

the defendants continued to introduce and deliver for introduction into interstate commerce the misbranded device.

DISPOSITION: 12-27-57. The defendants having consented, the court entered a decree of permanent injunction enjoining them against the acts complained of.

5488. Schramm's massage brushes, Diamix devices, and Model B-50 generators and B-50 cabinets. (F.D.C. No. 41301. S. Nos. 72-295/7 M.)

QUANTITY: 54 Schramm's *massage brushes*, 3 *Diamix devices*, and 4 *Model B-50 generators* and 5 *B-50 cabinets* at Hinsdale, Ill., in possession of Midwest Imports.

SHIPPED: Between 10-10-55 and 9-17-57, from Germany.

ACCOMPANYING LABELING: (Schramm's massage brush) leaflets entitled "Schramm's Massage Brush Ideal M.I."; (Diamix device) reference sheets entitled "Illinois Masonic Hospital Association," leaflets entitled "Diamix The Universal Apparatus," and a number of sheets entitled "Indications for the Helio-Therapy with Diamix"; and (Model B-50 generator and B-50 cabinet) booklets entitled "Praktische Erfahrungen," leaflets entitled "Statement—Alexian Brothers Hospital," and reprints entitled "Infrared Radiation Baths Protect Your Health."

RESULTS OF INVESTIGATION: Examination showed that the *Schramm's massage brush* was a rubber brush with a varnished wooden handle (de luxe model) or with a plain wooden handle (economy model); that the *Diamix device* was a radiant lamp with a wire-wound infraheat element and 5 interchangeable bulbs of different colors for ultraviolet, neon, red, blue, and green radiation, and with a fixed infrared emitter; and that the device, consisting of the *Model B-50 generator* and *B-50 cabinet*, comprised a cabinet, heater, and stool. The cabinet was covered with imitation leather, was heat and waterproof, with a steel spring inlayer, and was lined with reflective material. It had a top closure and floor cover of imitation leather and a thermometer for reading temperature. The cabinet weighed about 8 lbs., was 42 inches high when set up, and had a 10-inch radius when rolled. The heating unit was a nonglowing generator of rustproof metal, operated by an off-on switch inside the cabinet. The stool had a seat of plastic upholstery, was 12 inches in diameter, and had black, plastic-tipped legs.

The accompanying labeling of the articles, consisting of the above-mentioned booklets, was obtained by the consignee from Germany, and the other items of accompanying labeling were printed locally for the consignee.

LIBELED: 12-26-57, N. Dist. Ill.

CHARGE: *Schramm's massage brush*. 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article would be effective in the treatment and prevention of degenerative diseases, such as heart affections, rheumatism, sciatica, and circulation troubles; that it would stimulate the inner organism; that it would expedite skin regeneration; that it would help procure youthful complexion; that it would prevent debilitation of the back; and that it would strengthen nerve fibers of the spine.

Diamix device. 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the colors of the visible spectrum (neon, red, blue, and green), which were provided by the article, had therapeutic value, and that those colors, together with the ultra-

violet radiation provided by the article, were adequate and effective in the treatment for (ultraviolet) various types of dermatitis, eczema, psoriasis, scalp diseases, rachitis, scrofulosis, glandular disturbances, and "epidimytis"; (red) in all cases where hyperthermia is indicated—in place of diathermy, acute and subacute inflamed processes, rheumatism, lumbago, sciatica, neuralgia, neuritis; affections of the middle ear, irritations of frontal and maxillary sinus, rhinitis, gallbladder infections, and gynecological disturbances; (blue) for the relief and abolishment of pains, for bactericidal effect in cases of: furunculosis, infected surface wounds, infections of the middle ear, sinus, and jaws; parodontitis, all types of burns, after X-ray treatments, necrosis, and frostbites; (neon) in all chronic conditions of rheumatic nature, rheumatism, sciatica, arthritis deformans, pyelitis, cystitis, gynecological disorders, "pleuritis," and phlebitis; and (green) various respiratory disorders, small and large bronchial infections, and virus flu's.

Model B-50 generator and B-50 cabinet. 502(a)—while held for sale, the accompanying labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for rheumatoid arthritis, diseases of the heart, blood vessels, kidney, bladder, gallbladder, neuralgia, nervous disorders, respiratory infections, arteriosclerosis, grippe, eczema and dermatologic disorders, goiter, pneumonia, bronchial asthma, pleurisy, chronic constipation, phantom limb syndrome, high blood pressure, ankylosis, spondylitis, stomach disorders, menopausal difficulties, "Parkinson," diabetes, insomnia, obesity and other disease, and catarrhal disease; and that the articles would have a beneficial effect on the vegetative nervous system, increase circulation, intensify activity of the endocrine glands, accelerate metabolic processes, multiply white blood corpuscles, detoxicate the entire body, and kill disease germs; and 502(f)(1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from such requirement since the articles, because of their potentiality for harmful effect, method of use, and collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to direct the use of such articles; and their labels failed to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a -----," the blank to be filled with the designation of any practitioner licensed by the law of the State in which he practices, to use or order the use of the device.

DISPOSITION: 1-22-58. Consent—claimed by Karl Hausner, t/a Midwest Imports, and relabeled.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5489. Dextro-amphetamine sulfate timed disintegration capsules. (F.D.C. No. 40530. S. No. 69-500 M.)

QUANTITY: 28,500 capsules in bottles at Philadelphia, Pa.

SHIPPED: 1-28-57, from Brooklyn, N.Y., by Robin Pharmacal Corp.

LABEL IN PART: (Btl.) "500 T.D.C. (Timed Disintegration Capsule) Dextro-Amphetamine Sulfate 15 mgm. Each capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for timed disintegration

*See also Nos. 5481, 5483, 5484, 5486.