

leading since it created the impression that the article would supply significant quantities of the ingredients named, whereas it would not supply significant quantities of such ingredients, except sodium sulfate.

Further misbranding, Section 502 (b), the label on the sample packages failed to bear (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (f) (2), the article was a laxative and its labeling failed to warn that a laxative should not be used in case of abdominal pains, nausea, vomiting, or other symptoms of appendicitis; and, further, the labeling failed to warn that frequent or continued use of the article might result in dependence upon laxatives to move the bowels, since no warning of any type appeared on the sample packages, and the warning statement on the 8-ounce package label was not adequate for the purposes required in that it limited the warning to severe and persistent pains in the lower abdomen.

DISPOSITION: October 31, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1755. Misbranding of digestive tablets. U. S. v. 3 Drums of Digestive Tablets, and a quantity of repacked tablets. Default decree of condemnation and destruction. (F. D. C. No. 16093. Sample Nos. 4122-H, 4123-H.)

LABEL FILED: May 1, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 8, 1945, by Enzyme Therapys, from Los Angeles, Calif.

PRODUCT: 3 drums, each containing 20,000 *digestive tablets*, and a quantity of repacked tablets at Chalfont, Pa. Examination of the product showed that it consisted essentially of calcium carbonate, citric acid, and papain.

LABEL, IN PART: (Drum) "Tablets Each Tablet Contains Digestive Tablets W/D CT 13½ gr. 200 i. u. D Calcium 9 gr. Papain 1 gr. Citric Ac. 1 gr. Binder q. s."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Digestive" on the drum label was false and misleading since the article would not be effective in promoting digestion; Section 502 (b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; Section 502 (e), the label failed to bear the common or usual name of each of its several active ingredients since calcium is not the common or usual name of calcium carbonate; and, Section 502 (f), the label failed to bear adequate directions for use.

DISPOSITION: September 27, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1756. Misbranding of "Jarabe Calmante de la Sra. Winslow-Laxante" (Mrs. Winslow's Soothing Syrup). U. S. v. 30 Gross of "Jarabe Calmante de la Sra. Winslow-Laxante" (Mrs. Winslow's Soothing Syrup). Default decree of forfeiture and destruction. (F. D. C. No. 12720. Sample No. 33161-F.)

LABEL FILED: July 12, 1944; amended August 22, 1944, District of Puerto Rico.

ALLEGED SHIPMENT: On or about October 23, 1943, by the Anglo-American Drug Co., from New York, N. Y.

PRODUCT: 30 gross of 45-cc. bottles of *soothing syrup* at Santurce, P. R.

Examination showed that the product was a syrupy liquid containing laxative drugs such as rhubarb and senna, flavored with essential oils such as anise oil.

LABEL, IN PART: (Translated from the Spanish) "Each bottle contains 45 cubic centimeters of the following formula: Fluidextract of Rhubarb, 0.03—Fluidextract of Senna, 0.19—Sodium Citrate, 1.50—Sodium bicarbonate, 0.17—Glucose, 31.20—Anise Oil, 0.05 cc.—Caraway-seed Oil, 0.03 cc.—Coriander Oil, 0.01 cc.—Fennel Oil, 0.07 cc.—Glycerine, 2.8 cc.—water sufficient to make 45 cubic centimeters."

NATURE OF CHARGE: Misbranding, Section 502(a), the designation, "Jarabe Calmante" (soothing syrup), which appeared upon the wrapper, bottle label, and circular wrapped around the bottle, was false and misleading since the effect of the article would not be soothing; and certain statements in the labeling were false and misleading since they represented and suggested that the article was harmless and would be an effective and appropriate treatment for

colics, diarrhea, vomiting, congestions, fevers, gastric indigestion in children, stomach acidity, and constipation. The article, which contained irritant cathartic drugs, was not harmless and would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502(a), the following statement (translated from the Spanish) in the circular was misleading since it created the impression that the article contained no harmful and deleterious drugs: "To mothers so they may know the true quality of Mrs. Winslow's Soothing Syrup we describe as follows the ingredients and you will notice that it does not contain opium, morphine, alcohol, strong purgatives or other substances harmful to children." The article contained cathartic drugs which might be harmful.

Further misbranding, Section 502(a), the following statements (translated from the Spanish) in the circular were false and misleading since neither the formula nor the ingredients have been approved by the Department of Public Health of the United States: "Its formula and ingredients have been approved by all the Departments of Public Health of the different countries of North and South America"; and the statement on the wrapper, "Puramente vegetal," was false and misleading since the ingredients sodium bicarbonate and sodium citrate are not vegetal.

Section 502(f) (2), the labeling failed to bear adequate warnings against administration of the article in case of abdominal pain, nausea, vomiting, or other symptom of appendicitis, or warning that the frequent and continued use of the article might result in dependence upon laxatives to move the bowels.

DISPOSITION: December 21, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed. The containers were ordered salvaged and delivered to the Anglo-American Drug Co.

1757. Misbranding of Testavins. U. S. v. 57 Bottles and 35½ Dozen Bottles of Testavins. Default decrees of condemnation and destruction. (F. D. C. Nos. 16488, 16651. Sample Nos. 455-H, 22966-H.)

LIBELS FILED: June 21 and 28, 1945, Eastern District of Missouri and Northern District of Georgia.

ALLEGED SHIPMENT: On or about April 6 and May 10, 1945, by the Veltex Co., from Birmingham, Ala.

PRODUCT: 57 100-tablet bottles of *Testavins* at St. Louis, Mo., and 23¾ dozen 20-tablet bottles and 11¾ dozen 100-tablet bottles of *Testavins* at Atlanta, Ga. Examination showed that the article had essentially the composition claimed on the label.

LABEL, IN PART: "Testavins 100 [or "20"] Tablets Indicated in Functional Impotence of Neurasthenic Origin * * * Each Tablet Contains: Vitamin B₁ . . . 666 U. S. P. Units Yohimbin Hydrochloride 0.0005 Gram Orchic Substance 0.05 Gram Calcium Glycerophosphate 0.15 Gram Sodium Glycerophosphate 0.15 Gram Extract Nux Vomica 0.03 Gram Distributed by Vitamin Park * * * New York City."

NATURE OF CHARGE: Misbranding, Section 502 (a), all lots. The label statements, "Indicated in Functional Impotence of Neurasthenic Origin * * * Take 2 to 3 Tablets depending upon age and severity of Case," were false and misleading since the article would not be effective for impotence.

Further misbranding, Atlanta lot. Section 502 (a), the label statement, "Each Tablet Contains * * * Orchic Substance 0.05 Gram," was misleading since it failed to reveal the material fact that orchic substance possesses no therapeutic activity when taken by mouth; Section 502 (e), the label failed to bear a statement of the quantity or proportion of the strychnine contained in the article; and, Section 502 (f) (2), the label failed to warn that, in view of the yohimbine hydrochloride present, the article should not be taken by those suffering from heart disease, high blood pressure, or kidney disease, and that an article containing nux vomica might be dangerous, especially when used by elderly persons, and it also failed to warn that the use of a product containing yohimbine hydrochloride should be discontinued if stomach disturbance, nausea, vomiting, vertigo, or fainting occur.

DISPOSITION: July 27 and August 1, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.