

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