

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.

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\*See also No. 6546.

**DISPOSITION:** On 11-5-59, the order to show cause was issued. Thereafter, the defendant pled guilty to the charge of violating the injunction and, on 3-21-60, the court fined the defendant \$1,000.

**6563. Palivite.** (F.D.C. No. 45382. S. No. 26-602 R.)

**QUANTITY:** 40 cartoned vials at Los Angeles, Calif.

**SHIPPED:** 5-26-59, from Detroit, Mich.

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained less than 50 percent of the declared amount of vitamin B<sub>12</sub> activity.

**LIBELED:** 1-9-61, S. Dist. Calif.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from that which it purported to possess; and 502(a)—the label statement "Each Ml contains not less than: Vitamin B<sub>12</sub> Crystalline 50 mcg \* \* \* 0.5% Liver Injection (B<sub>12</sub> Activity Per Ml Equivalent to 10 mcg of Cyanocobalamin)" was false and misleading as applied to an article containing less than the declared amount of vitamin B<sub>12</sub>.

**DISPOSITION:** 2-2-61. Default—destruction.

**6564. Geralix syrup.** (F.D.C. No. 45338. S. No. 5-431 R.)

**QUANTITY:** 19 1-gal. ctnd. btls. at Baltimore, Md.

**SHIPPED:** 10-26-60, from Maplewood, Mo., by Na-Spra, Inc.

**LABEL IN PART:** (Btl. and ctn.) "Geralix Vitamin-Mineral Syrup A Dietary Supplement for Young and Old Each Tablespoonful Provides Methamphetamine Hydrochloride 1.0 mg. Choline Cihydrogen Citrate 250.0 mg. Inositol 50.0 mg. Vitamin B-1 (Thiamine Hydrochloride) 5.0 mg. Vitamin B-2 (Riboflavin) 3.0 mg. Vitamin B-6 (Pyridoxine Hydrochloride) 0.2 mg. Vitamin B-12 5.0 mcg. Niacinamide 10.0 mg. Calcium Pantothenate 3.0 mg. Iron from Ferric Ammonium Citrate 10.0 mg. Copper from Copper Sulfate 1.0 mg. Calcium from Calcium Glycerophosphate 20.0 mg. Phosphorus from Calcium Glycerophosphate 15.0 mg. \* \* \* Dosage \* \* \* Caution \* \* \* Control No. A4088 Distributed by Baare Drug Company, Baltimore, Md."

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin B<sub>12</sub>.

**LIBELED:** On or about 1-11-61, Dist. Md.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Vitamin B-12 5.0 mcg." was false and misleading as applied to a product containing less than the declared amount of vitamin B<sub>12</sub>, and the label contained statements which represented and suggested that the article was a special dietary food, which statements were false and misleading since the article was in fact a potent prescription drug, namely, a preparation of methamphetamine hydrochloride.

**DISPOSITION:** 2-17-61. Default—destruction.

**6565. Juniplex and liver injection.** (F.D.C. No. 44560. S. Nos. 62-210 P, 62-212 P.)

**QUANTITY:** 72 btls. of *Juniplex*, and 13 vials of *liver injection*, at San Francisco, Calif.

**SHIPPED:** Between 5-5-59 and 12-8-59, from Chicago, Ill.