

fully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the article was not to be dispensed upon prescription, as required by 503(b)(1); and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7-15-60. Default—delivered to the Food and Drug Administration.

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

6424. Amphetamine tablets or capsules and barbiturate tablets or capsules. (F.D.C. No. 45098. S. Nos. 3-758/9 R.)

QUANTITY: 135,000 amphetamine tablets or capsules and 10,000 barbiturate tablets or capsules at Baltimore, Md., in possession of Edward Michael Horvath.

SHIPPED: 11-20-60, from outside the State of Maryland.

LIBELED: 11-21-60, Dist. Md.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and the articles were not exempt from that requirement since they were prescription drugs in the possession of a person not lawfully engaged in distributing or dispensing prescription drugs.

DISPOSITION: 12-13-60. Default—delivered to the Food and Drug Administration.

6425. W & S Protein 90. (F.D.C. No. 44854. S. No. 20-470 R.)

QUANTITY: 9 cases, each containing 6 pkgs., each pkg. containing 1 30-capsule btl. and 1 360-tablet btl., at Warren, Mich.

SHIPPED: 4-13-60, from Riverside, Calif., by Ward & Stalnaker.

LABEL IN PART: (Pkg.) "W & S Protein 90 * * * Package contains 360 tablets W & S Protein 90 30 capsules W & S Protein 90 Supplement * * * Each tablet contains: Protein (Natural Meat) 90% Moisture 3% Ash 7% Carbohydrates 0 Fat 0 Supplement Ingredients: Sodium Carboxy Methyl Cellulose 8 grains Phenylasitin (conc. Prune) 9.5 mg. Essential Amino Acids; Natural Amino Acids of meat proteins essential in the daily diet * * * W-S Sales Riverside, California."

ACCOMPANYING LABELING: Folders entitled "Secrets of Natural Health" and "Secrets of Weight Control."

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained approximately 75 percent of the declared amount of protein.

LIBELED: 8-29-60, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for reducing and for the control of body weight, and thus to prevent heart failure, heart disease, varicose veins, gall-bladder trouble, arthritis, ruptures, hernia, cancer, diabetes, hardening of the arteries, high blood pressure, osteoarthritis of the lower back and knees, flat feet and other orthopedic disorders, psychoneurosis, and other serious diseases; and that the article would produce longevity; energy; strength, radiant health, maintain normal body weight,

*See also No. 6423.

produce a healthful, vigorous, youthful life, pep, vim, vigor, vitality, better appearance, happiness, rich blood, and step up the metabolism of the body; and 502(f) (2)—the article contained an irritant laxative and its labeling failed to warn that it should not be used when symptoms of appendicitis are present and that its frequent or continued use might result in dependence on laxatives.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 10-7-60. Default—destruction.

6426. Cannolene tetter salve and Cannolene scalp ointment. (F.D.C. No. 44886. S. Nos. 4-659/60 R.)

QUANTITY: 130 1-oz. jars and 14 2½-oz. jars of salve and 18 3-oz. cans of ointment at Baltimore, Md.

SHIPPED: Sometime in January or February 1960, and 7-5-60, from Atlanta, Ga., by Cannolene Co.

LABEL IN PART: (Jar) "Cannolene Tetter Salve" and (can) "Cannolene Scalp Ointment."

ACCOMPANYING LABELING: Leaflets entitled "You Can Get Relief From."

RESULTS OF INVESTIGATION: An establishment inspection showed that the tetter salve contained petrolatum, sulfur, ammoniated mercury, and oil of tar and that the scalp ointment contained petrolatum, pine tar, and oil of cade.

LIBELED: 9-8-60, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling of the salve contained false and misleading representations that the article was an adequate and effective treatment for growing hair, dandruff, itching scalp and other scalp disorders, scalp conditioning, and tetter; and the labeling of the ointment contained false and misleading representations that the article was effective in the treatment of splitting, breaking, and falling hair; 502(e) (2)—the tetter salve was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since sulfur and oil of tar were not declared on the label; and 502(f) (2)—the labeling of the tetter salve failed to warn that use of the article should be discontinued if rash or irritation developed, or if the condition persisted for which it was used; and that frequent or prolonged use, or application to large areas of the body may cause serious mercury poisoning.

DISPOSITION: 10-12-60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6427. Secobarbital sodium capsules. (F.D.C. No. 44754. S. No. 31-173 R.)

QUANTITY: 24 500-capsule btls. at Houston, Tex.

SHIPPED: 5-19-60, from Chicago, Ill., by Kasar Co.

LABEL IN PART: "1918 500 capsules Secobarbital Sodium, 1½ Grain—2153."

RESULTS OF INVESTIGATION: Examination showed that the article failed to comply with the United States Pharmacopeia specification for uniformity of drug content per individual capsule.

LIBELED: On or about 7-22-60, S. Dist. Tex.