

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 Phenolphthalein 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 $\frac{1}{2}$ gr. Pepsin 1-3000 $\frac{1}{2}$ gr. Aloin $\frac{1}{4}$ gr. Podophyllin $\frac{1}{6}$ gr. Diastase of Malt $\frac{1}{8}$ 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.