## DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

## DRUGS FOR HUMAN USE\*

5632. Soy lecithin. (F.D.C. No. 41514. S. No. 41-406 P.)

QUANTITY: 1 60-lb. drum and 11 ½-lb. btls. at Parma, Idaho, in possession of Arthur E. Yensen, t/a Yensen Mineral Co.

SHIPPED: 1-9-58, from Portland, Oreg.

LABEL IN PART: (Btl.) "½ Pound (one month's supply) Granular Lecithin

\* \* \* One level teaspoonful with each morning and evening meal, or as your
doctor directs \* \* \* Distributed by Yensen Mineral Company, Parma, Idaho."

Accompanying Labeling: Leaflets identified as "Lecithin and Health Compiled from recent literature by: Arthur E. Yensen."

RESULTS OF INVESTIGATION: The article in the btls. was repackaged by the dealer from the above-mentioned bulk drum, and the leaflets were printed locally for use by the dealer in promoting the sale of the article.

LIBELED: 4-16-58, Dist. Idaho.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading respresentations that the article was effective for overcoming hardening of the arteries, anemia, high blood pressure, coronary thrombosis, arthritis, diabetes, liver conditions, prostate troubles, "brain fag," nervousness, emotional irritability, headache, insomnia, and improving the general health of older people.

DISPOSITION: 5-20-58. Default—destruction.

5633. Soy and wheat germ oil concentrate and Energol germ oil concentrate. (F.D.C. No. 41518. S. Nos. 38-891/2 P.)

QUANTITY: 5 8-oz. btls. of soy and wheat germ oil concentrate, and 11 16-oz. and 5 32-oz. cans of Energol germ oil concentrate at San Francisco, Calif.

SHIPPED: 11-25-57 and 1-30-58, from York, Pa., by York Barbell Co.

LABEL IN PART: (Btl.) "Hoffman's Soy Germ Oil Wheat Germ Oil Concentrate" and (can) "Hoffman's Energol Germ Oil Concentrate."

ACCOMPANYING LABELING: Leaflets entitled "Hoffman's Germ Oil Concentrate" and "Test Taste Compare Hoffman's High Protein Food Products."

LIBELED: 4-21-58, N. Dist. Calif.

Charge: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the need in human nutrition for linoleic acid, choline, inositol, and vitamin E, contained in the articles, was recognized and established; that the use of the articles would insure a hormone balance in the body and build enzymes, would give one health, strength, and endurance; and would be effective in preventing or treating physical or sexual weakness, arteriosclerosis, coronary thrombosis, eczema, Buerger's disease, gallstones cell production, cirrhosis of the liver, gangrene, sore tongues, nervousness, anemia, epilepsy, difficulty in walking, pathological changes in the liver, thyroid and sex glands, inflamation of the intestines, extreme fatigue, oil secretion in eyelashes, bloodshot lip, swelling under eyes, quarrelsomeness, mental sluggishness, numbness, low blood pressure, shortage of breath, severe headaches, gas pains, flatulence, insufficient gastric juices, lack of hydro-

<sup>\*</sup>See also Nos. 5621, 5624-5630.

chloric acid, shingles, arthritis, alcoholism, underactive pituitary glands, waddling gait, unusual sensitivity to pain, changes in the bone marrow, changes in the nodes, lack of fertility, changes in the nerves, stunted growth, middle age spread, premature aging, overweight, stimulation of bile, coronary thrombosis, heart attacks, sore mouths, mental depression, insomnia, dizziness, irritability, tremors, nervous tics, blackouts, cataracts, tongue abnormalities, watery eyes, inefficiency, depression, sensitivity to noise, low basic metabolism, enlarged heart, vomiting, muscular contraction of the stomach, headache, diarrhea, trifacial neuralgia, sciatica, rheumatism, irregular menstruation, lack of strength, skin lesions, emaciation, sexual disturbances, coco pigmentation, changes in the brain cells, lagging secondary sex characteristics, swelling of the feet and ankles, inactive ovaries, muscular and joint stiffness, diabetes, gangreneous ulcers, coronary occlusion, premature old age, sore lips, menstrual irregularities, extreme weakness, nausea, convulsions, paralysis, tension, duodenal ulcers, adrenal deficiency, aching feet, neuritis, bloodshot eyes, early menopause, weak eyes, burning eyes, forgetfulness, constipation, high blood pressure, heart palpitation, pain in muscles, low energy production, sick stomach, heart abnormalities, severe headaches, lumbago, premature aging, premature menopause, lack of co-ordination, eye infection, ear infections, changes in the lymph, changes in the spleen, too rapid growth, edema, muscular distrophy, and strains.

DISPOSITION: 2-27-59. Default—5 btls. of the soy and wheat germ oil concentrate and 10 copies, each, of the accompanying leaflets were delivered to the Food and Drug Administration, and the remainder of the articles was destroyed.

5634. Honey with royal jelly and royal jelly capsules. (F.D.C. No. 41504. S. Nos. 3–870/3 P.)

QUANTITY: 18 1-lb. 4-oz. jars of honey with royal jelly, and 27 15-capsule btls., and 2 boxes, each containing 1 15-capsule vial of royal jelly, at Baltimore, Md., in possession of Special Diet Shop, Inc.

SHIPPED: Between 11-21-57 and 1-23-58, from New York, N.Y.

Accompanying Labeling: Posters entitled "Reprints of Scientific News Reports on Royal Jelly" and "Royal Jelly Universally Acclaimed."

RESULTS OF INVESTIGATION: The posters were used by the dealer for promotion purposes as part of a window display of the article.

LIBELED: 4-7-58, Dist. Md.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles would aid in the cure of cancer, prevent aging, would be efficacious in many physical ailments useful in treating premature, undernourished, and diseased infants, would successfully treat arthritis, leukemia, and ulcers, and restore vitality.

Disposition: 5-21-58. Default—destruction.

5635. Royal jelly capsules with vitamins and royal jelly cream. (F.D.C. No. 41515. S. Nos. 3-543/6 P.)

QUANTITY: 1 canister containing 175 capsules, 1 canister containing 1,050 capsules, 1 canister containing 1,450 capsules, and 1 150-capsule btl., 10 100-capsule btls., 3 50-capsule btls., and 6 30-capsule btls., of royal jelly with vitamins, and 286 jars of royal jelly cream, at Washington, D.C., in possession of Tipton & Myers.