

DISPOSITION: 9-8-58. Default—destruction.

5704. Meprobamate tablets. (F.D.C. No. 41894. S. Nos. 29-956/7 P.)

QUANTITY: 3 drums containing a total of 512,000 tablets and one drum containing a total of 94,000 tablets at Brooklyn, N.Y.

SHIPPED: A quantity of meprobamate powder was shipped from East Paterson, N.J., and, after its arrival at Brooklyn, N.Y., was tableted and packed into the 3 drums described above. The 1 drum lot was a return shipment which was made on 6-4-58, from Philadelphia, Pa.

LABEL IN PART: (3 drum lot) "2-methyl-2-n-propyl-1, 3-propanediol dicarbamate. For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use. Caution: * * * For Export Only"; (1 drum lot) "100,000 Tablets Meprobamate * * * 400 Mg. * * * Caution * * * Dosage: 1 Tablet 3 times Daily. For investigational and export use only Hall Pharmacal Co., Inc., New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article (both lots) contained approximately 400 milligrams of meprobamate per tablet.

Investigation showed that the article was not intended for export.

LIBELED: 7-7-58, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statement on the label of the article "For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use * * * For Export Only" was false and misleading; 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: 3-26-59. Consent—destruction.

5705. Meprobamate tablets and meprobamate powder. (F.D.C. No. 41764. S. Nos. 62-771 M, 29-942 P.)

INFORMATION FILED: 9-23-58, Dist. N.J., against Abraham J. Schwartz, Jersey City, N.J.

SHIPPED: *Meprobamate tablets* were shipped on 3-26-57, and *meprobamate powder* was shipped on 3-8-57, from New Jersey to New York.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (1)—the labeling of the articles failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use; 502(i)—the *meprobamate tablets* were (2) an imitation of another drug, namely, Miltown, and (3) were offered for sale under the name of another drug, namely, Miltown; and 503(b) (4)—the labeling of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the *meprobamate tablets* were a new drug, and an application filed pursuant to the law was not effective with respect to the drug.

PLEA: Guilty.

DISPOSITION: 5-22-59. \$1,800 fine and probation for 5 years.

5706. Vitamin B₁₂ injection. (F.D.C. No. 39431. S. No. 52-010 M.)

QUANTITY: 52 vials at Brooklyn, N.Y.

SHIPPED: 5-21-56, from Chicago, Ill., by Medical Chemicals Corp.