

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.

[or '360'] tablets" and "Formula '90' Supplement Reducing * * * 15 Capsules * * * an additional aid to weight reducing - to be taken in conjunction with MpDs Super Protein Tablets * * * Each Tablet Contains: Sodium Carboxy Methyl Cellulose . . . 8 grains Phenylasitin (conc. Prune) . . . 0.5 Mg."

ACCOMPANYING LABELING: Booklets entitled "Why Be Fat."

LIBELED: 3-5-58, Dist. Ariz.

CHARGE: 502(a)—the labeling of the *Super Protein Formula "90"* and the *Formula "90" Supplement*, when shipped, contain false and misleading representations that the articles contained no calories, would burn up extra fat, increase metabolism, and otherwise act as an adequate and effective treatment for obesity; and 502(f)(2)—the *Formula "90" Supplement* contained an irritant laxative, and its labeling failed to warn that it should not be used when symptoms of appendicitis were present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 5-7-58. Default—destruction.

5586. Trim-All capsules. (F.D.C. No. 41453. S. No. 23-306 P.)

QUANTITY: 3 drums containing a total of 41,500 capsules at North Hollywood, Calif.

SHIPPED: 11-6-57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABELED IN PART: (Drum) "Lot No. 3218 * * * Special Formula #2 * * * Each capsule contains 60 mg. Phenylpropanolamine Hcl. 3 gr. Sodium Caseinate, 50 mg. Ascorbic Acid, 0.5 mg. Acetphenolisatin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 77 percent of the labeled amount of phenylpropanolamine Hcl and 64 percent of the labeled amount of ascorbic acid, of which the article released 90 percent of both in 2 hours. The article was intended to be repackaged and relabeled by the consignee as follows: "21 Trim-All Capsules (an Appetite Depressant) Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. Sodium Caseinate 3 gr. Dextrose 3 gr. Ascorbic acid 50 mg. Acetphenolisatin 0.5 mg. In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours.

LIBELED: 3-6-58, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess since it contained less than the labeled amounts of phenylpropanolamine Hcl and ascorbic acid, and it failed to release its ingredients over an 8-hour period; 502(a)—the label statements of the article, when shipped and while held for sale, namely, "Each capsule contains 60 mg. Phenylpropanolamine Hcl. * * * 50 mg. Ascorbic Acid" and "Each Trim-All Timed Capsule Contains: Phenylpropanolamine Hcl 60 mg. * * * Ascorbic acid 50 mg. * * * In a specially prepared Timed disintegrating capsule that releases the ingredients over a period of approximately eight hours," were false and misleading; and 502(f)(2)—the article was a laxative, and its labeling, when shipped and while held for sale, failed to warn against use when symptoms of appendicitis are present and that frequent or continued use may result in dependence on laxatives.

DISPOSITION: 3-26-58. Default—destruction.

5587. Salicon tablets. (F.D.C. No. 40953. S. No. 76-626 M.)

QUANTITY: 135 100-tablet btls., 61 30-tablet btls., and 60 12-tablet btls. at Portland, Maine.