

wool wax (lanum). It was alleged to be misbranded in that the statements on the label, "Prostatic Absorbent" and "Soothing and relieving Chronic conditions of the Prostate and Bladder neck," were false and misleading; and for the five further reasons appearing in the first paragraph of this notice.

Analysis of a sample of Aesculus Pile Cerate showed that it consisted essentially of ichthammol, tar oil, and extracts of plant drugs incorporated in petrolatum. It was alleged to be misbranded in that the designation "Pile Cerate" and the statement "Relieves Bleeding, Itching, Blind, Protruding, Ulcerated Piles," on the carton label were false and misleading; and for the four further reasons appearing in the first paragraph of this notice.

Between December 31, 1940, and January 29, 1941, default decrees were entered ordering that the products be destroyed.

437. Misbranding of Syn-O-Scope and Synex. U. S. v. 9 Packages of Syn-O-Scope and 8 Bottles of Synex. Default decrees of condemnation and destruction. (F. D. C. Nos. 3551, 3552. Sample Nos. 52531-E, 52532-E.)

Each package of the Syn-O-Scope consisted of a vaporizing apparatus and a small unlabeled vial of liquid. The vaporizing apparatus would have been dangerous to health when used according to directions, and the label also bore false and misleading therapeutic claims. The vial of liquid and the bottles of Synex also failed to comply with certain labeling requirements of the law.

On December 23 and on or about December 27, 1940, the United States attorney for the Eastern District of Washington filed libels against the above-named products at Spokane, Wash., alleging that the articles had been shipped on or about August 24, 1940, by Syn-O-Scope Laboratories from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the liquid contained in each package of Syn-O-Scope and of Synex showed that they consisted essentially of alcohol (19.5 percent by volume), camphor, eucalyptus oil, and water.

The Syn-O-Scope was alleged to be misbranded: (1) In that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Syn-O-Scope The Modern and Scientific Instrument for the Application Of Medicaments To Irritated And Congested Nasal Passages. Directions: Unscrew the cap where hose is attached to Syn-O-Scope. Allow 15 to 20 drops of medicant to flow into the sponge within the barrel. Replace cap. Then, merely place the tip in the nostril, holding it in position by the hand. Grasp the mouthpiece between the lips and blow. Use the amount of pressure suitable to your own case, but not too hard at first. The harder you blow, the deeper the medicated vapor reaches into the nasal cavities. Each day of active use add 3 to 5 drops of medicament to the sponge." (2) In that the following statements, (carton) "Syn-O-Scope The Modern Treatment For Nasal Irritations And Congestions," and (circular) "Syn-O-Scope The Modern And Scientific Instrument For The Application of Medicaments To Irritated And Congested Nasal Passages," were false and misleading since they represented that it was efficacious for the purposes recommended; whereas it was not efficacious for such purposes. (3) In that the carton and vial containing the liquid did not bear the common or usual names of the active ingredients, including the quantity of alcohol. (4) In that the vial containing the liquid failed to bear a label containing the name and address of the manufacturer, packer, or distributor. (5) In that the carton and vial containing the liquid failed to bear a label containing a statement of the quantity of contents.

The Synex was alleged to be misbranded in that the label failed to bear (1) the common or usual names of the active ingredients; (2) the name and address of the manufacturer, packer, or distributor; and (3) an accurate statement of the quantity of contents.

On February 24, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

438. Misbranding of Wonder Salve. U. S. v. 13 Cans of Wonder Salve. Consent decree of condemnation and destruction. (F. D. C. No. 3164. Sample No. 19079-E.)

The labeling of this product bore false and misleading representations regarding its efficacy as indicated hereinafter. The article would be dangerous to health when used in the manner recommended and suggested in the labeling.

On October 10, 1940, the United States attorney for the Western District of Pennsylvania filed a libel against 13 cans of Wonder Salve at Pittsburgh, Pa.,

alleging that the article had been shipped in interstate commerce on or about December 21, 1939, by Brookgate Remedies Co. from Evansville, Ind.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of phenolic compounds, including 5.44 percent of carbolic acid, camphor, and turpentine in an ointment base.

The article was alleged to be misbranded in that the following statements on the label were false and misleading, since it would not be efficacious for the purposes for which it was so recommended: "For all cases of Inflammation or Infection. For * * * Mashed Members, Cinders or any other Foreign substances in the Eye." It was alleged to be misbranded further in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "Apply salve freely to affected parts and bandage. For cinders or other foreign substance in eye, place salve on absorbent cotton and place same over closed eye and bandage."

The product was also alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notice of judgment No. 103 published under that act.

On January 26, 1942, the shipper having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS FOR USE OR WARNING STATEMENTS¹

439. Misbranding of Pine-Orum Compound. U. S. v. John C. Schaffer (Pine-Orum Chemical Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 4169. Sample No. 11224-E.)

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of certain conditions and failed to comply with certain mandatory labeling requirements of the law as indicated hereinafter.

On September 13, 1941, the United States attorney for the Southern District of Mississippi filed an information against John C. Schaffer, trading as Pine-Orum Chemical Co., at New Augusta, Miss., alleging shipment on February 23, 1940, from the State of Mississippi into the State of Texas of a quantity of Schaffer's Pine-Orum Compound that was misbranded.

Analysis showed that the article was a medium heavy oil having a strong pine oil odor consisting essentially of a pine tar distillate containing sulfur or sulfur compounds and a small percentage of water.

It was alleged to be misbranded in that certain statements on the bottle label were false and misleading since they represented and suggested that the article was efficacious as a treatment and remedy for coughs, colds, flu, pneumonia, headache, indigestion, worms in humans and animals, cuts, burns, infections and blood poison, insect bites, tonsillitis, sore throat, toothache, pyorrhea, bruises, rheumatism, neuritis, sprains, stiff joints, old chronic sores, hemorrhoids, athlete's foot, itch, poison oak, dew poison and dandruff; that it would be efficacious to stop the flow of blood; that when used in the bath it would have medicinal properties, and it was efficacious for many animal ailments; whereas it was not efficacious for such purposes.

It was alleged to be misbranded further in that it was in package form and did not bear a label containing the name and place of business of the manufacturer, packer or distributor, placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read under customary conditions of purchase, since the name and place of business of the manufacturer did not appear on the panel of the bottle label which was displayed under customary conditions of purchase. It was alleged to be misbranded further in that it was in package form and did not bear a label containing an accurate statement of the quantity of the contents in terms of measure; in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient; and in that its labeling did not bear adequate directions for use, since it was recommended for conditions requiring external application and the labeling bore no directions for external use.

On October 13, 1941, the defendant having entered a plea of guilty, the court imposed a fine of \$50.

¹ See also Nos. 426, 427, 429-432, 434-436, 459, 460.