

CHARGE: (Drums of powdered drug and tablets manufactured therefrom), 501 (d) (2)—when shipped, a substance, namely, the ground root of one or more species of *Rauwolfia* other than *Rauwolfia serpentina*, had been substituted in whole or in part for *Rauwolfia serpentina*; (drums of powdered drug), 502 (a)—the label statement "Pow. *Rauwolfia Serpentina*" was false and misleading since it represented that the article consisted wholly of *Rauwolfia serpentina*, which was not the case; (tablets manufactured from powdered drug), 502 (a)—the statement "Each tablet contains: * * * *Rauwolfia Serpentina*" borne on the bottle label while held for sale was false and misleading as applied to the article, which contained one or more species of *Rauwolfia* other than *Rauwolfia serpentina*; and (drums of powdered drug and tablets manufactured therefrom), 502 (i) (3)—the article was a drug which was not *Rauwolfia serpentina*, and, when shipped, was offered for sale under the name of another drug, namely, *Rauwolfia serpentina*.

DISPOSITION: 3-12-55. Default—destruction.

4674. Adhesive bandages. (F. D. C. No. 33768. S. Nos. 3-617 L, 12-613 L, 26-078 L, 26-408 L.)

INFORMATION FILED: 5-28-53, E. Dist. N. Y., against Gotham Aseptic Laboratory Co., Inc., Long Island City, N. Y.

ALLEGED VIOLATION: On 2-4-52, the defendant caused *adhesive bandages*, adulterated and misbranded as hereinafter described, to be delivered for introduction into interstate commerce.

LABEL IN PART: "Sterilized Handy Adhesive Bands Supreme First Aid Co., Inc. New York, N. Y."

CHARGE: 501 (b)—the quality and purity of the article when shipped fell below the standard for adhesive absorbent bandage set forth in the United States Pharmacopeia, in that it was not sterile but was contaminated with viable micro-organisms; and, 502 (a)—the label statement "Sterilized" was false and misleading.

PLEA: Not guilty.

DISPOSITION: The defendant filed a motion for a bill of particulars, which the court, on 4-26-54, granted in part. Thereafter, on 7-11-55, the defendant entered a plea of guilty; and, on 7-28-55, it was fined \$500.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4675. Colusa Natural Oil and Colusa Natural Oil Capsules. (Inj. No. 172.)

COMPLAINT FOR INJUNCTION FILED: 8-26-48, S. Dist. Calif., against Colusa Remedy Co., a corporation, Los Angeles, Calif., and Chester Walker Colgrove, president of the corporation, to enjoin the interstate shipment of the above-mentioned articles misbranded under 502 (a).

LABEL IN PART: The labels of the articles are quoted in the findings of fact set forth below.

*See also Nos. 4661, 4664-4668, 4673, 4674.

CHARGE: The complaint alleged that the defendants had been and were at the time of filing the complaint introducing into interstate commerce *Colusa Natural Oil* and *Colusa Natural Oil Capsules* which were misbranded under 502 (a) in that their labeling contained representations that the articles were efficacious in the treatment of psoriasis, eczema, poison ivy and poison oak, athlete's foot, leg ulcers, acne, itch, and open sores, whereas the articles were not efficacious for such purposes.

The complaint alleged further that the defendants and the Empire Oil & Gas Corp., predecessor in interest of Colusa Remedy Co., had a long history of violations of the Act; that a default decree of condemnation had been entered against a shipment of *Colusa Natural Oil* which was seized in July 1940, on the charge that it was misbranded by reason of false and misleading representations concerning its effectiveness for certain diseases including psoriasis, eczema, and athlete's foot (notices of judgment on drugs and devices, No. 380); that with respect to such shipment, criminal proceedings subsequently were instituted against the Empire Oil & Gas Corp. and its president, Chester Walker Colgrove, and were terminated upon pleas of nolo contendere (notices of judgment on drugs and devices, No. 1040); that, thereafter, the labels of the *Colusa Natural Oil* and *Colusa Natural Oil Capsules* were changed by omitting any reference on the labels to the diseases for which the articles were to be used, and, in lieu of such label references the dealers were supplied with illustrated circulars in which the articles were offered and recommended in the treatment and cure of psoriasis, eczema, leg ulcers, itch, and athlete's foot; that between June 1944 and the time of filing the complaint, over 150 seizure actions had been instituted against the articles, most of which actions had been terminated by the entry of default decrees of condemnation; that the defendants abandoned the use of the misbranded circulars after a period of time and resorted to the use of newspaper advertising to stimulate the sale of the articles; that the labels of the articles as advertised failed to bear adequate directions for use of the articles in the conditions for which they were advertised; that the Government, contending that the articles were thereby misbranded, instituted injunction proceedings resulting in the issuance of an injunction on 4-23-47, prohibiting the defendants from introducing the articles into interstate commerce unless their labels contained adequate directions for use in the treatment of all conditions for which the articles were prescribed, recommended, and suggested in advertising material disseminated or sponsored by or on behalf of the defendants (notices of judgment on drugs and devices, No. 3061); that following the issuance of the injunction, the defendants reverted to their original practices of referring to psoriasis, eczema, leg ulcers, and athlete's foot on the labels of the articles; that subsequently a number of seizure actions were instituted against the articles on the charge of misbranding by reason of false and misleading representations in the labeling concerning the efficaciousness of the articles in the treatment and cure of psoriasis, eczema, leg ulcers, athlete's foot and open sores; that such seizure actions were consolidated for trial in the Northern District of Iowa and tried between 11-13-47 and 11-18-47; that at the conclusion of the trial, the court held the articles to be misbranded as charged (notices of judgment on drugs and devices, No. 2922); that a contempt action charging the defendants with violation of the injunction of 4-23-47 was instituted on 10-3-47; and that after full consideration of the activities of the defendants, the court found the defendants guilty of criminal contempt (notices of judgment on drugs and devices, No. 3061).

DISPOSITION: Pursuant to the Government's request, an order to the defendants to show cause why a preliminary injunction should not be issued was entered by the court on 8-26-48. On 2-9-49, after a hearing in the matter, the court denied the request for a preliminary injunction. Thereafter, the case came on for trial before the court without a jury on the question of issuing a permanent injunction. The trial was concluded on 5-24-49, and on 6-8-49, the court handed down the following findings of fact and conclusions of law:

MATHES, *District Judge*:

FINDINGS OF FACT

"1. The defendant, COLUSA REMEDY COMPANY, INC., is a corporation organized and existing under the laws of the State of Nevada and has its principal place of business and office in Los Angeles, California.

"2. Defendant, CHESTER WALKER COLGROVE, was the president of defendant, COLUSA REMEDY COMPANY, INC., but has sold his interest in the firm and is no longer associated with its operations.

"3. At the conclusion of the trial in this cause, the case of *United States v. 9 Bottles . . . 'Colusa Natural Oil' et al.*, 78 F. Supp. 721, (N. D. Iowa, 1947), was pending on appeal in the United States Court of Appeals for the Eighth Circuit.

"4. Defendant, COLUSA REMEDY COMPANY, INC., for some years has been introducing and delivering for introduction into interstate commerce articles of drug labeled 'Colusa Natural Oil' and 'Colusa Natural Oil in Capsules.' Said defendant will continue to ship such articles in interstate commerce unless restrained by this Court.

"5. The labeling of Colusa Natural Oil reads as follows:

COLUSA Natural Oil

A natural unrefined petroleum oil intended for trial use in external treatment of symptoms of Psoriasis, Eczema, including Poison Ivy and Poison Oak, Leg Ulcers, Athlete's Foot, Acne and Itch. Due to the various causative factors, types, kinds and/or stages of the diseases above named, we do not represent that Colusa Natural Oil will cure, alleviate or relieve any one's particular case. We recommend its trial use and represent that thousands of doctors, druggists and users have written us telling of great benefit derived from its use in their cases. We want to help YOU and invite your trial use on the following guaranteed basis, viz: if it fails to alleviate or relieve your case to your entire satisfaction you may return the unused portion with sales slip showing return mailed within not more than six weeks after date of purchase and your money will be refunded. See directions for use on back label.

Net Contents 4 fl. oz.

COLUSA REMEDY CO.

1507 Wilcox Ave. Los Angeles, Calif.

DIRECTIONS

for external use of Colusa Natural Oil: Apply to affected parts and rub it in thoroughly morning and night. For open sores, saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin, oil can be diluted 50% with olive oil. Continue treatment four weeks, or longer if you believe it is helping you. In treatment of symptoms of Psoriasis, Eczema, Acne and leg ulcers we suggest you try Colusa Natural Oil capsules internally in conjunction with Colusa Natural Oil externally, pursuant to the trial offer terms and directions for use printed on labels of bottles containing Colusa Natural oil capsules.

To remove oil stains from linen, use Energine or other solvent before putting into water.

"6. The labeling of Colusa Natural Oil in Capsules reads as follows :

COLUSA
Natural Oil

A natural unrefined petroleum oil in capsules. Intended for trial use in internal treatment of symptoms of Psoriasis, Eczema, Acne, Leg Ulcers. Due to the various causative factors, types, kinds and/or stages of the diseases above named, we do not represent that Colusa Natural oil capsules will cure, alleviate or relieve any one's particular case. We recommend their trial use and represent that thousands of doctors, druggists and users have written us telling of great benefit derived from the use of Colusa Natural oil externally and/or Colusa Natural oil capsules internally in their cases. We want to help YOU and invite your trial use on the following guaranteed basis, viz: If they fail to alleviate or relieve your case to your entire satisfaction you may return the unused portion with sales slip showing return mailed within not more than six weeks after date of purchase and your money will be refunded. See directions for use on back label.

Net contents 200 capsules

COLUSA REMEDY CO.

1507 Wilcox Ave. Los Angeles, Calif.

DIRECTIONS

for internal use of Colusa Natural oil capsules. For adults, start with one capsule at bed time, then after 3 days change to one capsule after each meal. For children under ten, one capsule or its content squeezed into milk or water at bed time. Continue four weeks or longer if you believe they are helping the case being treated. In treatment of symptoms of Psoriasis, Eczema, Acne and Leg Ulcers, we suggest you try Colusa Natural oil externally in conjunction with Colusa Natural Oil capsules internally, pursuant to the trial offer terms, and directions for use, printed on the labels on bottles containing Colusa Natural oil in liquid form.

"7. The article, Colusa Natural Oil, is a crude, natural, unrefined seepage, petroleum oil. The article, Colusa Natural Oil in Capsules, consists of capsules each containing approximately .18 grams of Colusa Natural Oil.

"8. The labeling of Colusa Natural Oil in effect represents and suggests that it is beneficial and efficacious in the treatment, mitigation, and cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, and open sores.

"9. The labeling of Colusa Natural Oil in Capsules in effect represents and suggests that it is beneficial and efficacious in the treatment, mitigation, and cure of psoriasis, eczema, acne, and leg ulcers.

"10. Psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, and open sores are diseases which manifest themselves on the surface of the human skin.

"11. Both the article, Colusa Natural Oil, and the article, Colusa Natural Oil in Capsules, are intended for use in the treatment, mitigation, and cure of disease in man.

"12. Colusa Natural Oil is not beneficial or efficacious in the treatment, mitigation, or cure of any of the disease conditions mentioned on its labeling.

"13. Colusa Natural Oil in Capsules is not beneficial or efficacious in the treatment, mitigation, or cure of any of the disease conditions mentioned on its labeling.

"14. Colusa Natural Oil and Colusa Natural Oil in Capsules, when taken or used as directed on their labeling or otherwise, separately or in combination, are worthless in the treatment, mitigation, or cure of any of the disease conditions mentioned on their labeling.

"15. The labeling of Colusa Natural Oil is false and misleading in the particulars and by reason of the facts hereinabove found.

"16. The labeling of Colusa Natural Oil in Capsules is false and misleading in the particulars and by reason of the facts hereinabove found.

CONCLUSIONS OF LAW

"1. This Court has jurisdiction over the subject matter in this case and over the parties thereto.

"2. The Complaint is dismissed as to CHESTER WALKER COLGROVE.

"3. This Court is not bound by the findings of fact in the case of *United States v. 9 Bottles . . . 'Colusa Natural Oil' et al.*, 78 F Supp. 721 (N. D. Iowa, 1947) since that case is pending on appeal and the findings of fact therein are not now final.

"4. Colusa Natural Oil and Colusa Natural Oil in Capsules are drugs within the meaning of 21 U. S. C. 321 (g) (2).

"5. The articles, Colusa Natural Oil and Colusa Natural Oil in Capsules, are misbranded within the meaning of 21 U. S. C. 352 (a).

"6. Plaintiff's prayer for an injunction should be granted permanently restraining defendant, COLUSA REMEDY COMPANY, INC., from introducing or causing to be introduced into interstate commerce, and from delivering or causing to be delivered for introduction into interstate commerce, in violation of 21 U. S. C. 331 (a), any Colusa Natural Oil or Colusa Natural Oil in Capsules which is misbranded within the meaning of 21 U. S. C. 352 (a), and in particular which contains any labeling representing or suggesting that these products, used separately or together, are or might be beneficial or efficacious in the treatment, mitigation, or cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, or open sores.

"7. Plaintiff is entitled to all costs properly taxable against the defendant, COLUSA REMEDY COMPANY, INC."

Pursuant to the above-mentioned findings of fact and conclusions of law, the court, on 6-8-49, entered a decree permanently enjoining the Colusa Remedy Co., its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with all or anyone or more of them from introducing into interstate commerce *Colusa Natural Oil*, *Colusa Natural Oil Capsules*, or any like products which are misbranded under 502 (a), and in particular which contain any labeling representing that the articles used separately or together are or might be beneficial or efficacious in the treatment, mitigation, or cure of psoriasis, eczema, poison ivy, poison oak, leg ulcers, athlete's foot, acne, itch, or open sores.

A motion for a new trial was filed by the Colusa Remedy Co., and on 9-19-49, was denied. A notice of appeal was filed by the company on 11-15-49, but no steps were taken thereafter to perfect the appeal. A stipulation subsequently was entered into between the parties agreeing to the dismissal of the appeal, and was approved by the court on 10-9-50.

4676. *Lymphex and Tracel*. (F. D. C. No. 35184. S. Nos. 38-376 L, 51-057/8 L, 56-602/3 L.)

INFORMATION FILED: 10-21-53, Dist. N. J., against H. Hall Marshall, t/a Consultants' Laboratories, Millington, N. J.

SHIPPED: Between 7-18-52 and 3-12-53, from New Jersey to New York, Maryland, and Tennessee.

LABEL IN PART: (Can) "Lymphex Myroxylon Bark Extract Osmotic Baths. * * * Active Ingredients Lymphex Osmotic Baths contain a new extract of the myroxylon tree from one particular tropical environment. This extract also contains eucalyptol, nerolidol and cinnamein (used as extractors) and is combined with laurel-sodium sulfonate (foaming and wetting agent) and sodium carbonate (water softener)"; (btl.) "Tracel Trace Element Mineral Concentrate Each Two Teaspoons Contain The Following Amounts: Cobalt