

LABEL, IN PART: "Calcium Polysulphide Solution Active Ingredients: Calcium Polysulphide . . . 31% Calcium Thiosulphate . . . 1% Inert Ingredients . . . 68% Total Sulphur (At Least) . . . 24%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the drug failed to bear adequate directions for use since the labeling contained no directions for use.

DISPOSITION: July 1, 1948. A plea of guilty having been entered, the court imposed a \$50 fine, plus costs, on count 1 and suspended sentence and placed the defendant on probation for 2 years on count 2.

DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3544. Action to enjoin and restrain the interstate shipment of adulterated and misbranded rubber prophylactics. *U. S. v. Joseph Lader, Clara Lader, and Anna Lader (Crown Rubber Sundries Co.)*. Permanent injunction granted. (Inj. No. 97.)

COMPLAINT FILED: On or about June 12, 1945, Northern District of Ohio, against Joseph Lader, Clara Lader, and Anna Lader, partners, trading under the name of the Crown Rubber Sundries Co., Akron, Ohio.

NATURE OF CHARGE: The complaint alleged that the defendants since about the month of July 1944 had been and were at the time of filing the complaint engaged in purchasing, packing, distributing, and selling, and introducing and causing to be introduced into interstate commerce, from Akron, Ohio, devices known as *rubber prophylactics* or condoms; that these devices were adulterated under Section 501 (c) since they consisted of defective, imperfect, and old material, and contained holes and defects and other imperfections, so that their strength differed from, and their quality fell below, that which they purported and were represented to possess; that the said devices were misbranded under Section 502 (a) in that they were recommended and labeled as suitable for the prevention of venereal disease, and the labeling was false and misleading since the devices were not suitable for such purposes, because of the presence of holes.

The complaint alleged further that a large number of shipments of *rubber prophylactics* by the defendants had been examined; that seizures had been instituted against many of the firm's consignments; that the defendants had been given notice on three occasions of contemplated criminal action; that Joseph Lader refused to permit inspection of the defendants' plant in December 1944, following the investigation of a shipment which had been found to consist of old, rejected stock; that on January 8 and 23, 1945, inspectors again were refused permission to inspect the premises; and that in 1945 a considerable number of the firm's interstate shipments again were sampled, and the examination showed the product to be from 12.5% to 33% defective.

The complaint alleged further that on March 24, 1945, notice again was given to the Crown Rubber Sundries Co. and Joseph Lader that opportunity would be afforded them to present their views with respect to contemplated criminal proceedings charging violation of the law; that statements made by Joseph Lader at a hearing on March 26, 1945, established that no tests were made by the firm in order to discover imperfections before shipment in interstate commerce; and that during inspections Joseph Lader had been informed of the imperfections found in the devices and had been warned