

6807. "He-Man" High-Potency Formula. (F.D.C. No. 45474. S. No. 44-040 R.)
QUANTITY: 169 24-capsule btls. and 24 60-capsule btls. at Tacoma, Wash.
SHIPPED: 10-31-60 and 12-5-60, from Portland, Oreg., by Registered Pharmaceuticals, Ltd.

LABEL IN PART: (Btl.) "HE-MAN High-Potency Formula Directions for use. Adult men only. * * * take one capsule twice a day, morning and night, preferably after meals, as a hematinic tonic and source of vitamins * * * Contains 24 [or "60"] capsules. * * * Hematinic Tonic for Men Each 2 capsules (Daily Dose) Contains: HEMOSEX (Registered Pharmaceuticals Brand Name for six hematinics, with vascular activity of niacin). * * * Enzymes and Glandular Substances * * * Amino Products * * * Minerals and Vitamins * * * in a base containing: Damiana Root 50.0 mg. Sarsaparilla Root 50.0 mg 09032 [or "09079"] Distributed by Registered Pharmaceuticals, Ltd. Portland, Oregon."

LIBELED: 2-20-61, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the label contained statements such as "He-Man Hematinic for Men," "High Potency Formula," "HEMOSEX," and "Adult Men Only," which, in the manner in which they were presented, represented and suggested that the article was effective as a tonic for increasing the sexual potency and/or virility of men, which representations and suggestions were false and misleading since the article was not an effective tonic for such purposes; the label statement "with vascular activity of niacin" was misleading since the ingestion of 50 milligrams of niacin, as supplied in the recommended dosage which may cause vasodilation of the vascular system resulting in a "flushing" that is transitory and fleeting, would not result in increased virility and/or sexual potency in men; the label reference to vitamin C (ascorbic acid) as a hematinic was false and misleading since vitamin C (ascorbic acid) is not a hematinic; and the listing on the label of certain enzymes, glandular substances, amino products, minerals and vitamins, suggested and implied that the named substances were of value as a tonic for men, particularly for increasing virility and sexual potency, which suggestions and implications were false and misleading since they are contrary to fact.

DISPOSITION: 7-17-61. Default—destruction.

6808. Vitamin B₁₂ injection. (F.D.C. No. 46490. S. No. 16-938 R.)

QUANTITY: 174 individually ctn'd. vials at Chattanooga, Tenn.

SHIPPED: 3-8-61, from Columbus, Ohio, by Warren-Teed Products Co.

LABEL IN PART: (Ctn. and vial) "1 vial Warren-Teed 10 cc. Sterilized Solution Vitamin B-12 100 Micrograms per cc. * * * Each cc. Contains: Vitamin B₁₂ (Crystalline Cyanocobalamin) 100 Micrograms * * * The Warren-Teed Products Co. Columbus, Ohio."

ACCOMPANYING LABELING: Leaflet entitled "Warren-Teed Sterilized Solution Vitamin B₁₂."

LIBELED: 10-5-61, E. Dist. Tenn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment of neurological disorders, trigeminal neuritis, tic douloureux, trigeminal neuralgia, neuritis, herpes zoster, tabes dorsalis, nonspecific disorders characterized chiefly by pain, migraine syndrome, acute porphyria,

peripheral vascular disorders, multiple sclerosis, amyotrophic lateral disorders, amyotonia congenita, Parkinson's disease, ascending lateral sclerosis, anterior poliomyelitis, liver disease, diabetes, hypothyroidism and atherosclerosis.

DISPOSITION: 2-28-62. Default—destruction.

6809. Vitamin B₁₂ injection. (F.D.C. No. 46064. S. No. 57-220 R.)

QUANTITY: 2 ctns., each containing 500 individually ctn'd. vials, at Long Island City, N.Y.

SHIPPED: 4-27-61, from Baltimore, Md., by Bio Ramo Drug Co., Inc.

LABEL IN PART: (Vial and ctn.) "10 cc. Crystalline Vitamin B₁₂ Injection U.S.P. 30 mcg. crystalline Vitamin B₁₂ per cc. * * * Usual Dose: * * * (see insert) Control: 04131 Bio Ramo Drug Co., Inc., Baltimore 1, Md."

ACCOMPANYING LABELING: Leaflets entitled "Vitamin B₁₂ Injection."

LIBELED: 7-10-61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for sensory neuropathies, trigeminal neuralgia (tic douloureux), diabetic neuritis, alcoholic neuritis, and other neuritides.

DISPOSITION: 8-29-61. Default—destruction.

6810. Sulf-Hydro-Sol and S-M-C (Sulfur Mineral Concentrate). (F.D.C. No. 46266. S. Nos. 54-452/3 R.)

QUANTITY: 311 1-oz. btls. and 132 2-oz. btls. of *Sulf-Hydro-Sol* and 8 1-pt. btls. of *S-M-C* (*Sulfur Mineral Concentrate*), at Minneapolis, Minn.

SHIPPED: 7-19-61, from Salt Lake City, Utah, by Colloidal Sulphur Co., Inc.

LABEL IN PART: "Pavo * * * Sulphur Sulf-Hydro-Sol Mixture An Exceptional Non-Toxic colloidal sulphur mixture containing as active ingredients Highly reactive sulphur complexes and colloidal trace minerals, in a high potency concentrate supplying the univalent radical SH. Directions: 6 to 10 drops in water * * * before meals * * * The Pavo Co., Inc., Minneapolis, Minn." and "Pavo * * * Sulphur-Mineral S-M-C Concentrate S-M-C Colloidal Sulphur— for Bath and External use only—Contains: Calcium Polysulfides, Mono-sulphide, Thiosulphate, Sulphate and Polysulfide Sulfur. Directions: * * * S-M-C is a new and effective preparation which brings the benefits of the world's outstanding sulfur mineral baths into your own home in a highly concentrated form. * * * The Pavo Co., Inc., Minneapolis, Minn."

ACCOMPANYING LABELING: Leaflets entitled "A Modern Spa In Your Home," and imprinted at the bottom "The Colloidal Sulphur Company, Incorporated, William A. Caudill, President, 599 Columbus Street, Salt Lake City 16, Utah."

LIBELED: 8-31-61, Dist. Minn.; amended libel 9-12-61.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles, when used as directed, were adequate and effective as a treatment for rheumatoid arthritis, and certain metabolic diseases due to sulfur deficiency; and that use of the articles would stimulate metabolism, revitalize and normalize cellular metabolism, and that one could bathe and drink his way to health and beauty by use of the articles; and that *Sulf-Hydro-Sol* possessed therapeutic and special dietary properties due to the presence therein of highly