

ments when so used; (3) in that the carton label failed to bear the common or usual names of the active ingredients; (4) in that the carton label failed to bear the name and place of business of the manufacturer, packer, or distributor; and (5) in that the carton label failed to bear a statement of the quantity of contents.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

547. Misbranding of Special Formula Tablets and McNeal's Laxative Cold Tablets. U. S. v. 88,020 Tablets in containers labeled "Special Formula Tablets—Mono. 'L'" and 41 Dozen Boxes of similar tablets labeled "McNeal's Laxative Cold Tablets." Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 4037. Sample Nos. 23397-E, 28398-E.)

These tablets were of identical composition. Those in boxes labeled "McNeal's Laxative Cold Tablets" would have been dangerous to health when used according to directions on the label; they also contained false and misleading therapeutic claims. These tablets and the loose ones in the large container failed to bear adequate directions for use and adequate warning statements. The label for the loose tablets also failed to bear the required ingredient statement.

On March 24, 1941, the United States attorney for the District of Maryland filed a libel against the above-named product at Baltimore, Md., alleging that it had been shipped from Buffalo, N. Y., on or about December 16, 1940, by Arner Co., Inc.; and charging that it was misbranded.

Analysis of a sample of the article showed that each tablet contained acetanilid (approximately 1 grain), quinine sulfate (approximately 0.38 grain), a laxative plant drug, and a small amount of atropine.

McNeal's Laxative Cold Tablets were alleged to be misbranded in that they would have been dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Directions;—Usual dose. 2 tablets just after meals & at bedtime. Delicate persons may take 1. When relieved take half dose for day or two. Children over 10, ½ adult dose. Limit 4 doses—24 hrs." They were alleged to be misbranded further in that the following statements appearing on the label were false and misleading, "Laxative Cold Tablets Relief for Common Colds * * * A Preparation for Colds * * * The 2nd or 3rd dose should relieve the Cold * * * partly as a result of bowel movement which should occur in 10 hours after taking," since they represented that the article would be efficacious for the purposes recommended; whereas it would not be efficacious for such purposes. The product in both types of containers was alleged to be misbranded in that the labeling did not bear adequate directions for use, and in that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. The Special Formula Tablets were alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients or a statement of the quantities or proportions of acetanilid and atropine contained therein.

On May 12, 1941, Kent Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Federal Security Agency (Food and Drug Administration).

548. Misbranding of Tabknoll Three Bromides Effervescent. U. S. v. 10 Dozen Bottles of Tabknoll Three Bromides Effervescent. Default decree of condemnation and destruction. (F. D. C. No. 3918. Sample No. 34893-E.)

This product contained ammonium, potassium, and sodium bromides, and would be dangerous to health when used as recommended in the labeling. Its labeling also failed to bear adequate directions for use and adequate warnings against its use where such use might be dangerous to health.

On March 6, 1941, the United States attorney for the District of New Jersey filed a libel against 10 dozen bottles of Tabknoll Three Bromides Effervescent at Newark, N. J., alleging that the article had been shipped in interstate commerce on or about January 6, 1941, by H. G. Knoll & Co., Inc., from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling, namely, (bottle and carton) "Adults, one to two tablets, dissolved in half a glass of water; or as ordered