LIBELED: 9–26–60, M. Dist. Ga.

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use, and the articles were not exempt from such requirement.

DISPOSITION: 6–1–61. Ronald G. Shawver, claimant, having filed an answer denying that the articles were misbranded and later having requested that such answer be dismissed, which request was allowed, judgment of condemnation was entered and the articles were destroyed.

6592. Mercier's radioactive device. (F.D.C. No. 45456. S. No. 49–319 R.)

QUANTITY: One device at Albuquerque, N. Mex.

SHIPPED: In 1954, from Phoenix, Ariz., by Mercier Laboratories.

LABEL IN PART: "Atomic Energy Applicator Intent of Energy Producing Applicator to Perfect the Chemistry of the Living Substance. Disease Will Disappear in Proportion to the Chemistry Correction."

RESULTS OF INVESTIGATION: The article consisted of a wooden base into which a lead foil-covered cylinder was fitted. In use, a radioactive material was placed in the cylinder between the wire inner wall and the lead foil outer wall. Examination with a Geiger counter showed a reading over the open end of the cylinder of 2.0 milliroentgen units per hour (beta radiations).

LIBELED: 2–2–61, Dist. N. Mex.

CHARGE: 502(a)—when shipped and while held for sale, the label contained false and misleading representations that the article was adequate and effective for perfecting the chemistry of the living substance and for correcting or curing disease conditions; 502(b)(1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling failed to bear adequate directions for use, since the article was worthless for any therapeutic purposes.

DISPOSITION: 3–3–61. Default—destruction.

6593. Harmonizer device. (F.D.C. No. 44421. S. No. 42–508 P.)

QUANTITY: One device at Lynnwood, Wash.

SHIPPED: 10–6–59, from Alhambra, Calif., by C. E. Harmon, D.C., t/a Sound Control Development Co.

LABEL IN PART: "'Harmonizer' Sound Control Development Co. Mach 09 117 Volt Ac 60 Cyl California."

ACCOMPANYING LABELING: Leaflets entitled "Harmonizer Instruction Chart," "Don't Give Up—Wake Up!!," and "Sound Control Development Co. Presents . . . The Harmonizer."

RESULTS OF INVESTIGATION: Examination indicated the device to be a box-shaped, portable cabinet fitted on the front with an instrument panel. The chassis within the cabinet, which consisted of a transformer, tubes, and other electronic components, was connected by an electric cord to the ordinary 110–115 volt house circuit. The unit was purported to be capable of emitting ultrasound, with the instrument panel controlling the "ultrasound frequency," "intensity," "audio-frequency," and "intensity variation." However, the available information indicated that the high and low frequency currents produced in the device were not converted to ultrasound energy.

LIBELED: 4–6–60, W. Dist. Wash.; amended libel 11–18–60.

CHARGE: 501(c)—when shipped, the strength of the device differed from, and its quality fell below, that which it purported to possess since it purported to produce (1) audible sound waves varying from a frequency of 0 to 20,000 cycles per second, and (2) ultrasound waves varying from a frequency of 100,000 to 400,000 cycles per second, whereas the device produced neither sound waves nor ultrasound waves; 502(a)—the labeling contained false and misleading representations that the device was an adequate and effective treatment for arthritis, asthma, sinus trouble, migraine, bursitis, sciatica, neuritis, goiter, epilepsy, prostate trouble, high blood pressure, heart disease, kidney disease, glandular and nerve degeneration, ulcers, cysts, anemia, colitis, osteomyelitis, varicose veins, skin diseases, chronic infections, bronchitis, tumors, and Parkinson's disease; 502(a)—the labeling declared that the device was the "Only Dual unit Sound Therapy for treatment of disease. Composed of Audible (low frequency) and Ultra-Sound controlled vibration," which statement was false and misleading since the device did not provide audible sound or ultrasound therapy and did not produce either audible sound energy or ultrasound energy; 502(a)—the labeling contained false and misleading representations that the device was specific as audible sound therapy for nerve regeneration, increased circulation, tissue repair, and gland and muscle stimulation, whereas the device was not specific or effective as audible sound therapy for such purposes; 502(a)—the labeling contained false and misleading representations that the device was unsurpassed as ultrasound therapy for control of inflammation, elimination of infection, decalcification, tumor disintegration, and pain relief, whereas the device was not effective as ultrasound therapy for such purposes; 502(a)—the labeling contained false and misleading representations that the application of pads of the device to the sinuses, thyroid, anterior and posterior cervicals, mastoid, parotid, submaxillary areas, chest, dorsals, hands, feet, shoulders, elbows, wrists, ankles, knees, arms, legs, viscera, lumbars, sacrum and hips would have therapeutic value as an ultrasonic treatment for disease conditions in those areas whereas the application of the pads to those areas would not have such therapeutic value; 502(a)—the labeling of the device was misleading because it failed to reveal the fact, which was material in the light of the representations which were made therein, that the device, when used as directed, produced only electrical impulses or radio-frequency waves and contained nothing capable of converting such waves to audible sound or ultrasound waves; and 502(f)(1)—the labeling of the device failed to bear adequate directions for use and it was not feasible to devise adequate directions for its use since the article was worthless as audible sound or ultrasound therapy for any medical purpose.

DISPOSITION: On 5–26–60, C. E. Harmon, D.C., and Ned E. Brown filed an answer to the libel denying the allegations of the libel pertaining to misbranding and affirmatively alleging that the device had therapeutic value. The Government filed an amended libel by stipulation with the claimants on 11–18–60. The amended libel added the adulteration charge, amplified the original misbranding charge, and specified two additional leaflets as part of the labeling. On 11–28–60, the Government filed interrogatories which were answered by the claimants in February 1961. Subsequently, without admitting any of the allegations in the amended libel, the claimants withdrew their claim and answer, so that a default decree might be entered.

On 5–5–61, a default decree was filed, in which the court declared that it appeared that the device was misbranded when shipped, because its labeling contained false and misleading representations that the device was an adequate

and effective treatment for a number of diseases and conditions, and because its labeling was false and misleading since the device did not provide audible sound or ultrasound therapy and did not produce audible sound energy or ultrasound energy; and that the device was adulterated when shipped, in that its strength differed from, and its quality fell below, that which it purported to possess since it purported to produce (1) audible sound waves varying from a frequency of 0 to 20,000 cycles per second, and (2) ultrasound waves varying from a frequency of 100,000 to 400,000 cycles per second, whereas the device produced neither sound waves nor ultrasound waves.

The default decree provided for the condemnation of the device and its delivery to the Food and Drug Administration.

DRUG FOR VETERINARY USE

6594. Dr. Bell's Veterinary Medical Wonder. (F.D.C. No. 44912. S. No. 35–675 R.)

QUANTITY: 3,887 individually cartoned bottles at New York, N.Y.

SHIPPED: Between 10–29–59 and 11–27–59, by Juan S. Garcia, Ave. Fdex. Juncos esq. San Andres, Pda. 4, Pta. de Tierra, P.R., San Juan, Puerto Rico, and on 7–11–59, from Kingston, Canada, by Dr. Bell Veterinary Medicine Co.

LABEL IN PART: (Ctn.) "Dr. Bell's Veterinary Medical Wonder * * * Net Contents 15 ml. Dr. Bell Veterinary Medicine Co., Kingston, Ontario, Canada * * * Each ml. contains 0.25 ml. Aconite Fluid Extract; 0.25 ml. Belladonna Root Fluid Extract; 0.25 ml. Digitalis Fluid Extract; 0.1875 ml. Liquid Extract of Nux Vomica."

ACCOMPANYING LABELING: Leaflet in carton entitled "Dr. Bell's VMW Veterinary Medical Wonder."

LIBELED: 10–13–60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the following statements contained in its labeling: (carton) "A 'first-aid' treatment for animals suffering the effects of injury, shock, exposure, or sudden illness. As an antispasmodic in nervous conditions. A restorative in exhaustion. * * * In acute cases, such as Colic," (leaflet) "A 'First-Aid' for animals displaying symptoms of Shock, Exposure or Sudden Illness. An Antispasmodic in Nervous Conditions A Restorative in Exhaustion. When veterinary service is not available, administer VMW at the first sign of Coughs, Colic, Pain, Fever, Inflammation, etc. * * * Dosages * * * Calf Scours: * * * Shipping Fever: (Hemorrhagic-Septicemia) When 'shipping fever' symptoms are observed: Difficult breathing, dry painful coughs, arched backs, discharges from nose and eyes, high temperature * * * Colic: * * *," and (bottle) "a 'first-aid' for sick animals * * * colic * * * for shock or exposure," were false and misleading since there was no scientific basis for regarding the article as a first aid for sick animals suffering the effects of sudden illness, shock, injury, or exposure; and the article would not act as an antispasmodic in nervous conditions, or as a restorative in exhaustion; 502(a)—the labeling contained statements which represented and suggested that the article was an adequate treatment for the diseases, conditions, and symptoms referred to therein, which statements were false and misleading since the article was not an adequate treatment for such diseases, conditions, or symptoms; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the conditions and purposes for which it was intended.