

labeling contained false and misleading representations that another drug, *Red Mountain Liver-Kidney Regulator*, was adequate and effective as a treatment for biliousness, poor digestion, acid stomach, colds, kidney and back troubles, and general elimination of body waste and poisons; 502(b) (1)—the label failed to bear the name of the place of business of the manufacturer; and 502(f) (2)—the label listed potassium iodide as an active ingredient and failed to bear the warning statement required for oral preparations containing iodides, "If a skin rash appears, discontinue use and consult physician"; (*cough syrup*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for coughs (unqualified), colds (unqualified and most severe), bronchial irritations, tight stuffy chest due to colds and exposure, and hoarseness; and the label contained false and misleading representations with reference to another drug, *Red Mountain Liver and Kidney Regulator Laxative*, that the use of the two drugs was adequate and effective as a treatment for deeply seated colds; (*liver-kidney regulator*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for eliminating wastes and poisons from the system, relief of sluggish liver and kidneys, backaches, headaches, colds, constipation (unqualified), indigestion, gastric stomach, dizziness, high blood pressure, bad breath, no pep due to a bilious system, and to prevent serious menstrual pain; and the label contained false and misleading representations that another drug, *Red Mountain Blood and Nerve Tonic* was an adequate and effective treatment for the suffering of nervousness, rheumatism, impure blood, general rundown condition, and for toning and pepping up the system; and the label paragraph "General Directions" contained a statement which directed use of the product continuously, "2 to 3 times per week," which statement was false and misleading since it was contrary to the label warning statement "Caution: Frequent usage may result in laxative dependency"; and 502(f) (2)—the label declared the presence of the active laxative ingredient, phenolphthalein, and its label failed to bear the required phenolphthalein warning statement, "Caution: If skin rash appears do not use this or any other preparation containing phenolphthalein."

DISPOSITION: 2-12-62. Default—destruction.

6924. **E-Hi capsules and Isomar tablets.** (F.D.C. No. 45663. S. Nos. 19-982 R, 36-731 R.)

INFORMATION FILED: 12-19-61, S. Dist. Calif., against McCollum Laboratories, Inc., North Hollywood, Calif., Edward McCollum, president, and Florence McCollum, secretary-treasurer.

SHIPPED: 3-3-60 and 4-15-60, from California to Pennsylvania and Ohio.

LABEL IN PART: (Ctn.) "McCollum E-Hi Capsules \* \* \* High Potency Source of Vitamin E \* \* \* Made from Natural Vegetable Oils" and "Isomar \* \* \* 150 Tablets \* \* \* Distributed by McCollum Laboratories, Inc. Hollywood 28, Calif."

CHARGE: 502(f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely (*Isomar tablets*), for the treatment and prevention of tiredness, indolence, cold hands and feet, loss of agility of mind, and sluggish memory; to build blood, and to keep blood in first class condition; and to produce vitality, warmth, proper tissue tone, and strength; and (*E-Hi capsules*), for the treatment and prevention of coronary heart

trouble, heart attacks, asthma, reduced blood pressure, diabetes and decreased need for insulin in diabetes, diseases of the glands, underactive thyroid, difficult menopause, female complaints, blood diseases, inflamed veins in the legs, leg cramps, and falling hair.

PLEA: Corporation and Florence McCollum—guilty to both counts of information; Edward McCollum—guilty to one count.

DISPOSITION: 2-20-62. Corporation—\$200 fine; Florence McCollum—\$200 fine; Edward McCollum—\$100 fine.

**6925. Controcal.** (F.D.C. No. 45721. S. No. 19-840 R.)

QUANTITY: 6,158 cases, 24 5-oz. cans each, at Detroit, Mich., in possession of Milk Proteins, Inc.

SHIPPED: Between 11-11-60 and 2-3-61, from Barrington, Ill.

LABEL IN PART: (Can) "Controcal Controls Calories Complete Balanced Concentrated Food For Weight Control Formula #2—to be mixed with skim milk nutritious . . . and it tastes good \* \* \* Controcal dietary for weight control \* \* \* A complete balanced food—high grade milk protein, vitamins and minerals \* \* \* controls calorie intake while supplying adequate nutrition and appetite satisfaction. Weight loss is achieved comfortably and pleasantly by the low calorie intake. \* \* \* Milk Proteins Inc. Detroit 16, Michigan \* \* \* Ingredients: \* \* \* When the contents of this can (5-oz.) are added to 1 quart of skim milk, the following nutrients are supplied: Calories 900; Protein, gm. 72; Fat, gm. 21; Carbohydrate, gm. 112; Minerals, gm. 14.5; Vitamin A, units 5000; \* \* \* Vitamin C, mg. 100; Thiamin, mg. 2; Riboflavin, mg. 3; \* \* \* Calcium, gm. 3.9; Phosphorus, gm. 2.9; \* \* \* Minimum Daily Requirements (adults)."

ACCOMPANYING LABELING: Folders entitled "Controcal Promotion Kit."

RESULTS OF INVESTIGATION: The article was manufactured by Milk Proteins, Inc., and sent to Barrington, Ill., for packaging. The accompanying labeling was printed at Omaha, Nebr., on order of Milk Proteins, Inc.

LIBELED: 4-19-61; amended libel 5-1-61, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective to promote full, vigorous health, promote growth in boys and girls, prevent decline in health, excessive fatigue, and susceptibility to colds and other contagious diseases; and 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, in losing, maintaining, and gaining weight, and in controlling weight.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2-20-62 and 2-26-62. Default—delivered to a charitable institution.

**6926. Menstrual pain relief tablets, Barosil, and Barogel.** (F.D.C. No. 46232. S. Nos. 74-854 R, 74-857/8 R.)

QUANTITY: 1 14,000-tablet bulk drum and 9 individually cntnd. repack btls. of *menstrual pain relief tablets*; 12 1-gal. bulk btls., 7 1-gal. repack btls., and 3 1-qt. repack btls. of *Barosil*; 16 1-gal. bulk btls., 4 1-gal. repack btls., and 2 1-qt. repack btls. of *Barogel*, at Coral Gables, Fla., in possession of Barry-Martin & Co.