The article in the original drum was alleged to be misbranded in that its labeling did not bear adequate directions for use, since there were no directions for use on the drum; and in that it had been fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient. The repackaged product was alleged to be misbranded in that statements in the labeling which represented that it would be efficacious in the treatment of chest colds, head colds, sore throat, croup due to colds, pneumonia, rheumatism, all skin diseases, dry, tickling coughs, sinus trouble, hay fever, flu, and that it would penetrate and relieve congestion, were false and misleading since it would not be efficacious for such purposes.

On August 7, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

613. Misbranding of Comfortt Tablets. U. S. v. 196 Boxes each containing 12 Comfortt Tablets. Default decree of condemnation and destruction. (F. D. C. No. 4895. Sample No. 65614–E.)

These tablets, which contained acetophenetidin, aspirin, and caffeine, originally were shipped in bulk, but subsequently were repackaged by the consignee. After such repackaging, the labeling in addition to failure to bear adequate directions for use and the required warning statements, also failed to declare the aspirin present by its common or usual name.

On June 10, 1941, the United States attorney for the District of Colorado filed a libel against the above-named product, alleging that on or about March 30, 1940, a consignment of a drug product labeled in part "Special Compressed Tablets R/2020 Eng. Comfortt" had been shipped from St. Louis, Mo., to College Laboratories, Inc., Denver, Colo., and that thereafter the latter firm had repackaged said product in boxes labeled in part "Comfortt Tablets"; and charging that as so repackaged it was misbranded as follows:

(1) In that it failed to bear adequate directions for use since those appearing on the box, namely, "Take one tablet and repeat in 30 minutes if needed, then one every 2 hours if needed. See your physician promptly if not relieved," did not limit dosage; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where 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, since it failed to warn that frequent or continued use might be dangerous, causing serious blood disturbances, and that not more than the recommended dose should be taken; and (3) in that the label did not bear the common or usual names of the active ingredients, since aspirin had been declared by its chemical name of acetylsalicylic acid and not by its common or usual name.

On August 2, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

614. Misbranding of Dye's Compound Tablets and Dye's Laxative Pellets. U. S. v. 8 Dozen Packages of Dye's Compound Tablets and 2 Dozen Packages of Dye's Laxative Pellets. Default decrees of condemnation and destruction. (F. D. C. Nos. 5083, 5084, 5636. Sample Nos. 7678–E, 7679–E.)

The labeling of the laxative pellets failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users. The labeling of both products bore false and misleading curative and therapeutic claims, and the containers were substantially larger than was necessary.

On July 8 and September 11, 1941, the United States attorney for the Southern District of California filed libels against the above-named drugs at Los Angeles, Calif., alleging that they had been shipped in interstate commerce on or about May 8 and 21 and June 10, 1941 by Dr. J. H. Dye Medical Co. from Buffalo, N. Y.; and charging that they were misbranded.

Analyses of samples showed that the compound tablets consisted of plant extractives, including valeric acid and alkaloid-containing plant drugs; and that the laxative pellets consisted essentially of aloin, podophyllum resin, and hydrastis.

The laxative pellets were alleged to be misbranded (1) in that the labeling did not bear adequate directions for use since the directions called for the administration of a laxative over an indefinite period of time; (2) in that the labeling did not bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling did not warn that frequent and continued