

**2377. Misbranding of D-M-C Prescription No. 49, D-M-C Tonic, D-M-C Anodyne Medicine Compound, D-M-C Levorette Tonic, and D-M-C Levorette Tablets. U. S. v. Dixie Medicine Corp. Plea of nolo contendere. Judgment suspended, conditioned upon defendant's action in changing the labels of the products; case subsequently dismissed without imposition of sentence.** (F. D. C. No. 11354. Sample Nos. 35416-F, 35417-F, 35419-F to 35421-F, incl.)

**INFORMATION FILED:** March 28, 1944, Western District of North Carolina, against the Dixie Medicine Corp., Charlotte, N. C.

**ALLEGED SHIPMENT:** On or about March 5 and April 8, 1943, from the State of North Carolina into the State of South Carolina.

**PRODUCT:** Analyses disclosed that the *D-M-C Prescription No. 49* consisted essentially of compounds of sodium and potassium, tartrates, sulfur, senna, licorice, and 2.11 percent of sodium salicylate; that the *D-M-C Tonic* consisted essentially of a small proportion of an iron compound and extracts of plant drugs including nux vomica, water, and 3.7 percent of alcohol; that the *D-M-C Anodyne Medicine Compound* consisted essentially of small proportions of ammonium salt, camphor, volatile oil, and extracts of plant drugs including ginger, alcohol 5.0 percent, and water; that the *D-M-C Levorette Tonic* consisted essentially of epsom salt, extracts of plant drugs including emodin bearing drugs, a compound of iron, alcohol 1.5 percent, and water; and that the *D-M-C Levorette Tablets* contained calomel in the proportion of 0.47 grain per tablet and extracts of plant drugs including capsicum and colocynth.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading, since the articles would not be efficacious for the purposes represented. The labels represented that the *D-M-C Prescription No. 49* would be efficacious in the cure, mitigation, treatment, and prevention of arthritis and rheumatism and would produce a remedial effect in rheumatism and arthritis in two weeks; that the *D-M-C Tonic* would be efficacious in the cure, mitigation, treatment, and prevention of loss of appetite, lack of vitality, and nervousness, and would be an efficacious purifier for the blood; that the *D-M-C Anodyne Medicine Compound* would be efficacious in the cure, mitigation, treatment, and prevention of dysentery, diarrhea, summer complaint, cholera morbus, flux, and pains in the stomach or bowels; that the *D-M-C Levorette Tonic* would be efficacious in the cure, mitigation, treatment, and prevention of colds, sick headaches, and all ills caused by an inactive liver; and that the *D-M-C Levorette Tablets* would be efficacious to regulate the liver.

Further misbranding, Section 502 (a), the statements on the labels of the *D-M-C Anodyne Medicine Compound* and the *D-M-C Levorette Tonic* which represented that the compound contained 7 percent of alcohol and that the tonic contained 5 percent of alcohol were false and misleading, since the compound contained not more than 5 percent of alcohol and the tonic contained not more than 1.5 percent of alcohol.

**DISPOSITION:** On April 17, 1944, an answer was filed on behalf of the defendant, denying the allegations of the information. Thereafter, a pre-trial conference was held, a result of which the court found as facts (1) that the defendant had changed and modified all labels on the products complained of and had used the changed and modified labels since making such changes and (2) that the defendant agreed to make further changes in its labels. On October 11, 1944, the court held that the new label of the *D-M-C Prescription No. 49* could be continued by striking out "Due To Arthritis, Rheumatism and Muscular Aches" and substituting the words "Muscular Aches and Pains"; that the new label of the *D-M-C Tonic* containing the statements "Intended to Help Increase the Appetite and as a tonic when lack of iron is indicated" could be continued, provided that the defendant increase the proportion of iron in the product; that the use of the *D-M-C Anodyne Medicine Compound* should be discontinued and stocks of such product withdrawn from the market; that the new label of the *D-M-C Levorette Tonic*, which designated such product as "Laxative Compound," could be continued by striking out the words "May be found helpful in relieving simple colds and headaches"; and that the new label of the *D-M-C Levorette Tablets*, which designated such product as "Laxative Tablets," could be continued upon striking out the words "and Regulation of the Bowels." Following this decision of the court, the defendant entered a plea of nolo contendere and the court suspended judgment. On April 7, 1947, the court was informed that there was no evidence

to indicate that the defendant was failing to comply with the decision of October 11, 1944, and the case was thereupon dismissed without imposition of sentence.

**2378. Misbranding of Estromone. U. S. v. Endo Products, Inc. Plea of guilty. Fine, \$900.** (F. D. C. No. 17848. Sample Nos. 31429-H, 31442-H, 31443-H.)

**INFORMATION FILED:** March 17, 1947, Eastern District of New York, against Endo Products, Inc., Richmond Hill, N. Y.

**ALLEGED SHIPMENT:** On or about March 31 and May 10, 1945, from the State of New York into the State of California.

**LABEL, IN PART:** "Endo Estromone."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements "Estrogenic Substance Derived from Equine Urine" and "Estrogenic Substance derived from pregnant mares' and stallions' urine" were false and misleading. The statements represented and suggested that the estrogenic material present in the article was estrogenic substance as it occurs in and is extracted from natural sources, i. e., pregnant mares' and stallions' urine and equine urine. The estrogenic material present in the article was not estrogenic substance as it occurs in and is extracted from natural sources.

Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, since the designation "Estrogenic Substance" is not the specific name of any particular substance but is a generic name for a class of substances.

**DISPOSITION:** May 20, 1948. A plea of guilty having been entered, the court imposed a fine of \$300 on each of the three counts of the information.

**2379. Misbranding of mixed estrogenic substance in oil. U. S. v. 38 Cartons \* \* \*.** (F. D. C. No. 23975. Sample No. 22487-K.)

**LIBEL FILED:** November 17, 1947, Western District of Texas.

**ALLEGED SHIPMENT:** On or about October 15, 1947, by Henry C. Haist & Co., from Kansas City, Mo.

**PRODUCT:** 38 cartons, each containing 1 30-cc. vial, of *mixed estrogenic substance in oil* at San Antonio, Tex.

**LABEL, IN PART:** (Vial) "30 CC. Multiple Dose Vial Mixed Natural Estrogenic Substance in Oil 10,000 International Units Per CC."; (carton) "10,000 I. U. Per CC. \* \* \* Manufactured for M. L. Claytor & Company San Antonio, Texas."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements "Mixed Natural Estrogenic Substance in Oil 10,000 International Units [or "10,000 I. U."] Per CC. \* \* \* A solution of mixed natural occurring estrogens, derived from pregnant mare's urine, consisting principally of estradiol and estrone, in sesame oil. Rated as estrone." were false and misleading, since the statements represented and suggested that the article consisted of a solution in oil of estrogens obtained from pregnant mares' urine equivalent in potency to 10,000 International Units of estrone per cubic centimeter, whereas the article did not possess such composition.

**DISPOSITION:** January 23, 1948. Default decree of forfeiture and destruction.

**2380. Misbranding of Marcillin. U. S. v. 7 Jugs \* \* \*.** (F. D. C. No. 23089. Sample No. 91872-H.)

**LIBEL FILED:** June 25, 1947, District of New Mexico.

**ALLEGED SHIPMENT:** On or about April 15, 1947, by Metabolic Research Laboratories, from Detroit, Mich.

**PRODUCT:** 7 1-gallon jugs of *Marcillin* at Central, N. Mex. Examination showed that the product consisted essentially of material extracted from bile dissolved in water.

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statements "Physiologically active by skin absorption \* \* \* A skin inunction treatment, useful in protein deficiency and biliary deficiency states; also in specific, virogenic, metabolic and allergic infections or syndromes" were false and misleading, since bile is not physiologically active by skin absorption and is not