

CHARGE: 403(j)—when shipped, the article purported to be and was represented as a food for special dietary uses and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for vitamins A, B<sub>1</sub>, D, riboflavin, niacinamide, and ascorbic acid, and minerals, calcium, phosphorus, and iron supplied by such food when consumed in a specified quantity during a period of one day, and the statement "The need for calcium pantothenate, zinc, and manganese in human nutrition has not been established."

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. 6774.

DISPOSITION: 10-23-61. Default—destruction.

**28293. Protein supplement. (F.D.C. No. 45949. S. No. 53-728 R.)**

QUANTITY: 82 365-tablet btls., and 2 drums containing a total of 32,500 tablets, at Minneapolis, Minn., in possession of Nu-Age Corp.

SHIPPED: 11-4-60, from St. Louis, Mo.

LABEL IN PART: (Drum) "S. C. Green w/Mint Flavor" and (btl.) "Formula 13 Protein Supplement \* \* \* Nu-Age, Box 5816, Minneapolis 19, Minn. 6287."

ACCOMPANYING LABELING: Additional bottle labels.

RESULTS OF INVESTIGATION: The tablets were shipped in bulk and bottled and labeled by the dealer.

LIBELED: 6-19-61, Dist. Minn.

CHARGE: 403(a)—while held for sale, the label contained false and misleading representations that the article supplied a significant amount of protein for special dietary supplementation.

The libel alleged also that the article was misbranded under the provisions of the Act relating to drugs as reported in notices of judgment on drugs and devices, No. 6770.

DISPOSITION: 7-31-61. Default—destruction.

**28294. All-In-One capsules. (F.D.C. No. 44558. S. No. 28-918 R.)**

QUANTITY: 5 cases of 72 80-capsule ctns., and 3 cases of 36 160-capsule ctns., at St. Paul, Minn.

SHIPPED: 2-2-60, from West Hempstead, N.Y., by John H. Mathis, Inc.

LABEL IN PART: (Ctn.) "All-In-One Capsules A Dietary Supplement \* \* \* Each capsule contains \* \* \* Packed for and Distributed by State Pharmacal Co., Chicago 1, Ill."

ACCOMPANYING LABELING: Leaflet entitled "The Story of All-In-One Capsules."

LIBELED: 5-2-60, Dist. Minn.

CHARGE: 403(a)—when shipped, the name of the article "All-In-One Capsules" and the accompanying labeling were false and misleading in representing that the article contained all nutrients required in human nutrition and in significant amounts; and (labeling only) that the article would supply significant amounts of protein material to its consumer; and that it was a blend of dietary supplements which were essential in good health; 403(a)—the label statement "The need for \* \* \* niacinamide and pyridoxine in human nutrition has not yet been established" was false and misleading since the need for such substances in human nutrition had been established; 403(a)—the label

statements "Malt diastase 25.00 mg." and "with \* \* \* Digestive Ferments," represented that the article, as a special dietary food, would supply significant amounts of malt diastase and digestive ferments to promote digestion, which statements were false and misleading since the addition of enzymes to the diet was of no value for special dietary food purposes; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin content and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for niacinamide supplied by such food when consumed during a period of one day.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6764.

DISPOSITION: On 6-3-60, John H. Mathis, Inc., filed a claim and answer. On 5-23-61, the action came on for hearing before the court, and there was no appearance on behalf of any claimant. On 1-15-62, the article was ordered condemned and destroyed.

**28295. Lecitabs (lecithin tablets).** (F.D.C. No. 46437. S. No. 70-975 R.)

QUANTITY: 8 cases, each containing 12 90-tablet btl., 1 case, containing 10 90-tablet btl., 8 cases, each containing 12 180-tablet btl., and 3 cases, each containing 12 540-tablet btl., at Minneapolis, Minn.

SHIPPED: Between 8-27-58 and 7-21-60, from Chicago, Ill., by National Lecithin, Inc.

LABEL IN PART: (Btl.) "National Lecitabs Lecithin Tablets A Natural Food Product Highly concentrated extra rich, Soya Lecithin formula of 95% oil-free Phosphatides. Ingredients: Soya Lecithin, in a base of non-fat, dry milk solids and soy protein. Natural flavoring added. Sole Distributors: National Lecithin, Inc. Chicago 26, Ill."

LIBELED: 9-11-61, Dist. Minn.; amended libel 9-15-61.

CHARGE: 403(a)—when shipped, the label of the article bore false and misleading representations that the article was of significant value for special dietary supplementation by reason of the presence therein of lipotropic factors, cephalin, and linoleic and linolenic acids; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of the presence of choline and inositol and its label failed to bear, as required by regulations, a statement as to the quantity of choline and inositol in a specified quantity of the food.

The libel alleged also that the article was misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6763.

DISPOSITION: 10-31-61. Default—destruction.

**28296. Coldene vitamin tonic with iron.** (F.D.C. No. 45764. S. No. 82-805 R.)

QUANTITY: 400 cases, each containing 2 display ctns., each of which contained 6 individually ctnd. btl., at New York, N.Y.

SHIPPED: Prior to September 1960, from Cranbury, N.J., by Pharma-Craft Corp.

LABEL IN PART: (Btl. & btl. ctn.) "Coldene Vitamin Tonic with Iron \* \* \* giving therapeutic amounts of vitamins important to supplement the diet of those in run-down conditions. Especially indicated for use in convalescence