

rial. The carton was nearly 1 inch taller than was necessary to hold the bottle and sample.

The article was alleged to be misbranded in that its labeling was false and misleading since it created the impression that the article, by virtue of its physiological activity, would have a substantial effect in the control of body weight, would enable one to arrive at a satisfactory weight, would enable one to attain an ideal and slender form, and would cause one to lose ugly fat, feel better and look better; whereas it would not be efficacious for such purposes.

It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use of the Venus Tablets and V-76 Laxative Tablets and failed to bear adequate warnings against their use by children or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. It was alleged to be misbranded further in that its container, i. e., carton, was so made, formed, or filled as to be misleading.

On October 21, 1940, and May 13, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**344. Misbranding of Wittone. U. S. v. 180 Dozen Bottles of Wittone. Default decree of condemnation and destruction. (F. D. C. No. 2331. Sample No. 1662-E.)**

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. Its labeling was further objectionable because of misleading representations regarding the quantities of certain minerals present, regarding its alleged tonic effects and because of failure to bear adequate directions and adequate warnings as required by law.

On July 8, 1940, the United States attorney for the District of Columbia filed a libel against 180 dozen bottles of Wittone at Washington, D. C., alleging that the article was being offered for sale in the District of Columbia at the Wittone Sales Agency of United Distributors, Inc., of Louisville, Ky., at Washington, D. C.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a water solution of Epsom salt (29.5 grams per 100 cc.) together with essentially inconsequential proportions of iron and ammonium citrate (0.8 gram per 100 cc.), sodium salicylate (0.5 gram per 100 cc.), sodium phosphate (0.7 gram per 100 cc.), sodium bicarbonate, and flavoring materials.

The article was alleged to be misbranded in that representations in the labeling that it was efficacious for the health, would help one eat well, sleep well, and keep well; that it was efficacious in bilious spells, dizziness, headaches, sour stomach, dull tired-out feeling, coated tongue, bad taste, and loss of appetite; that it was efficacious to correct the results of over-indulgence and constipation; would correct the cause of restless nights; that it was a mild diuretic and would stimulate elimination of urea and uric acid, regulate elimination, keep the system free from impurities, aid the blood, and cleanse the intestinal tract, were false and misleading since it would not be efficacious for such purposes.

It was alleged to be misbranded further in that the word "Tone," forming a part of the name "Wittone" appearing in the labeling, was false and misleading because the article contained no significant amount of tonic ingredient and would not act as a tonic. It was alleged to be misbranded further in that the statements in the labeling, "Ingredients—Epsom Salts (Magnesium Sulphate), 3.3 oz. Iron and Ammonium Citrate, 40 grs.; Sodium Salicylate, 27 grs.; Sodium Phosphate, 27 grs.; Sodium Bicarbonate, 40 grs.; Oil of Cassia, 2 $\frac{7}{10}$  min.; Oil of Cloves,  $\frac{9}{10}$  min.; Saccharine, 3 $\frac{3}{10}$  min.," were false and misleading since they failed to reveal the material fact that the amounts of iron and ammonium citrate, sodium salicylate, sodium phosphate, and sodium bicarbonate in the product, were in inconsequential proportions when the medicine was consumed in accordance with the directions in the labeling.

It was alleged to be misbranded further in that the statements in the labeling, (contact card) "Please Contact: Name \_\_\_\_\_ Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ I am confident he will be relieved of \_\_\_\_\_ through the consistent use of Wittone as I have been benefited," and the statements (business reply card) "Wittone Representative: I would like to use Wittone. Please deliver to me a bottle of your Famous and Celebrated Medicine for I believe Wittone will benefit me as it has countless other suffering people," were false and misleading since it was not efficacious for the purposes recommended.

It was alleged to be misbranded further in that the labeling failed to bear adequate directions for use since the directions appearing on the bottle, as follows, "Adults—1 to 2 tablespoonfuls once or twice a day in water before

eating. Children—1 teaspoonful to a tablespoonful as above. General Directions. Wittone is full-strength, with a pure, sharp taste. Adults should take About two tablespoonfuls twice a day in a glass of water before eating. Please note we say 'about' two tablespoonfuls. We say this because we do not believe it is possible to prepare directions which will fit all people. Perhaps you should take a trifle more than two tablespoonfuls as your dose. Or, you may find that less than two tablespoonfuls is your proper dose. You can easily determine this soon after you start using the medicine and should then continue to take your proper dose twice daily. Laxatives should not be used continuously so that the bowels may resume their normal action. For Children up to 10 years of age, two teaspoonfuls more or less, two times a day as for adults, later reducing to one dose per day for a sufficient period," were not appropriate for the product and were not adequate.

It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health and against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users since there was no warning against the administration of the medicine to young children to whom its use might be dangerous nor against frequent or continued use of the article which might result in the establishment of dependence upon laxatives.

On August 16, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

#### CRIMINAL PROSECUTIONS

**345. Adulteration and misbranding of Heron's Pure Eucalyptus Oil. U. S. v. Norman C. Heron (N. C. Heron Co.). Tried to the court and jury. Verdict of guilty. Fine, \$300. (F. D. C. No. 2091. Sample No. 97364-D.)**

This product did not meet the requirements of the United States Pharmacopoeia for eucalyptus oil. Its labeling also bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter.

On September 12, 1940, the United States attorney for the Southern District of California filed an information against Norman C. Heron, trading as N. C. Heron Co., Los Angeles, Calif., alleging shipment on or about November 23, 1939, from the State of California into the State of Idaho, of a quantity of Heron's Pure Eucalyptus Oil which was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia but its strength differed from, and its quality and purity fell below, the standard set forth in that compendium in that it contained not more than 68 percent of eucalyptol and was not soluble in 5 volumes of 70 percent alcohol; whereas the United States Pharmacopoeia provides that eucalyptus oil shall contain not less than 70 percent of eucalyptus and shall be soluble in 5 volumes of 70 percent alcohol, and the difference in strength, quality, and purity of the article from the standard for eucalyptus oil set forth in the said compendium was not stated plainly on its label.

The article was alleged to be misbranded in that the statements borne on the bottle label were false and misleading since they represented that it was pure eucalyptus oil; that it was an all-around family remedy, and was efficacious for internal or external use from the youngest to the oldest; that said article, when used alone or in connection with Heron's Liver Regulator, had no equal in the treatment of Bright's disease and diabetes; that it was the only remedy without an enemy, implying that it was a remedy approved by everyone; that it was efficacious in the treatment of anything that originated from a cold; that it was efficacious in the treatment of cough, whooping cough, croup, sore throat, diphtheria, pleurisy, pneumonia, fever, stomach and kidney troubles, diabetes, catarrh, asthma, bronchitis, headache, earache, toothache, neuralgia, burns, poison oak, wounds of all kinds, consumption in its first stages, fever of all kinds, rheumatism, gravel, dyspepsia, kidney disease, and cuts; whereas it was not pure eucalyptus oil and was not efficacious for the said purposes.

On October 25, 1940, the defendant having entered a plea of not guilty, the case came on for trial before the court and jury. The trial was concluded