

6207. Jacuzzi Whirlpool Bath. (F.D.C. No. 44573. S. No. 11-817 B.)

QUANTITY: 14 individually cartoned devices at Chicago, Ill., in possession of Hydro-Massage Health, Inc.

SHIPPED: Between 2-10-60 and 3-3-60, from Berkeley, Calif., by Jacuzzi Research, Inc.

LABEL IN PART: (Ctn.) "Jacuzzi Whirlpool Bath."

ACCOMPANYING LABELING: Pamphlet entitled "Hydrotherapy in General Practice * * * reprinted from Modern Medicine February 15, 1950"; a brochure entitled "Now Whirlpool Hydrotherapy for Hospital and Clinic"; and leaflets entitled "The Use of the Whirlpool Bath," "Relaxes—Refreshes—Revitalizes Jacuzzi Whirlpool Bath," and "Reprinted from The Journal of The American Medical Association * * * Brine Bath Treatments for Decubitus Ulcers."

RESULTS OF INVESTIGATION: The article was a portable unit containing an enclosed electric motor which would drive a water pump. Water was forcefully driven through a nozzle and an aspirator, thus producing a swirling air-water foam.

LIBELED: 5-16-60, N. Dist. Ill.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming peripheral neuritis; osteoarthritis; chronic gout; myositis; fibrositis; hypertrophic spondylitis; spastic constipation; spastic colitis; pylorospasm; neurasthenia; cerebral arteriosclerosis; convulsions; pruritis; scaly dermatitis; pemphigus; atonic constipation; biliary atony; impotence; vascular spasm; and for preventing deformities of arthritis and rheumatism, and other disease conditions; and 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use in the treatment of arthritis; multiple sclerosis; cerebral palsy; muscular dystrophy; rheumatoid arthritis; osteoarthritis; traumatic arthritis; third degree burns; cardiac cases; stroke; ulcers; ulcerated skin; mental cases; and for toning and firming the skin and muscles; which were the conditions and purposes for which the article was offered in oral statements made by a representative of the dealer firm.

DISPOSITION: 6-10-60. Consent—claimed by Hydro-Massage Health, Inc., and relabeled.

6208. Mercier's Radioactive device. (F.D.C. No. 44157. S. No. 52-955 P.)

QUANTITY: 6 assembled devices at Scottsdale, Ariz., in possession of A. H. Lee, and a number of component parts of such devices at Glendale, Ariz., in possession of A. F. Mercier. Such component parts consisted of 6 quartz tubes; 8 quartz test tubes; 1 article of plexiglass; 1 article of plexiglass and carbon mixture; 1 brass wire screen; and quantities of radium barium chloride, thorium oxide, and lanthanum oxide.

SHIPPED: The following components of the devices were shipped on unknown dates as follows: the quartz tubes and quartz test tubes from Willoughby, Ohio; the lanthanum oxide and thorium oxide from West Chicago, Ill.; and the radium barium chloride from Denver, Colo.

ACCOMPANYING LABELING: Literature entitled: "Atomic Theory in Molecular Reconstruction"; "A Process Originated to Readjust in proper Order the Law of the Individual as it Relates to the Chemical Balance"; "The Law of Nuclear

Action as it Relates to the Living Substance"; "Einstein's Law of Photo Electric Effect"; and "Blood Test."

RESULTS OF INVESTIGATION: Examination with the use of a beta-gamma survey meter disclosed that the center of the assembled devices possessed radioactivity in the amount of 17 milliroentgens per hour which is about 2 to 3 times that of a radium dial watch.

LIBELED: 1-11-60, Dist. Ariz.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the device was an adequate and effective treatment for arthritis, diabetes, anemia, cancer, numerous bone ailments, to dissolve blood clots and eliminate inflammation through irradiation of a series of samples of a person's blood and the re-injection of the blood plasma after irradiation; 502(b) (1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f) (1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, the prevention and treatment of epilepsy, leukemia, cancer, arthritis, and mentally retarded children, which were the conditions and diseases for which the device was recommended orally by A. F. Mercier.

DISPOSITION: On 2-24-60, A. F. Mercier appeared as claimant and filed a motion to dismiss, which was denied by the court on 3-15-60. On 3-21-60, the claimant filed a claim and answer denying that the article was misbranded. Thereafter, the Government filed interrogatories against the claimant which were answered in part after which the Government filed supplemental interrogatories. On 4-13-60, the Government filed a motion for summary judgment on the ground that there was no genuine issue as to any material fact with respect to the charges of misbranding under 502(b) (1) and 502 (f) (1). The motion was granted on 5-6-60, and, on 7-1-60, the articles were ordered condemned and delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6209. Thyroid-digitalis tablets and thyroid tablets. (F.D.C. No. 43708. S. Nos. 23-389/90 P.)

INFORMATION FILED: 4-11-60, S. Dist. Calif., against Joseph L. Jones, t/a J. L. Jones & Co., Sun Valley, Calif.

SHIPPED: 9-18-58 and 10-16-58, from California to Nevada.

LABEL IN PART: (Ctn.) "J. L. JONES & COMPANY Manufacturing Chemists 7200 Vineland Ave., Sun Valley, California MANUFACTURED FOR * * * Each tablet contains: Thyroid U.S.P. 3 grains Digitalis Leaves Powder $\frac{3}{4}$ grain Plus added excipients 10 = 71 grains * * * IMPORTANT This is a bulk shipment, intended for further processing only." or "J. L. JONES & COMPANY Manufacturing Chemists * * * Each tablet contains: Thyroid 5 grains Plus added excipients 10 = 165 grains * * * S. C. Blue."

RESULTS OF INVESTIGATION: The *thyroid-digitalis tablets* contained about 76 percent of the labeled amount of thyroid and 58 percent of the labeled amount of digitalis per tablet, and the *thyroid tablets* contained about 65 percent of the labeled amount of thyroid per tablet.