

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5584. Various drugs. (F.D.C. No. 40985. S. Nos. 79-421 M, 79-423/4 M, 79-426/9 M.)

QUANTITY: 10 vials of *Suavitil benactyzine hydrochloride tablets*, 700 tablets of *Belladenal* in an unlabeled btl., 1 700-tablet labeled btl. of *Doriden*, 1 800-tablet btl. of *Metamine with butabarbital*, 1 850-tablet btl. of *Ritalin*, 1 1,000-tablet btl. of *Plimasin*, and 7 100-tablet btls. of *Premarin*, at Jersey City, N.J., in possession of Carl H. Kaplan Sales Co.

SHIPPED: Between November 1956 and October 1957, from Rouses Point, Yonkers, and New York, N.Y.

RESULTS OF INVESTIGATION: The articles, except for the *Premarin tablets*, consisted of physicians' samples which the consignee, Carl H. Kaplan Sales Co., had obtained from various drug salesmen, drug firms, and unknown sources, and had transported to Jersey City. All of the articles, including the *Premarin tablets*, were repacked and relabeled after receipt by the consignee.

LIBELED: 12-2-57, Dist. N.J.

CHARGE: 502(b)—while held for sale, the labels of the *Suavitil benactyzine hydrochloride tablets*, *Belladenal tablets*, *Doriden tablets*, *Metamine with butabarbital tablets*, and *Plimasin tablets* failed to bear (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(d)—the *Belladenal tablets* and *Metamine with butabarbital tablets* contained chemical derivatives of barbituric acid, and while held for sale, their labels failed to bear the name, and quantity or proportion of such dervative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e) (2)—the label of the *Belladenal tablets*, while held for sale, failed to bear a statement of the quantity or proportion of the alkaloids of belladonna contained therein; 502(f) (1)—while held for sale, the labeling of the *Suavitil benactyzine hydrochloride tablets*, *Belladenal tablets*, *Doriden tablets*, and *Metamine with butabarbital tablets* failed to bear adequate directions for use; and 503(b) (4)—all of the articles were drugs subject to 503(b) (1), and the labels of the articles, while held for sale, failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that an article labeled "Obbron" was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-15-58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5585. Super Protein Formula "90" and Formula "90" Supplement. (F.D.C. No. 41434. S. No. 75-649 M.)

QUANTITY: 7 pkgs. containing 1 btl. of *Super Protein Formula "90"* and 1 btl. of *Formula "90" Supplement* at Phoenix, Ariz.

SHIPPED: 7-10-57, from Hollywood, Calif., by Hi-Pro Products Co.

LABEL IN PART: (Btl.) "MpDs * * * Super Protein Formula '90' An aid to Weight Reducing Increases Energy - Helps Reduce Weight * * * MpDs is a Balanced Protein Food Supplement Contains No Calories * * * 180

*See also No. 5584.