

**LBELED:** 6-29-59, Dist. Mass.

**CHARGE:** 403(a)—while held for sale, the labeling of the article contained representations that the need for choline bitartrate, inositol, manganese sulfate, sodium molybdate, and zinc sulfate in human nutrition has been established; that the article as compared to other foods was nutritionally superior in vitamin and mineral content and included all the nutritional factors of the foods to which it was compared; that the choline and inositol content of the article were geriatric-lipotropic factors required in human nutrition; that the article contained optimum amounts of vitamins and minerals and lipotropic factors; and that the article was unconditionally guaranteed to comply with the United States Food and Drug laws. Such representations were false and misleading since a need for choline bitartrate, inositol, manganese sulfate, sodium molybdate, and zinc sulfate in human nutrition has not been established; the article was not nutritionally superior in vitamin and mineral content to foods recognized as being good sources of vitamins and minerals; the article did not contain optimum amounts of vitamins and minerals and lipotropic factors; it did not contain all the nutritional factors of the foods to which it was compared; and it did not comply with the Federal Food, Drug, and Cosmetic Act.

403(j)—while held for sale, 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 required by regulations, a statement of the proportion of the minimum daily requirement of calcium, phosphorus, iron and iodine supplied by a specified quantity of the article when consumed during a period of one day, and since the need in human nutrition for manganese sulfate, manganese, sodium molybdate, molybdenum, zinc sulfate, and zinc has not been established, its label failed to bear the statement "The need for manganese sulphate, manganese, sodium molybdate, molybdenum, zinc sulphate, and zinc in human nutrition has not been established."

The article was also alleged to be misbranded under the provisions of the law applicable to drugs as reported in notices of judgment on drugs and devices, No. 6020.

**DISPOSITION:** 9-14-59. Default—delivered to a public institution.

**26745. Vitamin drops and vitamin tablets.** (F.D.C. No. 44690. S. Nos. 36-338/9 R.)

**QUANTITY:** 1,372 individually cartoned 15-cc. btls. of vitamin drops and 1,696 individually cartoned 30-tablet btls. of vitamin tablets at Fort Washington, Pa.

**SHIPPED:** Between November 1959 and June 1960, from Pearl River, N.Y., by Lederle Laboratories Div., American Cyanamid Co.

**LABEL IN PART:** (Ctn.) "Lederle Incremin Lysine-Vitamin Drops Each cc. (20 drops) contains: 1-Lysine HCl 300 mg. Vitamin B<sub>12</sub> 25 mcgm. as present in concentrated extractives from streptomyces fermentation. Thiamine HCl (B<sub>1</sub>) 10 mg. Pyridoxine HCl (B<sub>6</sub>) 5 mg. Sorbitol 330 mg. Alcohol 0.75% \* \* \* Lederle Laboratories Division, American Cyanamid Company, New York, N.Y." and (btl. and ctn.) "Lederle Incremin Lysine-Vitamin Tablets \* \* \* Each contains: 1-Lysine 300 mg. Vitamin B<sub>12</sub> 25 mcgm. as present in concentrated extractives from streptomyces fermentation. Thiamine Mononitrate (B<sub>1</sub>) 10 mg. Pyridoxine HCl (B<sub>6</sub>) 5 mg. Lederle Laboratories Division, American Cyanamid Company, New York, N.Y."

**LIBELED:** 6-27-60, E. Dist. Pa.

**CHARGE:** 403(a)—when shipped, the label statements (drops) "for promotion of growth in infants and stimulation of appetite of children and adults," and (tablets) "for the stimulation of appetite and growth in children and for the stimulation of appetite in adults" were false and misleading since the articles were not effective for such purposes.

**DISPOSITION:** 7-27-60. Default—destruction.

**26746. Vitamin products.** (F.D.C. No. 43554. S. Nos. 65-136/9/P.)

**QUANTITY:** 5 ctns., each containing 3 120 tablet btl. of Eden Food Supplement, 58 tins of Eden High Protein Wafers, 40 tins of Eden Treat, and 14 16-oz. cartoned btl. of Eden Chlorophyll Solution, at Salt Lake City, Utah.

**SHIPPED:** Between 5-8-59 and 7-6-59, from Sun Valley, Calif., by Garden of Eden Co.

**LABEL IN PART:** (Ctn. and btl.) "Eden Food Supplement A high potency Organic or Natural source dietary food supplement \* \* \* The Garden of Eden Company \* \* \* Sun Valley, California 10249"; (tin) "Contents 180 Wafers \* \* \* Eden High Protein Energy Wafers"; (tin) "Eden Treat . . . From the Garden of Nature's Laboratory \* \* \* Contents: 16 ounces"; and (btl.) "16 Oz. \* \* \* Eden 100% Pure Chlorophyll Solution Each tablespoonful (15 cc) contains 100 milligrams pure chlorophyllins."

**ACCOMPANYING LABELING:** Phonograph records, side 1, "Nutritional Forum" and side 2, "Opportunity Knocks"; booklets entitled "Nutritional Forum Text Questions and Answers," "Opportunity Knocks," and "Your Guidebook to Better Living"; reprints from "Modern Nutrition June 1958," and from "Reader's Digest" entitled "The Vitamins, the Food and Dr. Spies"; leaflets entitled "Why Feel Old?," "A Report on the Health of the Nation," "Let Me Put You Into Your Own Fast-growing business," "Hidden Hunger," "Eden Food Supplement," "High Protein Energy Wafers!," "Eden Chlorophyll Solution," and "Eden Treat"; and starter kits containing promotional statements.

**LIBELED:** 9-28-59, Dist. Utah.

**CHARGE:** 403(a)—when shipped and while held for sale, the labeling which accompanied the articles contained false and misleading representations that the Food Supplement was advantageously derived completely from organic or natural sources; was superior in vitamins and mineral content to the various foods to which it was compared and contained the nutrients of such foods; would prevent and eliminate "hidden hunger"; would build rich, red blood, strong internal organs, steady nerves and good bones, teeth, hair and nails, and promote secretion of hormones; was a miracle of modern science; would produce happy and healthy living; was a perfect balance of nutritional factors; would provide pep and vigor; and would bolster health, energy, and resistance; contained secret ingredients; would add years to one's life without feeling old; provide all of the essential blood strengthening and tissue nourishing food factors; contained more potent vitamin A than fish liver oil; and would be effective because Americans generally are poorly nourished; that the Protein Energy Wafers would provide high protein; furnish high, quick energy; continuous vigor; satisfy the desire for high caloric foods; burn up excess fat and sustain vitality; renew strength and energy; rebuild wornout and damaged tissues; convert poor dietary proteins into high quality proteins; and that it was comparable to milk, eggs, and meat but exceeded them in quality,