

DISPOSITION: 8-29-60. Consent—claimed by Lucerne Laboratories of Utah, and released for relabeling.

27295. Kelp-Ette tablets. (F.D.C. No. 43959. S. No. 79-796 P.)

QUANTITY: 24 500-tablet btls., 24 1,000-tablet btls., and 24 2,000-tablet btls. at Hobart, Ind., in possession of Nelson's Natural Foods.

SHIPPED: Powdered kelp was shipped on 11-19-57, from Outer Harbor, San Pedro, Calif.

LABEL IN PART: (Btl.) "5-Grain Tablets \* \* \* Nelson's Kelp-Ettes \* \* \* A Pure Vegetable Sea Food Containing an abundance of Safe Natural Iodine Plus Other Minerals, Trace Elements, Organic Compounds and Vitamins Pressed from Pure Ocean Kelp. \* \* \* Packed and Distributed by Nelson's Natural Foods \* \* \* Battle Creek, Michigan \* \* \* Nelson's Kelp-Ettes also contain Traces of the following Vitamins: Choline-Niacin-Carotene-Riboflavin Plus the following Organic Compounds: Alginic Acid-Chlorophyll-Lecithin-Manitol \* \* \* 18 tablets \* \* \* contain in milligrams \* \* \* iron 5.8 \* \* \* also undeterminable small amounts of Trace Elements of: Aluminum, Barium, Boron, Chromium, Lithium, Nickel, Silicon, Silver, Strontium, Titanium, Vanadium and Zinc."

ACCOMPANYING LABELING: Leaflets entitled "More Buoyant Health" and loose bottle labels for all size bottles.

RESULTS OF INVESTIGATION: The Kelp-Ette tablets were manufactured by the dealer from powdered kelp which had been shipped as described above. Examination showed that the tablets contained approximately 50 percent of the declared amount of iron.

LICENSED: 12-14-59, N. Dist. Ind.

CHARGE: 402(b)(1)—while held for sale, a valuable constituent, iron, had been omitted from the article; 403(a)—the statement in the labeling of the article that each 18 tablets contained 5.8 milligrams of iron was false and misleading; 403(a)—the labeling also contained false and misleading representations that the article, as compared to generally available foods, was superior in its content of minerals, trace elements, organic compounds, and vitamins; that the food supplies generally available were nutritionally deficient and inferior and that they lack sufficient quantities of the minerals, including trace minerals, contained in the article; that the trace elements in the article were needed in human nutrition to build and maintain the body; that the article was superior, as compared to foods generally available, in view of its content of choline, potassium, sodium, sulfur, magnesium, manganese, copper, trace elements, chlorine, carotene, riboflavin, niacin, alginic acid, chlorophyll, lecithin, and manitol; 403(a)—the statement in the labeling, "Your body, you know, is formed of mineral elements," was false and misleading since it was contrary to fact; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content and its label failed to bear, as prescribed by regulations, a statement of the minimum daily requirement for niacin, vitamin A and riboflavin supplied by such food when consumed in a specified quantity during a period of one day; and the label also failed to bear the statement "The need for choline, sulfur, manganese, aluminum, barium, boron, chromium, lithium, nickel, silicon, silver, strontium, titanium, vanadium, and zinc in human nutrition has not been established," and a statement of the

quantity of such elements in a specified quantity of such food customarily or usually consumed during a period of one day.

The libel alleged also that the article was misbranded under the provisions of the law relating to drugs as reported in notices of judgment on drugs and devices, No. 6394.

DISPOSITION: 8-10-60. Default—destruction.

27296. Vitamin tablets. (F.D.C. No. 44680. S. Nos. 18-743/4 R, 19-071 R.)

QUANTITY: 21 180-tablet btl. of Vita-Lea; 15 180-tablet btl. and 12 360-tablet btl. of Pro-Lecin; and 5 pkgs. of 2 360-tablet btl. each, of Pro-Vita, at Delta, Colo.

SHIPPED: 5-1-60 and 6-10-60, from Oakland, Calif., by Shaklee Products.

LABEL IN PART: (Btl.) "Shaklee \* \* \* Food Supplement With Digestive Enzymes \* \* \* Vita-Lea;" "Shaklee \* \* \* Pro-Lecin;" and (pkg.) "Shaklee Twin Pack Pro-Vita \* \* \* Protein Vitamins Lecithin Minerals \* \* \* Distributed by Shaklee Products, Oakland, Calif."

ACCOMPANYING LABELING: Folders entitled "4 Aids to The Wealth of Health Through Better Nutrition" and "The Best Way to Health is Nature's Way."

LIBELED: 7-11-60, Dist. Colo.

CHARGE: 403(a)—when shipped, the labeling of "Vita-Lea" and "Pro-Vita" contained false and misleading representations that the articles were food supplements containing fresh ingredients, that they contained enzymes which would promote digestion, that all ingredients in the articles were from the land and from the sea, and that all such ingredients were organic and as they existed in nature; that all ingredients in the articles were present in nutritionally significant amounts and that the articles contained significant amounts of secret food factors for special dietary use; that the articles had an "all natural and organic base \* \* \* a special blend of Nature's finest vegetable food sources from the land and from the sea," and that the need for vitamin E, sodium, and folic acid in human nutrition had not been established; and the labeling of "Pro-Lecin" contained false and misleading representations that the article was a food supplement containing fresh ingredients; that it contained enzymes which would promote digestion; that all ingredients in the article were from the land and from the sea and that all such ingredients were organic and as they existed in nature; that all ingredients in the article were present in nutritionally significant amounts and that the article contained significant amounts of secret food factors for special dietary use; that the article would supply a significant amount of protein to the diet; was "Balanced Nutrition" and was "The finest and only complete protein"; and 403(j)—when shipped, the "Pro-Lecin" purported to be and was represented as a food for special dietary use by reason of its vitamin and mineral properties and its label failed to bear, as required by the regulations, the statement "The need for choline and inositol in human nutrition has not been established," a statement of the quantity of choline and inositol in a specified quantity of the food; and a statement of the quantity of the trace minerals in a specified quantity of the food when consumed during the period of one day.

The articles were alleged also to be misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6432.

DISPOSITION: 9-6-60. Default—destruction.