

DISPOSITION: 8-10-60. Default—destruction.

6395. Vitamin tablets. (F.D.C. No. 44751. S. Nos. 7-188/93 R.)

QUANTITY: 3 5,000-tablet cartoned btls., 32 1,000-tablet cartoned btls., 3 cases, each containing 48 250-tablet btls., 8 cases, each containing 144 100-tablet cartoned btls., and 3 cases, each containing 144 50-tablet cartoned btls., of *Vita-Kaps*; 7 1,000-tablet cartoned btls., 45 cases, each containing 12 250-tablet cartoned btls., 6 cases, each containing 12 100-tablet btls., and 14 cases, each containing 12 50-tablet cartoned btls., of *VitaKaps-M*; 6 5,000-tablet btls., 6 1,000-tablet btls., 7 cases, each containing 48 250-tablet btls., 342 cases, each containing 12 100-tablet btls., and 4 cases, each containing 144 50-tablet btls., of *Dayalets*; 3 1,000-tablet btls., 13 cases, each containing 36 250-tablet btls., and 136 cases, each containing 12 100-tablet btls., of *Dayalets-M*; 3 cases, each containing 24 1,000-tablet cartoned btls., 85 cases, each containing 48 100-tablet btls., and 16 cases, each containing 48 30-tablet btls., of *Optilets*; and 4 1,000-tablet btls., 20 cases, each containing 48 100-tablet btls., and 12 cases, each containing 48 30-tablet btls., of *Optilets-M*, at Needham Heights, Mass.

SHIPPED: Between 3-5-60 and 5-4-60, from North Chicago, Ill., by Abbott Laboratories.

LABEL IN PART: (Btl.) "Vita-Kaps Abbott Multivitamins for all the family A, D, C, and Vitamin B Complex, including B₁₂ ("VitaKaps-M Abbott Multivitamins and Minerals for all the family. A, D, C and Vitamin B Complex, including B₁₂ and Minerals," "Dayalets Abbott's Multiple Vitamin Tablets Potent, daily maintenance vitamins 10 important vitamins in each tiny tablet," "Dayalets-M Abbott Vitamin Mineral Tablets 10 Important Vitamins 9 Important Minerals," "Optilets * * * Therapeutic Formula Multivitamins," and "Optilets-M Abbott's Therapeutic Formula Vitamins with Minerals") * * * Abbott Laboratories, North Chicago, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "Vitamins for Your Family."

LIBELED: 8-3-60, Dist. Mass.

CHARGE: 502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that additional quantities of vitamins, far in excess of the amount recommended for adequate nutrition, would provide additional benefits to persons in good health; and would assist in returning a sick or injured person, or one convalescing from an operation, to good health; that the body has a greatly increased need for vitamins when the individual is under mental stress, tension, or strain, is physically fatigued, or is suffering from injury, infection, or illness, or is undergoing surgery, and which increased need is an indication for the use of the excess quantities of vitamins offered by the products, which statements were false and misleading, since they were contrary to fact;

502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that the products were offered as a medicine and as a preventive medicine for the treatment and prevention of night blindness; beriberi; pellagra; scurvy; rickets; osteomalacia; and nutritional macrocytic anemia; and suggested that these diseases are quite likely to occur unless the ordinary diet of the usual person in this country is supplemented by a vitamin or vitamin and mineral supplement, which statements were false and misleading, since the occurrence of such

diseases is extremely rare in this country and could occur only with the use of an extremely limited diet over a long period of time;

502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that pernicious anemia results from a dietary deficiency of vitamin B₁₂, and would be corrected by supplementation of the diet with that vitamin, which statements were false and misleading, since lack of intrinsic factor is a result of failure of the function of the body to produce that factor, leading to the disease, pernicious anemia, which disease is not amenable to treatment or correction, nor can the intrinsic factor be replaced by use of the supplements offered; and

502(a)—the listing, in the accompanying labeling of the articles, of the following symptoms: defects of tooth development; swollen bleeding gums; gingivitis; lip and skin lesions; skin and tongue inflammation; skin hemorrhages; seborrheic dermatitis; optical disturbances; gastrointestinal disturbances; vomiting of pregnancy; nerve diseases; dysfunction of the nervous system; convulsions; impaired growth; and muscular weakness as the result of a deficiency of one or more of the vitamins contained in the products; suggested that anyone suffering from one or more of these conditions and symptoms was suffering from a dietary deficiency and could eliminate the symptoms and conditions by adding a vitamin supplement to their diet, which suggestion was false and misleading, since it is contrary to fact in that such conditions and symptoms are rarely due to a dietary deficiency, are more commonly due to other causes not related to a dietary deficiency, and are not amenable to treatment with a vitamin supplement.

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

DISPOSITION: 9-19-60. Default—delivered to a charitable institution.

6396. Palm Beach Skin Specialists Lotion. (F.D.C. No. 44715. S. No. 28-831 R.)

QUANTITY: 23 4-oz. btl., 40 8-oz. btl., and 6 16-oz. btl., at Fargo, N. Dak.

SHIPPED: Between 2-18-60 and 7-13-60, from Minneapolis, Minn., by Miriam Collins Palm Beach Cosmetic Co.

LABEL IN PART: (Btl.) "Palm Beach Skin Specialists Lotion * * * Contains hexachlorophene, resorcinol, allantoin, and ethanol."

ACCOMPANYING LABELING: Booklet attached to each bottle entitled "Beautiful Skin is Clean Skin Palm Beach Skin Specialists Lotion."

LIBELED: 7-13-60, Dist. N. Dak.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for pimples, blackheads, enlarged pores, itching, eczema, sunburn, dandruff, for building tissue, impetigo, burns, scalds, wounds, and other skin conditions; and that it was a new hope for acne sufferers; 502(b) (2)—the bottle label failed to bear an accurate statement of the quantity of the contents; and 502(e) (2)—the label of the article failed to bear the common or usual name of each active ingredient and the quantity, kind, and proportion of alcohol contained therein.

DISPOSITION: 7-29-60. Default—destruction.

6397. Plasmatic therapy device. (Inj. No. 359.)

COMPLAINT FOR INJUNCTION FILED: 9-11-59, S. Dist. Ind., against Physical Medicine Instrument Co., a corporation, Indianapolis, Ind., and Eulalia Op-