

LIBELED: 4-5-60, S. Dist. Calif.

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, for developing the human breast; and 502(j)—the labeling of the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in the labeling thereof.

DISPOSITION: 5-10-60. Default—destruction.

6162. Ray of Life device. (F.D.C. No. 44011. S. No. 51-138 P.)

QUANTITY: 11 devices at St. Paul, Minn., and 2 devices at Stillwater, Minn., in possession of Henry Amundson.

SHIPPED: 5-20-58, from Racine, Wis.

LABEL IN PART: "Electronic High Frequency Generator * * * The Ray of Life."

RESULTS OF INVESTIGATION: The device was a type of electronic high-frequency generator which produced a glow discharge in a variety of gas-filled glass applicators.

LIBELED: 12-29-59, Dist. Minn.

CHARGE: 502(f) (1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 502(j)—the article was dangerous to health when used as directed.

DISPOSITION: 3-23-60. Consent—claimed by Henry Amundson, Stillwater, Minn., and dismantled.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

DRUG FOR HUMAN USE

6163. Les-Wate capsules. (F.D.C. No. 44370. S. No. 85-084 P.)

QUANTITY: 5 cans, 5,000 capsules each, and 8 display cartons, each containing 4 30-capsule btls., at Baltimore, Md., in possession of Reyman Drug Co., Inc.

SHIPPED: 1-29-60, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Can) "Phenylpropanolamine HCl Prolongsul's Each Prolongsul contains: Phenylpropanolamine HCl 75 mg. * * * Caution: Federal law prohibits dispensing without prescription. Lot No. 9919 Richlyn Laboratories, Philadelphia, Pa.," (btl.) "Les-Wate Capsule-A-Day to Melt Fat away Les-Wate Laboratories, Baltimore, Md. Distributor * * * Each capsule contains: Phenylpropanolamine HCl. 75 mg. released gradually and equivalent to 3 doses over a period of approximately 8 hours."

RESULTS OF INVESTIGATION: The article in the bottles was repacked and re-labeled by the dealer from bulk stock shipped as described above.

LIBELED: 3-9-60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name "Les-Wate" and other statements on the label of the article contained false and misleading representations that the article was effective for weight reduction; 503(b) (4)—when shipped, the label bore the statement "Caution: Federal law prohibits dispensing without a prescription" and the article was a drug not subject to section 503(b) (1); and 505(a)—the article was a new drug and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 4-1-60. Default—destruction.