ounce Herbs—including Senna, Buchu, Juniper Berries, Rhubarb, Jalap; Magnesium Sulphate, Cascara, & Iron (Ferric Chloride)," were misleading since they failed to reveal the fact that the physiological effects of the article were due essentially to its content of Epsom salt (magnesium sulfate), senna, and cascara sagrada; (4) in that the label failed to bear the common or usual name of each active ingredient, since magnesium sulfate is not the common or usual name of Epsom salt; and (5) in that its label failed to bear the name and quantities or proportions of strychnine, atropine, hyoscine, and hyoscyamine that were present.

On March 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

715. Misbranding of Starr's Wonderful M. L. & K. Pills. U. S. v. Fred Marion Starr (Starr Medicine Co.). Plea of nolo contendere. Fine, $100. (F. D. C. No. 6415. Sample No. 30265–E.)

The labeling of this product, in addition to failure to bear adequate warning statements, contained false and misleading claims and failed to bear the required ingredient and accurate quantity of contents statements.

On March 24, 1942, the United States attorney for the Northern District of California filed an information against Fred Marion Starr, trading as the Starr Medicine Co. at San Francisco, Calif., alleging shipment on or about February 18, 1941, from the State of California into the State of Illinois of a quantity of the above-named product that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs, including a laxative drug, coated with calcium carbonate.

It was alleged to be misbranded: (1) In that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative drug, and the labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements on the label, representing that it would be efficacious in the treatment of weak back, liver and kidney complaints, biliousness, fever, headaches, and indigestion were false and misleading since it would not be efficacious for such purposes. (3) In that it was fabricated from two or more ingredients and its label did not bear a statement of the common or usual name of each active ingredient. (4) In that it was in package form and did not bear a label containing an accurate statement of the quantity of contents in terms of numerical count.

On April 6, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of $100.

716. Misbranding of Weltone. U. S. v. 4 Cartons of Weltone and Accompanying Circulars. Default decree of condemnation and destruction. (F. D. C. No. 6792. Sample No. 70631–E.)

The labeling of this product failed to bear adequate directions for use and also bore false and misleading curative and therapeutic claims.

On January 31, 1942, the United States attorney for the Middle District of North Carolina filed a libel against 4 cartons (144 bottles) of Weltone and accompanying circulars, alleging that the article had been shipped in interstate commerce on or about January 10, 1942, by Standard Chemical, Inc., from Brooklyn, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted of a water solution of Epsom salt (28 percent) with inconsequential amounts of other salts, flavored with cassia and clove oils and sweetened with saccharin.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since the following directions "Adults, about one to two tablespoonfuls twice daily in water before meals. Children (7 years or older): One teaspoonful in water before meals," provided for continued use, which might result in dependence upon laxatives. (2) In that the syllable "tone" forming a part of its name and the statements in an accompanying circular which represented that it would increase the appetite, prevent or cure headaches or run-down feeling, establish regularity in elimination, correct sluggish digestion, remedy incomplete elimination or sour stomach, prevent weakening run-down feeling due to constipation; that a periodic dose would

always help one; that it would eliminate any danger to general health or assist in digestive processes, would help one to feel his best, would not cause shock or strain or weakening aftereffects and would be good for every member of the family; and that unusual benefits would be derived from its use, were false and misleading since it possessed no tonic properties but was merely a laxative; it would not accomplish the results claimed, it might cause shock, strain, and weakening aftereffects; it would not necessarily be good for every member of the family; and there was nothing unusual about any benefits it might give. (3) In that the statement "Weltone Laxative is labeled in compliance with the Federal Food, Drug and Cosmetic Act" was false and misleading.

On April 17, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS

717. Adulteration and misbranding of Endocrine Extract Formula Nos. 2, 131, and 157; misbranding of Colloidal Dextro Calcium Bleything. U. S. v. The Bleything Laboratories. Plea of guilty. Fine, $520. (F. D. C. No. 4150. Sample Nos. 44102–E, 44425–E, 65833–E to 65835–E, incl.)

This case involved three shipments of endocrine extracts that were deficient in potency, and one of colloidal dextro calcium that contained a smaller amount of calcium than that indicated and implied in the labeling.

On April 28, 1942, the United States attorney for the Southern District of California filed an information against the Bleything Laboratories, a corporation at Los Angeles, Calif., alleging shipment within the period from on or about October 17, 1940, to on or about July 2, 1941, from the State of California into the State of Colorado of quantities of endocrine extracts that were adulterated and misbranded, and of colloidal dextro calcium that was misbranded.

Endocrine Extract Formula No. 2 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 was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 20 milligrams of the crystalline principle of entire ovary; whereas it contained no detectable amount of the crystalline principle of thyroid or of entire ovary. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Entire Ovary . . . 20 mgm.," were false and misleading.

Formula No. 131 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 was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid and 10 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amount of the crystalline principle of the thyroid or of the male orchic gland. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. * * * Male Orchic . . . 10 mgm.," were false and misleading.

Formula No. 157 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 was represented to contain in each 33 cc., 3 milligrams of the crystalline principle of thyroid, 10 milligrams of the crystalline principle of the pineal gland, and 5 milligrams of the crystalline principle of the male orchic gland; whereas it contained no detectable amounts of the crystalline principles of the thyroid, pineal, or male orchic glands. It was alleged to be misbranded in that the statements in the labeling, "Endocrine Extract * * * For Sublingual Use * * * Extracted principles of glands from government inspected animals and distilled water. * * * Extracted Crystalline Principles of the following glands: Thyroid . . . 3 mgm. Pineal . . . 10 mgm. * * * Male Orchic . . . 5 mgm.," were false and misleading.

The colloidal dextro calcium was alleged to be misbranded; (1) In that the statements, (bottle label) "Colloidal Dextro Calcium Bleything * * * Dosage: One teaspoonful three times daily before meals. May be taken in milk or