

DISPOSITION: October 15, 1948. The defendant having consented to the entry of a decree, an order was entered enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce the above-mentioned product, which was misbranded within the meaning of Sections 502 (a), 502 (f) (1) and (2), 502 (e) (2), and 502 (b) (1) and (2).

2454. Misbranding of Formalon Cream. U. S. v. Daniel Platt (Formalon Company). Plea of guilty. Defendant fined \$3,000, given suspended sentence of 3 years in jail, and placed on probation for 3 years. (F. D. C. No. 21466. Sample Nos. 70802-H, 12947-K, 12948-K.)

INFORMATION FILED: January 23, 1948, Southern District of New York, against Daniel Platt, trading as the Formalon Co., New York, N. Y.

ALLEGED SHIPMENT: From the State of New York into the States of Delaware, California, Pennsylvania, Massachusetts, and New Jersey. The product was shipped during March and April 1946, and January and March 1947, and a circular letter was shipped during March, April, and November 1946, and January and March 1947.

PRODUCT: Analysis disclosed that the product consisted of a pale-yellow semisolid containing 27.2 mg. diethylstilbestrol in each 2 ounces. Examination showed that the circular letter contained a number of statements relating to the efficacy of the product for the development of the breasts and pictures of women purportedly before and after the use of the product.

LABEL, IN PART: "Directions Apply $\frac{1}{2}$ teaspoon of Formalon daily to each breast and massage gently at bedtime, or as otherwise directed by physician. Formalon Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and pictures appearing in the circular letter were false and misleading. The statements and pictures represented and suggested that the article would be effective to develop the breasts of women, whereas it would not be effective for such purposes.

Further misbranding, Section 502 (a), the before and after pictures designated "Case 5469" and the statement underneath "showing breast growth produced after using Formalon 8 weeks" and the before and after pictures designated "Case 1721" and the statement underneath "showing breast growth produced after 12 weeks of applying Formalon Cream," appearing in the circular letter, were false and misleading. The pictures and statements represented and suggested that the pictures were pictures of women which had been taken before and after treatment with the article, whereas the pictures were pictures of women which had been taken before and after treatment with another drug.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions which appeared on the label failed to reveal the conditions for which the article was to be used.

DISPOSITION: August 4, 1948. A plea of guilty having been entered, the court fined the defendant \$3,000 and sentenced him to serve 3 years in jail. The jail sentence was suspended and the defendant was placed on probation for 3 years, conditioned that he should not directly or indirectly engage in the sale of drugs or food preparations of any kind, nature, or description.

2455. Misbranding of Emerson's Medicine, Emerson's K-A-C Cough Syrup, and Emerson's Lightning Liniment. U. S. v. 7 Bottles, etc. (F. D. C. No. 24854. Sample Nos. 22544-K to 22546-K, incl.)

LIBEL FILED: On or about May 27, 1948, Southern District of Texas.

ALLEGED SHIPMENT: By the Emerson Medicine Co., from Kansas City, Mo.; the products were shipped on or about April 8, 1948, and a number of circulars were shipped on or about January 5, 1948.

PRODUCT: 7 12-ounce bottles of *Emerson's Medicine*, 7 2-ounce bottles of *Emerson's K-A-C Cough Syrup*, and 18 2-ounce bottles of *Emerson's Lightning Liniment* at Houston, Tex., together with 32 circulars entitled "Emerson's Medicine," which were enclosed with the syrup and wrapped around the bottles of the liniment, and 50 circulars entitled "Emerson's Medicine is Mother Nature's Own Laxative Medicine," which were shipped separately from the products.

Analyses disclosed that the *Emerson's Medicine* consisted of water and extracts of plant drugs, including a laxative drug, together with a small propor-

tion of sodium salicylate; and that the *Emerson's K-A-C Cough Syrup* consisted essentially of sugar, menthol, camphor, ammonium chloride, potassium antimony tartrate, alcohol, and water.

NATURE OF CHARGE: *Emerson's Medicine*. Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading, since they represented and suggested that the other ingredients named are adjuvants to the laxative action of aloes and that the article was effective to fulfill the promises of benefit stated and implied, whereas the other ingredients named are not adjuvants to the laxative action of aloes and the article was not effective to fulfill the promises of benefit stated and implied: (Carton and bottle label) "Active Ingredient: Curacao Aloes to which is added as Bitter Adjuvants Honduras Sarsaparilla, Poke Root, Dandelion Root, Prickly Ash Bark, Liverwort Leaves, Mandrake Root, Gentian Root, Stillingia, Burdock and Yellow Dock"; (circular entitled "Emerson's Medicine") "Carefully extracted juices from these well known roots and herbs according to Dr. Ray's specifications are added to the curacao aloes as bitter adjuvants. We believe that the combination of these ingredients is what has made Emerson's Medicine famous nationwide . . . Feel better . . . work better . . . eat better . . . sleep better"; and (circular entitled "Emerson's Medicine is Mother Nature's Own Laxative Medicine") "Tonic in action . . . Carefully extracted juices from these well known roots and herbs according to Dr. Ray's specifications are added to the Curacao aloes as bitter adjuvants. We believe that the combination of these ingredients is what has made Emerson's Medicine famous nationwide . . . Feel better . . . work better . . . eat better . . . sleep better . . . Health Brings Success. Healthy men and women stand a much better chance of gaining success in this busy world. Nothing is so valuable as physical fitness! Steady Nerves, firm muscles, a painless body, all make the quick active brain. Develop that pep and punch so necessary to overcome obstacles. Bring success to social and business life."

Further misbranding, Section 502 (f) (2), the labeling of the *Emerson's Medicine*, failed to bear such adequate warnings against unsafe duration of administration, in such manner and form as are necessary for the protection of users, since the article was essentially a laxative and its labeling failed to warn that frequent or continued use may result in dependence on a laxative to move the bowels.

Emerson's K-A-C Cough Syrup. Misbranding, Section 502 (a), the label statement "Relieves * * * colds, spasmodic croup * * * sore throat * * * congestion of upper respiratory organs, whooping cough" were false and misleading, since the article was not effective to relieve such conditions.

Emerson's K-A-C Cough Syrup and *Emerson's Lightning Liniment*. Misbranding, Section 502 (a), certain statements in circulars enclosed with the syrup and wrapped around bottles of the liniment, were false and misleading. These circulars contained representations regarding *Emerson's Medicine* which were similar to those in the circulars accompanying that product.

DISPOSITION: July 9, 1948. Default decree of condemnation and destruction.

2456. Misbranding of Sanite Ergot and Apiol Compound. U. S. v. 30 Dozen Boxes
* * * (F. D. C. No. 24748. Sample No. 345-K.)

LIBEL FILED: On or about April 28, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about March 2, 13, and 16, 1948, by the American Pharmaceutical Co., Inc., from New York, N. Y.

PRODUCT: 30 dozen boxes, each containing 25 capsules, of *Sanite Ergot and Apiol Compound* at Atlanta, Ga.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since its labeling failed to reveal the conditions for which the drug was to be taken.

DISPOSITION: June 15, 1948. Default decree of condemnation and destruction.

2457. Misbranding of potassium soap. U. S. v. 11 Tubes * * * (F. D. C. No. 24378. Sample No. 22351-K.)

LIBEL FILED: March 15, 1948, Western District of Louisiana.

ALLEGED SHIPMENT: On or about January 24, 1948, from Dallas, Tex., by F. H. Jordan.