

ganese, and zinc in human nutrition has not been established" and also a statement of the proportion of the minimum daily requirement for iron or iodine supplied by such food when consumed in a specified quantity during a period of one day.

DISPOSITION: 7-18-60. Default—delivered to a public institution.

26743. Vitamin capsules. (F.D.C. No. 44073. S. No. 80-398 P.)

QUANTITY: 2 15,000-capsule bulk ctns., 20 200-capsule btls., and 10 300-capsule btls. at Hammond, Ind.

SHIPPED: 9-18-59, from Detroit, Mich.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 77 percent of the declared amount of vitamin B<sub>1</sub>.

The article in the bottles had been repacked at Hammond, Ind., from bulk stock which had been shipped as described above.

LIBELED: 2-29-60, N. Dist. Ind.

CHARGE: 402(b) (1)—while held for sale, the valuable constituent, vitamin B<sub>1</sub>, had been in part omitted or abstracted from the article; and 403(a)—the label statement "Thiamine Mononitrate 3 MG" was false and misleading.

DISPOSITION: 5-6-60. Default—destruction.

26744. Vitamin and mineral capsules. (F.D.C. No. 43283. S. No. 63-656 P.)

QUANTITY: 2 ctns. containing 26,500 capsules in bulk, 88 30-capsule unlabeled vials, and 34 30-capsule labeled vials, at Holyoke, Mass., in possession of Vitamin Center.

SHIPPED: The vitamin capsules were shipped in bulk on 3-17-59, from Newark, N.J.

LABEL IN PART: (Ctn.) "Vitamin Center Formula #76"; (vial) "Vitamin Center 30 Capsules FORMULA #76 Vitamin A \* \* \* 12,500 USP Units 312% Vitamin D \* \* \* 1,000 USP Units 250% Vitamin B-1 \* \* \* 5 MGM 500% Vitamin B-2 \* \* \* 25 MGM 208% Vitamin B-6 \* \* \* 0.5 MGM \* \* \* Vitamin B-12 USP 1 MGM \* \* \* Vitamin C \* \* \* 75 MGM 250% Niacinamide USP 40 MGM 400% Calcium Pantothenate 4 MGM \* \* \* Vitamin E \* \* \* 2 I.U. \* \* \* Folic Acid USP 0.5 MGM \* \* \* DiCalcium Phosphate (A) 260 MG Calcium 75 MGM 10% Phosphorus 58 MGM Choline Bitartrate 31.4 MG Inositol 15 MG Di-Methionine 10 MG Ferrous Sulphate USP 102 MG Iron 30 MGM Cobalt Sulphate 0.193 MG Cobalt 0.04 MGM Copper Sulphate 1.257 MG Copper 0.45 MGM Magnesium Sulphate 1.573 MG Manganese 0.5 MGM Sodium Molybdate 0.253 MG Molybdenum 0.1 MGM Potassium Iodide USP 0.099 MG Iodine 0.075 MGM Potassium Sulphate 4.458 MG Potassium 2 MG Zinc Sulphate 1.388 MG Zinc 0.5 MGM Magnesium Sulphate 21.583 MG Magnesium 3 MGM \* \* \* Vitamin Center, Granby, Mass."

ACCOMPANYING LABELING: A guaranty card; leaflets entitled "The Magic Power" and "Yours for Good Health"; form letters on the letterhead of the Vitamin Center plant, Granby, Mass., beginning with the words "Dear Friend: It is gratifying to know," "Dear Friend: If I could have had breakfast with you," "Dear Friend: We appreciate the opportunity"; and a number of loose vial labels.

RESULTS OF INVESTIGATION: The article in the vials was repacked by Vitamin Center from the bulk stock which was shipped as described above. The above-mentioned accompanying labeling was prepared by Vitamin Center.

**LIBELED:** 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. btl. of vitamin drops and 1,696 individually cartoned 30-tablet btl. 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."