

the bulk stock of those articles which had not been repacked as of the time of seizure.

LIBELED: 6-26-57, Dist. Md.

CHARGE: 501 (c)—the strength of the *elixir Merbutal*, while held for sale, differed from that which it was represented to possess, namely, 3 grains of butabarbital sodium per each 5 cc. (examination showed that the article contained about 80 percent less than the declared amount of butabarbital sodium); 502 (a)—the labeling of the *elixir Albephen*, while held for sale, namely, the labels intended for use in repacking the article, contained statements representing and suggesting that the article contained d. amphetamine sulfate, thiamine, riboflavin, and niacin, which statements were false and misleading since the article did not contain those ingredients; 502 (d)—the *elixir Merbutal*, while held for sale, contained a derivative of barbituric acid, and the label of the article, while held for sale, failed to bear in juxtaposition with the name and quantity of such derivative the statement "Warning—May be habit forming"; and 503 (b) (4)—the *elixir Albephen* (1-pt. btl.), *Merhistin expectorant*, and *elixir Duophen* were drugs subject to 503 (b) (1), and, while held for sale, their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that another article, vitamin tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 7-24-57. Consent—claimed by Meredyth Co. The drugs were relabeled.

5402. Vitamin capsules. (F. D. C. No. 40238. S. No. 65-996 M.)

QUANTITY: 12 100-capsule btl., 21 50-capsule btl., and 13 30-capsule btl. at San Francisco, Calif.

SHIPPED: 11-13-56, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: (Bulk container) "NRC No. 2 Therapeutic Vitamin Formula Each Capsule Contains: Thiamin HCL 10 Mgm. Riboflavin 10 Mgm. Niacinamide 100 Mgm. Calcium Pantothenate 20 Mgm. Pyridoxine HCL 2 Mgm. Folic Acid 1.5 Mgm. Ascorbic Acid 300.0 Mgm. Vitamin K 2 Mgm. Vitamin B-12 * * * 4.0 Mcgm."

RESULTS OF INVESTIGATION: The article was shipped in a bulk container from Philadelphia, Pa., and upon arrival at San Francisco, Calif., was repacked and relabeled by the consignee.

Analysis showed that the article contained a significant amount of estrogenic hormone.

LIBELED: 5-6-57, N. Dist. Calif.

CHARGE: 501 (c)—the quality and purity of the article, when shipped, differed from that which it purported to possess; 501 (d) (2)—an estrogenic hormone had been substituted in part for vitamins; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; and 503 (b) (4)—the article was a drug which was subject to 503 (b) (1) (B), and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 5-21-57. Default—destruction.

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

5403. Mediatric (estrone) capsules, pentaerythritol tetranitrate tablets, and diphenmethanil methylsulfate tablets. (F. D. C. No. 40220. S. Nos. 62-528 M, 62-530/2 M.)

QUANTITY: 1 300-capsule btl. of *Mediatric (estrone) capsules*, 1 3,500-tablet btl. and 1 1,500-tablet btl. of *pentaerythritol tetranitrate tablets* and 1 250-tablet btl. of *diphenmethanil methylsulfate tablets* at New York, N. Y.

SHIPPED: On unknown dates, from Detroit, Mich., Cleveland, Ohio, and Morris Plains and Bloomfield, N. J.

LIBELED: 5-29-57, S. Dist. N. Y.

CHARGE: *Mediatric capsules.* 502 (b)—while held for sale, the article failed to bear a label 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) (2)—the label of the article failed to bear the common or usual name of each active ingredient; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

Pentaerythritol tetranitrate tablets. 503 (b) (4)—the article was a drug subject to 503 (b) (1); and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Diphenmethanil methylsulfate tablets. 502 (d)—the article contained a chemical derivative of barbituric acid (phenobarbital); and, while held for sale, the label failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: 7-16-57. Default—destruction.

5404. Botanical Medicine. (F. D. C. No. 39316. S. No. 27-771 M.)

QUANTITY: 302 16-oz. btls. and 67 32-oz. btls. at Tampa, Fla., in the possession of M. M. Moran.

SHIPPED: Between 3-29-56 and 9-29-56, from Cincinnati, Ohio.

LABEL IN PART: (Btl.) "Chief Whahoo Brand Botanical Medicine * * *
Active Laxative Ingredients: Buckthorn, Senna, Cascara Sagrada and Aloe.
Inactive Ingredients: Ginger, Calamus, Anise, Licorice, Mandrake, Methyl Salicylate, Salicylic and Benzoic Acid, Iron and Ammonium Citrate, Saccharin Soluble, Cassia and Spearmint Oil, Wahoo, Butternut, Uva Ursi, Sarsaparilla, Colocynth, Buchu, Juniper Berries and Wild Cherry."

ACCOMPANYING LABELING: Circulars designated "Your Digestive System."

RESULTS OF INVESTIGATION: The circulars were printed locally on order of the consignee and were used by the consignee, together with oral statements, to promote the sale of the article.

LIBELED: 8-6-56, S. Dist. Fla.; amended libel on or about 10-30-56.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for headache, dizziness, sour stomach, coated tongue, bad breath, skin eruptions, loss of appetite, indigestion, and sickness generally; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in purifying the blood and removing poisons from the liver, kidneys, bowels, stomach, and blood stream, which were the conditions and purposes for

*See also No. 5402.