

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for inoperable neoplasm, advanced malignancy, leukemia, Hodgkin's disease, and inoperable cancer; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 9-16-60. Default—destruction.

6422. Phyltone capsules. (F.D.C. No. 42811. S. Nos. 24-177/9 P.)

QUANTITY: 57 100-capsule btls. and 33 30-capsule btls. at Phoenix, Ariz.

SHIPPED: Between 11-29-58 and 1-21-59, from Boling, Tex., by Texophyl Corp.

LABEL IN PART: (Btl.) "Phyltone Capsules Each Capsule Contains: $\frac{1}{4}$ Gram or $3\frac{3}{4}$ Grains Potassium Hydrogen Phytochlorin. Indicated for the treatment of Arteriosclerosis Arthritis and conditions of similar etiology. Manufactured by Texophyl Products, Boling, Texas. Dosage One capsule daily" and "Phyltone * * * $\frac{1}{2}$ Gram Plant Porphyrins Dosage One Per Day Texophyl Corp. Boling, Texas."

ACCOMPANYING LABELING: Brochure entitled "Phyltone A Porphyrin Compound."

LIBELED: 2-9-59, Dist. Ariz.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for (on bottle label) arteriosclerosis, arthritis, and conditions of similar etiology, and (in brochure) resistant anemia, muscular atrophy, osteoporosis, impaired cerebation, depressive states, exhaustion, fatigue and manifest anoxia; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2-1-61. Texophyl Corp., claimant, having answered the interrogatories filed by the Government and failing to pursue the matter further, and being in default, judgment of condemnation was entered and the article was ordered destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6423. Amphetamine tablets or capsules. (F.D.C. No. 44358. S. Nos. 70-946 P, 70-948 P, 70-952 P.)

QUANTITY: 15,000 *amphetamine tablets*, and an unknown quantity of *amphetamine tablets or capsules*, in possession of Chester Menk, t/a Shifting Sands Truck Stop, and Elmer Menk, in the vicinity of Oaktown, Ind.

SHIPPED: Prior to 3-2-60, from outside the State of Indiana.

LIBELED: On or about 3-2-60, S. Dist. Ind.

CHARGE: 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)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since the article was in the possession of persons who were not regularly and law-

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.