joints; bursitis; acne; eczema; dermatitis; psoriasis; allergies; and that it would relieve itching and burning irritations on hands, arms, and body; and would maintain a youthful skin and keep one free of pain, healthy, and young; and 502(f)(2)—the labeling of the *Natural Formula 52 Sulphur Cream Lotion* failed to bear such adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users since the article contained sulfur and its labeling failed to warn that if undue skin irritation developed or increased, the use of the article should be discontinued and a physician consulted.

DISPOSITION: 2-10-60. Default—destruction.

6166. Mills Aloin, Cascara and Phenolpthalein Compound tablets. (F.D.C. No. 44402. S. No. 25-404 R.)

QUANTITY: 1 drum of 72,096 tablets at Reseda, Calif., in possession of Mills Pharmaceutical Co.

SHIPPED: 12-4-59, from Portland, Oreg., by Don Hall Laboratories.

LABEL IN PART: (Drum) "Tablets Mills Aloin, Cascara & Phenolphthalein Compound."

RESULTS OF INVESTIGATION: The tablets, after their receipt at Reseda, Calif., were to be repacked, in the normal course of the dealer's business operations, into bottles labeled in part "28 Tablets 11901 Control No. Mills Aloin, Cascara & Phenolphthalein Compound D-4 * * * Formula: Phenolphthalein 1 gr. Ext. Cascara ½ gr. Pepsin 1-3000 ½ gr. Aloin ¼ gr. Podophyllin ⅛ gr. Diastase of Malt ⅛ gr. Oleo Resin Ginger 1/100 gr. Directions: Adults * * * Children * * * Manufactured for Mills Pharmaceutical Co. Encino, California."

Examination showed that the article contained 1 grain of phenolphthalein, pepsin, aloin, and probably other plant extractive material.

LIBELED: 3-29-60, S. Dist. Calif.

CHARGE: 502(f)—the labeling of the article, when shipped and while held for sale, failed to bear (1) adequate directions for use and (2) a warning statement that use of the article should be discontinued when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, that frequent or prolonged use of the article may result in dependence on laxatives, and that preparations containing phenolphthalein should not be used if a skin rash appeared.

DISPOSITION: 5-24-60. Consent—claimed by Mills Pharmaceutical Co. and relabeled.

6167. Hunt's 3-Minute Balm. (F.D.C. No. 44364. S. No. 88-146 P.)

QUANTITY: 504 2-oz. btls. at Morehead, Ky.

SHIPPED: On various dates between July 1959, and the week of 1-14-60, from Detroit, Mich., by Hunt Bros. Product Co.

LABEL IN PART: (Btl.) "Hunt Bros. Product Company 3-minute Balm * * * Active Ingredients: Menthol, Methyl Salicylate * * * Manufactured by Hunt Bros. Directions: Rub on affected parts."

ACCOMPANYING LABELING: Blue and yellow leaflets entitled "Hunt's 3-Minute Balm."

LIBELED: 3-8-60, E. Dist. Ky.

CHARGE: 502(a)—when shipped, the labeling accompanying the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, headache, sinusitis, toothache, sore throat, all muscular aches, soreness, lameness, and stiffness; and 502(f)(1)—the labeling of the article failed to bear a warning that the article should be kept out of the reach of children to avoid accidental poisoning, that its use should be discontinued if excessive irritation of the skin developed, and that users should avoid getting the articles into the eyes or on mucous membranes.

DISPOSITION: 4–19–60. Default—destruction.

6168. Amphetamine tablets and barbiturate capsules. (F.D.C. No. 44027. S. Nos. 65–377/8 P.)

QUANTITY: About 100,000 amphetamine tablets and 10,000 barbiturate capsules at Rock Springs, Wyo., in possession of T. R. Finney, D.O.

SHIPPED: Prior to 1–14–60, from outside the State of Wyoming.

LIBELED: 1–15–60, Dist. Wyo.

CHARGE: 502(f)(1)—while held for sale, the labels of the articles failed to bear adequate directions for use and the articles were not exempt from that requirement by regulations since they were prescription drugs which, although in the possession of a licensed practitioner, were not to be dispensed by such practitioner in the course of his professional practice as required by 503(b).

DISPOSITION: 4–19–60. Consent—claimed by Theodore R. Finney, D.O., Rock Springs, Wyo., and delivered to the Food and Drug Administration.

6169. Vitamin C (ascorbic acid) tablets. (F.D.C. No. 44156. S. Nos. 76–891 P, 76–893 P.)

QUANTITY: 1,488 cases, each containing 12 sets of 2 100-tablet btls. of vitamin C (100 mgms.), 735 cases, each containing 12 sets of 2 100-tablet btls. of vitamin C (250 mgms.), at Seattle, Wash., in possession of McKesson & Robbins, Inc.

SHIPPED: Between 8–18–59 and 11–12–59, from Bridgeport, Conn., by McKesson & Robbins, Inc.

LABEL IN PART: (Btl.) "McKesson's Ascorbic Acid Vitamin C U.S.P. * * * Each tablet contains 100 [or "250"] milligrams of Ascorbic Acid * * * McKesson & Robbins, Incorporated, New York, N.Y.—Bridgeport, Conn."

ACCOMPANYING LABELING: Leaflets entitled "History and Uses of Vitamin C."

LIBELED: 1–4–60, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was capable of neutralizing toxins (poisons); that it would act as a chemotherapeutic agent in infectious diseases; that it was effective to aid in relief of symptoms of colds, "flu," fever, sinus, and colds; to relieve muscular aches and pains; to treat and prevent bleeding gums, "pink toothbrush," sore gums, spongy gums, and loosening of the teeth; to regulate cholesterol content of the body; to treat and prevent heart disease; to treat acute alcoholism; to control and treat allergies, hay fever, etc.; to prevent the convulsive states of whooping cough and to reduce the duration, and to eliminate all complications of the disease; and to treat circulatory disorders, arteriosclerosis, and anemia; and that practically all adults and children are deficient in vitamin C; and 502