for rheumatism, neuritis, sprains, colds, etc.; and 502(f)(2)—the labeling failed to warn that the article should not be used otherwise than as directed; that it should be kept out of the reach of children; and that its use should be discontinued if excessive irritation of the skin developed.

DISPOSITION: 2–8–61. Default—destruction.

6560. Figurama device. (F.D.C. No. 42969. S. No. 27–707 P.)

QUANTITY: 20 devices individually cartoned at St. Paul and Minneapolis, Minn.

SHIPPED: 1–27–59 and 1–29–59, from Milford, Conn.

LABEL IN PART: "Tempulse Figurama By Streamform Corp., New York, N.Y."

RESULTS OF INVESTIGATION: Examination indicated that the device was a streamlined box-shaped housing containing an electric motor which provided vibrating and/or oscillating action to two pads located atop the housing. The pads contained a controlled heating element; and detachable tubular padded extensions converted the housing to a table-type device.

LIBELED: 4–7–59, Dist. Minn.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a treatment for relieving polio or any disease of that type; reducing; easing an incurable disease; relieving arthritis, bursitis, rheumatism, and neuritis; increasing blood circulation to all parts of the body to keep one from becoming sick, losing hair, getting wrinkles, or having high blood pressure; improving posture and firming the body tissues; banishing nervous tension; as a "help for everything"; spot reducing and taking off inches; which were the conditions and purposes for which it was offered in oral statements made by a sales representative in Minneapolis, Minn., on 2–2–59 and 2–3–59.

DISPOSITION: In May 1959, the Streamform Corp. filed a claim to the articles. Thereafter, the action was removed at the claimant's motion to the United States District Court of New Jersey where an answer was filed by the claimant denying that the articles were misbranded. After further litigation including the submission of written interrogatories by the Government, the submission of answers by the claimant, a motion by the Government to compel further and more complete answers, and an order of the court that the claimants submit further and more complete answers, a consent decree of condemnation was filed on 10–20–60. The claimant failed to file the bond required by the consent decree for the release of the goods to the claimant for relabeling under Government supervision. A default decree was filed on 1–27–61, and the devices were ordered to be turned over to the Department of Health, Education, and Welfare, Food and Drug Administration, Minneapolis, Minn., for exhibit purposes.

6561. Ultra-Sonic device. (F.D.C. No. 44591. S. No. 43–699 R.)

QUANTITY: 1 device at Great Falls, Mont., in possession of Elizabeth Webb Hill.

SHIPPED: 8–14–59, from Los Angeles, Calif., by Ace Medical Instrument Co.

LABEL IN PART: (Metal plate on device) "Ace Ultra-Sonic * * * Manufactured by Electronics Instrument Co., Los Angeles, Calif."

ACCOMPANYING LABELING: Leaflets entitled "Operating Instructions" and "Ace Ultra-Sonic Deluxe Model."

RESULTS OF INVESTIGATION: Examination indicated the device to be an electronic device producing ultrasound energy at 960,000 cycles per second through a 10 square centimeter sound head. The instrument cabinets con-

tained an oscillator and power supply. The front panel contained a timer, intensity control, and power output meter.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, the treatment of disease or abnormal conditions of the nerves, head, neck, shoulders, thoracic region, lumbosacral region, arteries, joints, upper extremity, and lower extremity; 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for any condition and it was not exempt under the provisions of Regulation 21 CFR 1.106(d) from bearing adequate directions for use since it was a prescription device sold to and in possession of a person not entitled to use such a device.

DISPOSITION: 10-20-60. Consent—claimed by W. M. Jacobson, t/a Ace Medical Instrument Co. and relabeled.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

6562. Verutal-T tablets. (Inj. No. 335. S. No. 39-980 P.)

PETITION FILED: 11-5-59, N. Dist. N.Y., against Rand Pharmaceutical Co., Inc., Rensselaer, N.Y., to show cause why it should not be punished for criminal contempt for violation of the permanent injunction which had been entered against the Delmar Pharmacal Corp., on 7-22-58 (see preceding notice of judgment No. 6546).

LABEL IN PART: "Verutal-T * * * Each tablet contains: Veratrum Viride 100 mg. Rutin 10 mg. Reserpine .075 mg. Mannitol Hexanitrate ½ gr."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 22 percent of the labeled amount of mannitol hexanitrate and 66 percent of the declared amount of rutin.

CHARGE: The petition alleged that the Rand Pharmaceutical Co., Inc., on 10-11-58, caused to be introduced and delivered for introduction into interstate commerce at Rensselaer, N.Y., for delivery to South San Francisco, Calif., a number of bottles of "Verutal-T" which were adulterated within the meaning of 501(c) in that the strength of the drug differed from that which it purported and was represented to possess.

It was alleged further that the Rand Pharmaceutical Co., Inc., had been and was affiliated with the Delmar Pharmacal Corp. in the distribution of drugs in interstate commerce, and that Rand Pharmaceutical Co., Inc., had violated the injunction by causing the adulterated drug to be introduced and delivered for introduction into interstate commerce while the Delmar Pharmacal Corp. continued to operate its plant without complying with the following requirements of the injunction:

(a) that sufficient qualified and experienced personnel be employed to properly operate the plant;
(b) that incoming raw materials be analyzed;
(c) that all finished products be analyzed; and
(d) that a control system be installed which a representative of the U.S. Food and Drug Administration had determined to be adequate and which embodied all of the safeguards listed in the injunction as necessary to good pharmaceutical manufacturing practice.

*See also No. 6546.