

National Formulary does not recognize the name "Ampul Sterile Solution Sodium Citrate, 2½%."

Between February 26 and April 26, 1943, no claim having been presented for the release of the product, judgments of condemnation were entered and it was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1103. Misbranding of Formula No. 1520. U. S. v. 2 Cases of Formula No. 1520. Default decree of condemnation and destruction. (F. D. C. No. 10259. Sample No. 22782-F.)

On July 15, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 cases of Formula No. 1520 at Philadelphia, Pa., alleging that the article had been shipped on or about June 11, 1943, from New York, N. Y., by J. L. Hopkins and Company; and charging that it was misbranded.

The article consisted of a mixture of Epsom salt, sulfur, baking soda, and plant drugs including senna.

It was alleged to be misbranded (1) in that its label failed to bear the common or usual name of each active ingredient; (2) in that its label failed to bear adequate directions for use since no directions for use appeared on the label; (3) in that its label failed to bear adequate warnings against use since the article was a laxative and its label failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (4) in that its label failed to bear adequate warnings against unsafe duration of administration since its label failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On August 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1104. Misbranding of mixed drugs. U. S. v. 4 Cartons of Mixed Drugs. Default decree of condemnation and destruction. (F. D. C. No. 10139. Sample No. 22779-F.)

On June 23, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against an article consisting of 4 cartons containing 2 unlabeled packages (about 10 pounds each) of mixed drugs, 9 1-pound packages of powdered sugar, and miscellaneous labeling, at Philadelphia, Pa., alleging that the article had been shipped on or about June 9, 1943, from New York, N. Y., by Elsie Bleeker; and charging that it was misbranded. The cartons, some of which bore the name "Natura," others "Nu-Vita," all carried the statement: "Contents: Licorice, Sulphur, Cascara Sag., Senna, Bicarb. Soda, Magnesium Sulphate, USP, Sugar."

Examination of the unlabeled mixed drugs showed that they contained senna, Epsom salt (magnesium sulfate), sodium bicarbonate, and sulfur.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it was an effective treatment for low or high blood pressure, rheumatism, backache, getting up nights, child bed-wetting, and swollen feet; that it was an "Herb Powder"; and that it was a product of either Mexico or America. It was alleged to be misbranded further (1) in that it 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; (2) in that its label failed to bear the common or usual name of each active ingredient of the preparation; (3) in that its labeling failed to bear adequate directions for use since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and (4) in that its labeling failed to bear adequate warnings against unsafe duration of administration since its labeling failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On July 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1105. Misbranding of Dr. Sibbett's Improved Big Six and Original Big Six. U. S. v. 23½ Dozen Bottles and 3¾ Dozen Bottles of Dr. Sibbett's Improved Big Six, and 1¾ Dozen Bottles of Dr. Sibbett's Original Big Six. Default decree of condemnation and destruction. (F. D. C. No. 9985. Sample Nos. 37874-F, 37675-F.)

On May 21, 1943, the United States attorney for the Eastern District of Michigan filed a libel against 23½ dozen bottles, each containing 3 fluid ounces, and

3¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Improved Big Six; and 1¾ dozen bottles, each containing 6 fluid ounces, of Dr. Sibbett's Original Big Six at Detroit, Mich.; alleging that the articles had been shipped by the Sibbett Medicine Co., Cleveland, Ohio, on or about April 9, 1943; and charging that they were misbranded.

Examination disclosed that the articles were of the same composition, consisting essentially of 227 grains of Epsom salt per fluid ounce, together with small amounts of ammonium chloride, caffeine citrate, tincture of ferric chloride, and oil of lemon in water.

The articles were alleged to be misbranded in that the statements appearing on their labels which represented and suggested that the articles would be effective in relieving colds and headaches; that they contained quinine sulfate and glycerin; and that they contained solution of iron (tincture of iron chloride), citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients, were false and misleading since the articles would not be effective in relieving colds and headaches, did not contain quinine sulfate and glycerin, and did not contain solution of iron, citric acid, caffeine citrate, and oil of lemon in amounts sufficient to constitute active ingredients. The articles were alleged to be misbranded further (1) in that the words, statements, and information required by the law to appear on the label or labeling were not prominently placed thereon with such conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the required words, statements, and other information were obscured by a red figure 6 covering the main portion of the label, except the firm's name and address; and (2) in that the labeling failed to bear adequate directions for use, since the articles were laxatives and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously.

On July 16, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS³

1106. Adulteration and misbranding of "Be" Bex, and misbranding of Hi-Test Pine Extract. U. S. v. Oxford Products, Inc., and Jerome H. Rose. Pleas of guilty. Fine of \$300 and costs imposed against each defendant; sentence against corporate defendant suspended. (F. D. C. No. 9673. Sample Nos. 6725-F, 8706-F.)

On September 16, 1943, the United States attorney for the Northern District of Ohio filed an information against Oxford Products, Inc., Cleveland, Ohio, and Jerome H. Rose, president of the corporation, alleging shipment from the State of Ohio into the State of Iowa of a quantity of "Be" Bex, on or about December 23, 1942, and from the State of Ohio into the State of Missouri of a quantity of Hi-Test Pine Extract, on or about January 16, 1943.

Analysis of the "Be" Bex disclosed that it contained approximately 330 International Units of vitamin B₁ per fluid ounce. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, since it was represented to contain 660 International Units of vitamin B₁ per fluid ounce, whereas it contained less than that amount. It was alleged to be misbranded because of false and misleading statements on its label which represented and suggested that the article would aid in promoting the appetite and in protecting the body from nerve disorder resulting from vitamin deficiency; that it would be efficacious in the cure, mitigation, treatment, or prevention of retarded growth, constipation, migraine headaches, and nutritional anemia; and that it would be helpful in the promotion of greater vigor, better functional digestion, and wholesomeness of the skin. It was alleged to be misbranded further in that the statements on its label were misleading which represented and suggested that poor appetite, nerve disorder, retarded growth, constipation, migraine headaches, nutritional anemia, lack of vigor, poor digestion, and unwholesomeness of the skin were usually caused by lack of the vitamins contained in the article; and that the user might reasonably expect correction and alleviation of those conditions by the use of the article, whereas such conditions are not usually caused by lack of the vitamins contained in the article, but usually result from other causes, and the user might not

³ See also No. 1102.