

**NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION**

**3541. Misbranding of Sulfa Salverol ointment. U. S. v. 8,148 Tubes \* \* \*.**  
(F. D. C. No. 15287. Sample No. 6315-H.)

**LIBEL FILED:** February 19, 1945, Southern District of New York.

**ALLEGED SHIPMENT:** On or about July 10 and 17 and August 9, 1944, from Newark, N. J., by Day Chemical Co., Inc.

**PRODUCT:** 8,148 tubes of *Sulfa Salverol ointment* at New York, N. Y.

**LABEL, IN PART:** "Contains: Sulfanilamide 4%, Sulfathiazole 3%, with Oil of Cade, Calamine, and Menthol combined in a specially Prepared absorption base."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying circular entitled "New Sulfa Formula Works Wonders on the Home Front!" were false and misleading. The statements represented and suggested that the article was effective as a remedy in many stubborn skin diseases; that it would permit natural healing; and that it would be efficacious in the treatment of eczema, dermatitis, athlete's foot, acne, psoriasis, skin rashes, pimples, scabies, scalp seborrhea, sores, barber's itch, insect bites, abrasions, cuts, and minor burns. The article was not an adequate treatment for the conditions mentioned, and it would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods and duration of administration or application since there were no warnings to the effect that the article may produce a sensitivity to sulfonamides, preventing their subsequent use in serious conditions for which those drugs could have been life-saving, or that the article should not be used on persons with known sensitivity to the sulfonamides.

Section 505 (a), the article was a new drug within the meaning of the law, and no application filed pursuant to the law was, or had been, effective with respect to the article.

**DISPOSITION:** March 2, 1945. The Research Drug Co., Inc., New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**3542. Action to enjoin and restrain the interstate shipment of misbranded Gingisol. U. S. v. David J. Barben (Gingisol Laboratories). (Inj. No. 196.)**

**COMPLAINT FILED:** June 28, 1948, Northern District of Ohio, against David J. Barben, trading as Gingisol Laboratories, Cleveland, Ohio.

**NATURE OF CHARGE:** That the defendant had been and was at the time of filing the complaint introducing and causing the introduction into interstate commerce, at Cleveland, Ohio, consignments of a drug designated as *Gingisol*, consisting of a solution of phenol and alkali in flavored, perfumed, colored water;

\* See also No. 3541.

that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (a), in that the labeling contained statements which represented and suggested that the drug would be efficacious in the cure, mitigation, treatment and prevention of gingivitis and pyorrhea; would be efficacious to restore soft, spongy, bleeding gums to a healthy pink color, and would help keep gums firm and healthy; would cause swelling, bleeding, and tenderness in gums to subside; would aid materially in the healing process after tooth extractions; would be efficacious in the treatment of abscessed teeth, infected gums, and infected tonsils; would aid in the correction of the chief causes of rheumatism, heart trouble, kidney disorders, stomach trouble, and nervous disorders; and would prevent the absorption of germs and poisons developing in diseased teeth and in infected gums and tonsils; and that the said statements were false and misleading since the product would not be efficacious for the purposes represented, suggested, and implied.

The complaint alleged further that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (f) (1), in that the labeling failed to bear adequate directions for use in all conditions for which it was intended to be used and for which it was prescribed, recommended, or suggested in its advertising, disseminated or sponsored by or on behalf of the defendant, namely, bleeding gums, pyorrhea, loss of all teeth, soft, spongy, bleeding gums, and gingivitis.

The complaint alleged further that the defendant still continued to introduce into interstate commerce the drug which was misbranded as stated above, and alleged on information and belief that he would continue to do so unless restrained. The complaint prayed the entry of a decree perpetually enjoining the defendant from introducing the drug under the name *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1), and that he be ordered to show cause why he should not be restrained from such acts during the pendency of the proceedings.

**DISPOSITION:** On December 17, 1948, the defendant having consented to the entry of a decree, the court entered an order perpetually enjoining and restraining the defendant and all persons acting upon his behalf from directly or indirectly introducing into interstate commerce the above-described drug under the designation *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1). The decree contained the proviso that the defendant could introduce the drug, *Gingisol*, composed of a solution of potassium phenolate and a small proportion of fluorides, into interstate commerce under appropriate labeling so long as it was intended for use solely as a simple mouth wash for which no therapeutic claims were made.

**3543. Misbranding of calcium polysulfide solution. U. S. v. Wilfred S. McKeon.**  
Plea of guilty. Fine of \$50, plus costs, on count 1; suspended sentence and probation for 2 years on count 2. (F. D. C. No. 24253. Sample Nos. 68292-H, 68293-H.)

**INFORMATION FILED:** April 19, 1948, Western District of Pennsylvania, against Wilfred S. McKeon.

**INTERSTATE SHIPMENT:** On or about February 26 and 27, 1947, from the State of Pennsylvania into the State of Kansas, of quantities of *calcium polysulfide solution*.