quate directions for use since the directions appearing on the label provided for an excessive amount of acetanilid and were therefore not adequate for an article of such composition; (3) in that its labeling failed to bear such adequate warnings against use by children, and in those pathological conditions wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and since the article contained acetanilid and its labeling failed to warn against use by children; (4) in that its labeling failed to bear such adequate warnings against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that frequent or continued use of a preparation containing acetanilid might cause serious blood disturbances, anemia, collapse, or a dependence on the drug, and since its labeling also failed to warn that frequent or continued use of a laxative might result in dependence upon laxatives; and (5) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling thereof, since the article, when taken in accordance with the directions appearing on the labeling, "Directions Adults: Take 2 tablets every 2 or 3 hours until bowels move freely, then take 1 or 2 tablets 3 or 4 times a day until relieved. Warning! Do Not Take More Than Six Tablets In Any Twenty-Four Hour Period," would provide, even with the limitation of 6 tablets a day, a maximum of 9 grains of acetanilid a day for an indefinite period of time, and was dangerous to health.

On April 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

952. Misbranding of triple bromide tablets. U. S. v. 11⅔ Dozen Packages of Triple Bromide Tablets. Decree of condemnation and destruction. (F. D. C. No. 8967. Sample No. 17109–F.)

On December 5, 1942, the United States attorney for the Northern District of New York filed a libel against 11⅔ dozen packages of triple bromide tablets at Albany, N. Y., alleging that the article had been shipped in interstate commerce on or about September 21, 1942, from Chicago, Ill., by the Savoy Drug & Chemical Co.; and charging that it was misbranded. The article was labeled in part: "Wards 50 Triple Bromide Tablets * * * Distributed by Montgomery Ward & Co."

Examination showed that the article contained a total of 15 grains per tablet of the combined sodium, potassium, and ammonium bromides.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling thereof, "Adult Dose: One tablet three times daily."

On January 23, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

953. Adulteration and misbranding of solution of magnesium citrate. U. S. v. 222 Bottles of Effervescing Solution Citrated Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 8388. Sample No. 19441–F.)

This product was sold under a name recognized in the United States Pharmacopoeia and its strength, quality, and purity differed from the standard prescribed in such authority. It was a laxative and its labeling failed to warn that it should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, or that frequent or continued use might result in dependence upon a laxative to move the bowels.

On September 22, 1942, the United States attorney for the District of Rhode Island filed a libel against 222 bottles of the above-named product at Providence, R. I., alleging that the article had been shipped on or about August 5, 1942, by the White-Stone Laboratories from Boston, Mass.; and charging that it 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, an official compendium, and its strength differed from and its

*See also No. 951.

quality and purity fell below the standard set forth therein since it did not contain, in each 100 cc., magnesium citrate corresponding to not less than 1.6 grams of magnesium oxide, as provided in the Pharmacopoeia, but contained Epsom salt (magnesium sulfate) corresponding to 1.14 grams of magnesium oxide per 100 cc.; and it possessed 1/16 of the quantity of citric acid and approximately ½ of the quantity of sucrose required in the Pharmacopoeia for solution of magnesium citrate.

It was alleged to be misbranded in that is labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

On October 19, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

954. Adulteration and misbranding of miscellaneous drugs. U. S. v. 223 Cases of Miscellaneous Foods, Drugs, and Cosmetics. Decree of condemnation. Products ordered released under bond for reprocessing and relabeling good portion. (F. D. C. No. 8509. Sample No. 28246–F.)

Some of these products had been water-damaged and others were very old and deteriorated. They included, among other items, proprietary medicines and surgical dressings.

On October 5, 1942, the United States attorney for the Northern District of Georgia filed a libel against 223 cases of miscellaneous foods, drugs, and cosmetics at Atlanta, Ga., alleging that the articles had been shipped on or about September 16, 1942, by Wells and Harris from Norfolk, Va.; and charging that the drug items were adulterated and misbranded.

The drug items were alleged to be adulterated in that water had been mixed therewith so as to reduce their quality.

They were alleged to be misbranded (1) in that the labeling of some of the items contained false and misleading statements regarding the curative or therapeutic effects of the articles; (2) in that some of the items failed to bear labels containing an accurate statement of the quantity of contents of the packages; (3) in that the labels of some of the items did not bear the common or usual name of the active ingredients of the articles; and (4) in that the labeling of some of the items did not bear adequate warnings against use in those pathological conditions wherein their use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

The food and cosmetic items were alleged to be adulterated under the provisions of the law applicable to foods and cosmetics as reported in the notices of judgment on foods and on cosmetics.

On October 12, 1942, John W. Harris, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the products were ordered released under bond for segregation and destruction of the unfit portion, and for reprocessing and relabeling of the good portion under the supervision of the Food and Drug Administration.

955. Misbranding of Bi-Sal Tablets. U. S. v. 237 Bottles of Bi-Sal Tablets. Default decree of condemnation and destruction. (F. D. C. No. 9051. Sample No. 37708–F.)

On December 24, 1942, the United States attorney for the Northern District of Illinois filed a libel against 237 bottles of Bi-Sal Tablets at Chicago, Ill., alleging that the article had been shipped on December 3, 1942, in interstate commerce from Cleveland, Ohio, by Oxford Products, Inc.; and charging that it was misbranded.

Analysis showed that the article contained phenolphthalein, extracts of plant drugs, including capsicum (cayenne pepper), bile extract, and an alkaloid-bearing drug, such as nux vomica.

The article was alleged to be misbranded in that the name "Panogestic Enzymes with Bile Salts Compound" was misleading since the article was essentially a laxative and its physiologic effect was due principally to phenolphthalein, which is neither an enzyme nor a bile constituent, but is a coal tar derivative. The article was alleged to be misbranded further (1) in that the statement appearing in its labeling, "This combination is used * * * in certain forms of Gall Bladder and Bile Duct Infections," was false and misleading since the statement represented and suggested that the article was effective in the treatment of certain forms of gall bladder and bile duct infections, whereas it was not an effective