

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

29689. Various special dietary foods. (Inj. No. 437.)

COMPLAINT FOR INJUNCTION FILED: 10-18-62, Dist. Md., against Burrough Bros. Manufacturing Co., a corporation, Baltimore, Md., and Benjamin Gaboff, president.

ALLEGED VIOLATIONS: The complaint alleged that the defendants were engaged in the business of manufacturing, packing, labeling, selling, and introducing and causing to be introduced and delivering and causing to be delivered for introduction into interstate commerce, articles of food and drug; that the defendants violated the law by the shipment, as above, of various articles of drug and food which were adulterated and misbranded; and that typical of the foods which were introduced or caused to be introduced or delivered or caused to be delivered for introduction into interstate commerce, by the defendants on the dates indicated, in an adulterated or misbranded condition, were the following:

(a) On October 29, 1960, 900 Calorie Food Concentrate (chocolate flavor), which was 48% deficient in protein and contained 21% excess fat;

(b) On October 29, 1960, 900 Calorie Food Concentrate (vanilla flavor), which was 21% deficient in protein and contained 13% excess fat;

(c) On November 23 and 28, 1960, 900 Calorie Food Concentrate (vanilla flavor), which was 34% deficient in protein, 38% deficient in phosphorus, 39% deficient in calcium, and 89% deficient in iron, and whose label failed to bear the common or usual name of several ingredients;

(d) On December 8, 1960, 900 Calorie Food Concentrate (chocolate flavor), which was 38% deficient in phosphorus, 44% deficient in calcium, and 69% deficient in iron, and whose label failed to bear the common or usual names of several ingredients;

(e) On May 10, 1961, 900 Calorie Food Concentrate (chocolate flavor), which was deficient in vitamin A.

The complaint alleged further that the defendants were well aware that their actions were in violation of the law, and that despite a number of warnings, the defendants continued to introduce and cause to be introduced and to deliver and cause to be delivered for introduction into interstate commerce, articles which were adulterated and misbranded.

CHARGE: 402(b)(1)—when shipped, a number of articles which purported to be and were represented as foods for special dietary uses had had a valuable constituent in whole or in part omitted or abstracted therefrom; and 403(a)—the labeling of a number of articles which purported to be and were represented as foods for special dietary uses was false and misleading in particulars concerning the articles' vitamin, mineral, and other dietary properties which were prescribed by regulations as necessary in order fully to inform purchasers as to their value for such uses.

A number of drugs were alleged to be adulterated and misbranded as is reported in drugs and devices notices of judgment, No. 7789.

DISPOSITION: On 10-18-62, the court issued a temporary restraining order. On 12-4-62, a consent decree of permanent injunction was filed which perpetually restrained and enjoined the defendants from, directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, in violation of the law, any

article of drug that was misbranded or adulterated in a number of specified ways, and any article of food:

(a) That purported to be, and was represented as, a food for special dietary use and was adulterated in that a valuable constituent had been in whole or in part omitted or abstracted therefrom; or

(b) That purported to be, and was represented as, a food for special dietary uses and was misbranded in that its labeling was false and misleading in particulars concerning its vitamins, minerals, and other dietary properties.

The decree further perpetually restrained and enjoined the defendants from, directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, any article of food or drug unless a number of specified manufacturing safeguards were established and maintained, and representatives of the Food and Drug Administration were given free access to various specified records and controls, including those embodying the safeguards for interstate commerce necessary for the maintenance of current good pharmaceutical manufacturing practice.

29690. Dried comfrey leaf and comfrey tablets. (F.D.C. No. 49378. S. No. 31-776 X.)

QUANTITY: 74 4-oz. bags of dried comfrey leaf, and 17 96-tablet boxes of comfrey tablets, at Riverside, Calif.

SHIPPED: On an unknown date, from Otorohanga, New Zealand, by Comfrey Supplies (N.Z.) Ltd.

LABEL IN PART: (Bag) "Vitamin Nimativ Dried Comfrey Leaf * * * Analysis * * * Mineral * * * Vitamin B Group * * * Manufactured by Comfrey Supplies (N.Z.) Ltd. * * * Otorohanga, N.Z." (box) "Comfrey Tablets Energy Strength Health * * * Recommended Dose * * * Standard Analysis * * * Mineral * * * Vitamin B Group Comfrey Supplies (N.Z.) Ltd."

ACCOMPANYING LABELING: Brochures entitled "Comfrey The Wonder Plant."

LIBELED: 10-1-63, S. Dist. Calif.

CHARGE: 403(j)—when shipped, the articles purported to be and were represented as food for special dietary use by reason of their vitamin and mineral content and their labels failed to bear as required by regulations, a statement of the proportion of the minimum daily requirement for vitamins A, B₁, C, D, riboflavin, niacin or niacinamide, and calcium, phosphorus, iron or iodine supplied by the articles when consumed in a specified quantity during the period of 1 day.

The libel alleged also that the articles were misbranded under the provisions of the Act relating to drugs as reported in notices of judgment on drugs and devices, No. 7802.

DISPOSITION: 11-15-63. Default—destruction.

29691. Dextra Sugar. (F.D.C. No. 45698. S. No. 14-996 R.)

QUANTITY: 224 cases, of 12 3-lb. bags each, at Hamilton, Ohio.

SHIPPED: 2-2-61, from Delray Beach, Fla., by Sugarlogics World Corp.

LABEL IN PART: (Bag) "New! Dextra Sugar Fortified with Vitamins and Minerals 27 Health Building Nutrients White—Granulated Packed with Health Power for the Entire Family! * * * Dextra Gives You These Nutritional Benefits! * * * A Product of The Sugarlogics World Corporation Manufactured and Distributed in Florida by The Sugarlogics Southern Corpo-