

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-

perman, president, A. Henry Opperman, secretary-treasurer, and Homer A. Keller, vice president.

ACCOMPANYING LABELING: Booklets headed "Warning" and "The Blood is the Life"; book entitled "Practical Physical Therapy"; and loose-leaf book formerly entitled "Twenty Years Record"; circular headed "Re: Plasmatic Therapy"; and sheet headed "Technical Information."

RESULTS OF INVESTIGATION: Examination showed that the device was a metal cabinet with a control panel containing lead-in wires for an alternating current electric power line and for any of the various applicators, a timer dial, a double-throw switch, a Variac voltage transformer, and various electrical connections; that it was essentially an indicator and timing device for the applicators; that the accessories included: two systemic applicators, one infrared applicator, one vaginal applicator, one rectal applicator, a jiffy wrapper, pillow and plastic sheet, stockinet covers for pads, a metal stand on casters, and line cords; and that the applicators were long, plastic sheets wound with resistance wires. The device also included "Eye Goggles" consisting of a plastic case equipped with nichrome resistance wire fixed on asbestos and an "Eye Control Unit" (which is essentially a timer) consisting of a small metal cabinet with an input plug, a switch, a rheostat, a timer, and an output plug.

CHARGE: The complaint alleged that the defendants were engaged in the business of promoting, selling, servicing, replacing, and repairing a device called the "*Plasmatic therapy device*" which included an "Eye Control Unit" and "Goggles," as well as attachments, parts, accessories, and labeling thereof; that the device had been and was being sold to chiropractors, naturopaths, physiotherapists, masseurs, and other nonmedical practitioners; that the business of the defendants was then largely confined to servicing and supplying parts for the devices in the possession of such users; that the device furnished nothing more than a mild form of heat; that the device had no therapeutic effect; and that when shipped, the device was misbranded as follows:

502(a)—the labeling accompanying the article contained statements which represented and suggested that the device had therapeutic usefulness in the treatment and cure of arthritis, syphilis, septicemia, uremia, pneumonia, hemiplegia, diabetes, Bright's disease, cirrhosis of the liver, dementia praecox, chronic cardiac conditions, chronic infections, dropsy, encephalitis, epilepsy, Parkinson's disease, hypertension, hypochondria, locomotor ataxia, mental disorders, metabolic disorders, multiple sclerosis, neuralgia, malarial fever, jungle rot, poliomyelitis, neuritis, sciatica, neurasthenia, pleurisy, psoriasis, glaucoma, conjunctivitis, stye, corneal ulcer, scleritis, toxemic iritis, optic atrophy, acute middle ear catarrh, tinnitus, hemorrhoids, pruritus ani, and leukorrhea, which statements were false and misleading since the device had no therapeutic usefulness in the treatment and cure of the diseases and conditions stated and implied; or for any other diseases or conditions since the device possessed no therapeutic usefulness whatsoever.

The complaint alleged further that the defendants continued to advertise the devices and were preparing additional labeling; that the stock of parts on hand, sufficient to repair many hundreds of devices, constituted a menace to interstate commerce; and that such repair and replacement service allowed many operators of the devices to continue to use them in the treatment of serious diseases for which the devices were recommended but for which they were useless.

DISPOSITION: 9-26-60. The defendants having consented without either admitting or denying the allegations of the complaint, the court entered a decree of permanent injunction enjoining the defendants from—

- (a) introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce, any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories or the same device by any other designation, or any similar device, which is accompanied by the booklets headed "Warning" and "The Blood is The Life"; the book entitled "Practical Physical Therapy"; the loose-leaf book formerly entitled "Twenty Years Records"; the circular headed "Re: Plasmatic Therapy"; or the sheet headed "Technical Information," or by any other written, printed, or graphic matter which represents and suggests that the device has therapeutic usefulness in the treatment and cure of the diseases and conditions named in the complaint;
- (b) doing or causing to be done any act with respect to any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories, or the same device by any other designation, or any similar device, while such device is held for sale after shipment in interstate commerce, which will result in such device being accompanied by the aforesaid labeling, or by other written, printed, or graphic matter containing the same representations and suggestions;
- (c) introducing or delivering for introduction or causing to be introduced or to be delivered for introduction into interstate commerce, any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories, or the same device by any other designation, or any similar device, which fails to bear in its labeling all of the conditions, purposes, and uses for which such device is intended and for which it is represented, by any means, to the public.

6398. Radiant Cosmic Disc and Radiant Spark-O-Life. (F.D.C. No. 45021. S. Nos. 41-284/6 R.)

QUANTITY: 9 discs (1-gal. size), and 2 discs (5-gal. size), known as *Radiant Cosmic Discs*; and 16 discs (1-gal. size) known as *Radiant Spark-O-Life*, at Oakland, Calif. Each disc was packaged in an envelope.

SHIPPED: On or about 5-13-60, from Tumtum, Wash., by Thomas Health Enterprises.

LABEL IN PART: (Envelope) "Radiant * * * Cosmic Disc Radiant Laboratories Leads the Nation in Natural Organic Food Growing Supplies Tum Tum, Washington;" and "Radiant * * * Spark-O-Life For Fowl and Animals Radiant Laboratories Leads the Nation in Natural Organic Food Growing Supplies Tum Tum, Washington."

ACCOMPANYING LABELING: Mimeographed booklets entitled "Announcing Radiant Living" and "Index for Radiant Analysis Kits"; and one-page sheets entitled "Join Radiant Associates, Inc."

RESULTS OF INVESTIGATION: Examination showed that the articles were gray-colored, solid, porous, disc-shaped devices of various sizes, as follows: (1-gal. size) $1\frac{15}{16}$ " in diameter x $\frac{3}{4}$ " thick; (1-gal. size) $2\frac{5}{16}$ " in diameter x $1\frac{1}{2}$ " thick; and (5-gal. size) $2\frac{11}{16}$ " in diameter x $1\frac{1}{2}$ " thick.

In use, the discs were allowed to soak, usually for 24 hour periods, in one- or five-gallon containers of water (depending on the size of the discs). The disc reportedly served to treat the water with natural cosmic rays. The