

of the liver cells; that it would improve digestion and assimilation; and that it would be efficacious in the prevention of premature old age, rheumatism, high blood pressure, Bright's disease, diabetes, and constant headaches, and would produce normal bowel movements. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the directions suggested continuous use of the article, whereas laxative preparations should not be used continuously, and the directions were not explicit with respect to the dosage for children; and in that its labeling failed to bear such adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or against unsafe dosages or methods or duration of administration, in such manner and form as are necessary for the protection of users, since the article contained laxatives, phenolphthalein and emodin-bearing drugs, and its labeling failed to bear a warning that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and it did not bear a warning that frequent or continued use might result in dependence upon laxatives.

On November 8, 1943, the defendants having entered pleas of nolo contendere, the court imposed a fine of \$150 against each defendant.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1012. Adulteration and misbranding of salicylate soda, strychnine sulfate, Rheumatic No. 3, phenobarbital tablets, and acetanilid, caffeine and sodium salicylate compound tablets. U. S. v. Charles Killgore Co., Inc. Plea of guilty. Fine, \$1,000. (F. D. C. No. 7659. Sample Nos. 84880-E, 84881-E, 84943-E, 84944-E, 90441-E.)

The Rheumatic No. 3 Tablets and the acetanilid, caffeine and sodium salicylate compound tablets differed from their own declared standards of strength and quality. The remainder of the products were sold under names recognized in the National Formulary and differed in strength from the standards prescribed in that compendium.

On April 5, 1943, the United States attorney for the Southern District of New York filed an information against the Charles Killgore Co., Inc., Yonkers, N. Y., alleging shipments on September 8 and December 1 and 4, 1941, from the State of New York into the States of Connecticut, New Jersey, and Rhode Island of quantities of the above-named drugs which were adulterated and misbranded.

The salicylate soda tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 89 percent of the labeled amount of sodium salicylate, whereas the National Formulary provides that tablets of sodium salicylate shall contain not less than 91 percent of the labeled amount; and their difference in strength from the standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Salicylate Soda 5 grains," appearing on the label, was false and misleading.

The strychnine sulfate tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which, tablets of strychnine sulfate, is recognized in the National Formulary, but their strength differed from the standard set forth in that compendium since each tablet contained the equivalent of not more than 79.2 percent of the labeled amount of strychnine sulfate, whereas the National Formulary provides that tablets of strychnine sulfate of this size shall contain not less than 91 percent of the labeled amount of strychnine sulfate; and their difference in strength from the standard was not plainly stated on their label. They were alleged to be misbranded in that the statement "Strychnine Sulph 1-30 gr.," appearing on the label, was false and misleading.

The Rheumatic No. 3 Tablets were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since each tablet was represented to contain $7\frac{1}{2}$ grains of soda salicylate, i. e., sodium salicylate, whereas each tablet contained not more than 6.18 grains of sodium salicylate. They were alleged to be misbranded in that the statement "Soda Salicylate $7\frac{1}{2}$ grs.," appearing on the label, was false and misleading.

The phenobarbital tablets were alleged to be adulterated in that they purported to be and were represented as a drug the name of which is recognized in the

*See also Nos. 1002, 1003.

National Formulary, but their strength differed from the standard set forth in that compendium, since each table contained the equivalent of not more than 85.1 percent of the labeled amount of phenobarbital, whereas the National Formulary provides that tablets of phenobarbital of this size shall contain not less than 92.5 percent of the labeled amount of phenobarbital; and their difference in strength from the standard was not plainly stated on the label. They were alleged to be misbranded in that the statement "Phenobarbital 1½ gr.," appearing on the label, was false and misleading.

The acetanilid, caffeine and sodium salicylate compound tablets were alleged to be adulterated in that their strength differed from and their quality fell below that which they purported and were represented to possess, since each tablet was represented to contain 2½ grains of acetanilid and 1¾ grains of sodium salicylate, whereas each tablet contained not more than 2.22 grains of acetanilid and not more than 1.19 grains of sodium salicylate. They were alleged to be misbranded in that the statement, "Acetanilid 2 1-2 grs. * * * Sodium Salicylate 1, 3-4 grs.," appearing on the label, was false and misleading.

On May 28, 1943, the defendant having changed his original plea of not guilty to a plea of guilty, the court imposed a fine of \$1,000.

1013. Adulteration and misbranding of Sun-Glow Cod Liver Oil Concentrate Tablets. U. S. v. Brewer & Co., Inc. Plea of guilty. Fine, \$150. (F. D. C. No. 7306. Sample No. 75736-E.)

On October 8, 1942, the United States attorney for the District of Massachusetts filed an information against Brewer & Co., Inc., Worcester, Mass., alleging shipment on or about July 15, 1941, from the State of Massachusetts into the State of Maine of a quantity of the above-named product.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it purported and was represented to contain not less than 3,140 U. S. P. XI units of vitamin A and not less than 314 U. S. P. XI units of vitamin D per tablet, whereas it contained not more than 2,740 U. S. P. XI units of vitamin A and not more than 235 U. S. P. XI units of vitamin D per tablet. It was alleged to be misbranded in that the statements in its labeling, "Each tablet contains not less than 3140 U. S. P. XI units Vitamin A and 314 units Vitamin D," and "These tablets are biologically standardized to contain not less than 3140 U. S. P. XI units Vitamin A and 314 U. S. P. XI units Vitamin D per tablet. * * *," were false and misleading; and in that the statements in its labeling which represented and suggested that it would be efficacious in the prevention and treatment of disease in man by increasing general resistance and toning the system, and that it would develop strong bones and good teeth, were false and misleading since it would not be efficacious for such purposes.

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in the notices of judgment on foods.

On October 5, 1943, the defendant having entered a plea of guilty, the court imposed a fine of \$150.

1014. Adulteration and misbranding of Analgesic Tablets, boric acid compound ointment, Boro-Oxyquinoline Compound Vaginal Suppositories, aspirin tablets, and Eye Unguent, and misbranding of Hexamide Compound No. 1. U. S. v. McDonald Pharmacal Co., Inc., and Edmund L. McDonald. Pleas of guilty. Fines, \$50. (F. D. C. No. 8758. Sample Nos. 76713-E, 76714-E, 76735-E, 76890-E, 76893-E, 76928-E.)

The aspirin tablets differed from the requirements of the National Formulary; the Hexamide Compound No. 1 bore on its labeling false and misleading therapeutic claims; and the remaining products differed from their declared standards.

On April 6, 1943, the United States attorney for the District of Minnesota filed an information against the McDonald Pharmacal Co., Inc., St. Paul, Minn., and Edmund L. McDonald, alleging shipment within the period from on or about December 10, 1941, to on or about April 15, 1942, from the State of Minnesota into the State of South Dakota of a quantity of Hexamide Compound No. 1 which was misbranded, and into the State of Iowa of a quantity of Boro-Oxyquinoline Compound Vaginal Suppositories, and into the State of Wisconsin of quantities of the other above-named products which were adulterated and misbranded.

Adulteration of the Analgesic Tablets was alleged in that their strength differed from and their quality fell below that which they were represented to possess since they were represented to contain in each tablet 3 grains of aspirin, 2 grains of acetphenetidin, and ½ grain of caffeine citrate, whereas they contained in each tablet not more than 2.38 grains of aspirin, not more than 1.60 grains of acetphenetidin, and not more than 0.40 grain of caffeine citrate. They