton, hardening of the arteries, high and low blood pressure, hypertension, psoriasis, and pulmonary troubles; and that the article would be effective in the prevention of fatty livers and would check tendencies toward arteriosclerosis. The article was not a tonic; it was not an adequate and effective treatment for the diseases and conditions represented; and it would not be effective for the purposes stated.

Dicalcium phosphate tablets. Misbranding, Section 502 (a), certain statements in a letter of November 9, 1950, from J. F. Wischhusen to C. W. Berger, and in an invoice dated November 8, 1950, accompanying the article, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the treatment of polio, diabetes, and Buerger's disease. The article would not be adequate and effective in the treatment of such diseases.

Calcium phytate tablets. Misbranding, Section 502 (a), certain statements in an invoice dated March 13, 1951, accompanying the article, were false and misleading. The statements represented and suggested that the article would be adequate and effective in the prevention and treatment of polio and would effect steady improvement in the general health of the user. The article would not be adequate and effective in the prevention and treatment of polio, and it would not effect steady improvement in the general health of the user. The *calcium phytate tablets* were alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 15, 1953. The defendants having entered pleas of nolo contendere, the court fined each defendant \$300.