

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 25,000 I. U. estrogens per cubic centimeter; 502(a)—the carton label statement "Per CC * * * Estrogens * * * 25,000 I. U." was false and misleading as applied to the article, which contained 21.6 percent of the declared amount of estrogens; 502(b)(1)—the label of the article failed to bear the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—the label of the article failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each ingredient.

DISPOSITION: 8-9-57. Default—destruction.

5451. Pyrilamine maleate Prolongsules. (F.D.C. No. 40358. S. No. 41-858 M.)

QUANTITY: 1 drum containing 24,935 capsules, and 238 12-capsule vials at Buffalo, N.Y.

SHIPPED: 3-30-56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Drum) "Pyrilamine Maleate Prolongsules * * * Delayed Action, Time Disintegrating Capsules * * * Released Gradually * * * Over A Period of Approximately 8 Hours * * * Each Prolongsule Contains: Pyrilamine Maleate 75 Mgm."

RESULTS OF INVESTIGATION: Analysis showed that the capsules of the article did not allow gradual release of pyrilamine maleate over a period of approximately 8 hours, but, instead, the pyrilamine maleate was released in a much shorter time. Examination showed that the capsules in vials had been repacked from the bulk drum.

LIBELED: 6-27-57, W. Dist. N. Y.

CHARGE: 501(c)—the quality of the article, when shipped, fell below that which it was represented to possess since the active ingredient was not gradually released over an 8-hour period, but was, instead, released in a much shorter time; and 502(a)—the statements in the label which represented and suggested that the active ingredient was gradually released over an 8-hour period were false and misleading.

DISPOSITION: 8-15-57. Default—destruction.

5452. Bennett Arben capsules. (F.D.C. No. 40199. S. Nos. 74-867/70 M.)

QUANTITY: 24,000 capsules of *Formula No. 2*, 23,000 capsules of *Formula No. 6A*, 24,000 capsules of *Formula No. 8A*, and 17,000 capsules of *Formula No. 12A* at Santa Monica, Calif. The capsules were packed in bulk drums.

SHIPPED: On an unknown date, from Miami Beach, Fla., by Arthur Bennett Pharmaceuticals.

LABEL IN PART: "Bennett Arben Capsules *Formula No. 2* * * * Amphetamine Sulfate 1.2 mgm. * * * Lot No. 2016," "Bennett Arben Capsules *Formula No. 6A* * * * Amphetamine Sulfate 1.8 mgm. * * * Lot. No. 3010," "Bennett Arben Capsules *Formula No. 8A* * * * Amphetamine Sulfate 2.5 mgm. * * * Lot No. 3008," and "Bennett Arben Capsules *Formula No. 12A* * * * Amphetamine Sulfate 5 mgm. * * * Lot No. 3014."

RESULTS OF INVESTIGATION: Examination showed that the capsules contained the following amounts of amphetamine sulfate per capsule: *Formula No. 2*—2.3 mgs., *Formula No. 6A*—3.3 mgs., *Formula No. 8A*—4.9 mgs., and *Formula No. 12A*—9.8 mgs.