adequate directions for use—in the former case because no limitation was put on the amount of bromide that might be administered daily, and in the latter case because the directions provided for excessive dosage. The labeling of both products also failed to bear adequate warning statements, but did bear false and misleading therapeutic claims.

On March 4, 1941, the United States attorney for the District of New Jersey filed a libel against the above-named products at Newark, N. J., alleging that the articles had been shipped by Kells Co. from Newburgh, N. Y., on or about November 29, 1940, and January 9 and 25, 1941; and charging that they were misbranded.

Analyses of samples of the articles showed that Grover Graham Remedy consisted essentially of magnesia, sodium bicarbonate, sodium bromide, alcohol, water, and small amounts of chloroform, ginger, and peppermint oil; and that Graham's Pills consisted essentially of laxative plant drugs.

Both products were alleged to be misbranded: (1) In that they failed to bear adequate directions for use as stated above. (2) In that the labeling failed to bear such adequate warnings against use in those pathological conditions where their 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. (3) In that statements in the labeling which represented that Grover Graham Remedy would give instant relief for severe attacks of indigestion and all stomach ills, and that it would be efficacious as a dyspepsia remedy and for gastritis and bloating; and that Graham's Pills were efficacious in the treatment of biliousness, were false and misleading since they would not be efficacious for such purposes. Graham's Pills were alleged to be misbranded further in that the label did not bear an accurate statement of the quantity of contents.

On April 18, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

446. Adulteration and misbranding of Heads-Up Headache Powders and misbranding of Digesto-Pep and Coldlax. U. S. v. 126 Packages of Heads-Up, 70 Packages of Digesto-Pep, and 31 Bottles of Coldlax. Default decree of condemnation and destruction. (F. D. C. No. 4026. Sample Nos. 20666–E, 20667–E, 20668–E.)

The labeling of the headache powders and the Coldlax failed to bear such adequate warnings as are necessary for the protection of users and failed to bear adequate directions and the common or usual names of the active ingredients. The "Heads-Up" contained acetylsalicylic acid, sodium bromide, and phenolphthalein in excess of the amount declared. The labels of all products bore false and misleading representations regarding their curative and therapeutic efficacy.

On March 25, 1941, the United States attorney for the Northern District of Georgia filed a libel against the above-described drugs at Atlanta, Ga., alleging that the articles had been shipped in interstate commerce on or about December 10, 1940, by Smith Bros. Drug Co. from Greensboro, N. C.; and charging that they were misbranded and that the Heads-Up Headache Powders were also adulterated.

Analyses showed that the average Heads-Up headache powder contained 4.68 grains of aspirin, 6.62 grains of sodium bromide, and 0.57 grain of phenolphthalein; that the Digesto-Pep contained alkaline compounds, including a bismuth compound and diastase; and that the Coldlax consisted essentially of water, alcohol, sodium salicylate, a laxative plant drug, menthol, camphor, and traces of alkaloids.

The Headache Powders were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, since each powder contained materially more acetylsalicylic acid, sodium bromide, and phenolphthalein than the amounts stated on the label. They were alleged to be misbranded in that the statement on the label, "Each Powder Contains: Acidum Acetylsalicylic * * * 4 Gr. * * * Sodium Bromide * * * 6 Gr. Phenolphthalein * * * ¼ Gr.," was false and misleading since it was incorrect. They were alleged to be misbranded further in that the statements on the label, "Brace Up! with Heads-Up," "With Heads-Up You'll Brace Up!," and "'Go Smiling Thru' As Thousands Do," were false and misleading as the article could not be depended upon to brace one up or to enable one to "go smiling through" when suffering from the various disease conditions mentioned on the label. They were alleged to be misbranded further in that the statements, "Take With Confidence," "Heads-Up is different * * * safe * * * faster," and

"Heads-Up contains no acetanilid, harmful or habit forming drugs," were false and misleading, since they might cause potentially harmful effects, they were not essentially different from or safer than various other preparations on the market, were not safe under all conditions, and contained potentially harmful and habit-forming drugs. They were alleged to be misbranded further in that the label failed to bear the common or usual name of each of the active ingredients since acidum acetylsalicylic is not the common name for aspirin. They were alleged to be misbranded further in that the labeling failed to bear adequate directions for use, since the direction "Take one powder every two or three hours as needed" was not adequate for an article of the composition of Heads-Up Headache Powders.

The Digesto-Pep was alleged to be misbranded in that the designations "Digesto-Pep," "Aids Digestion," and "Intended for use in correcting conditions associated with * * * sluggish digestion," appearing on the label, were false and misleading, since it was not a digestant of the various constituents of food, could not be depended upon to produce "pep" and aid digestion and correct sluggish digestion. It was alleged to be misbranded further in that the statements on the label " 'Keep in step with Digesto-Pep' " and " 'Go smiling thru' as thousands do" were false and misleading, since the article could not be depended upon to fulfill the promises of benefit expressed and implied by this language.

The Coldlax was alleged to be misbranded in that the designation "Coldlax" and the statement "For the relief of colds," appearing on the carton and bottle label, and the statement "For Colds," appearing in the directions, were false and misleading, since it did not constitute an adequate treatment for colds; and in that the unmodified statement "For Coughs" in the directions was false and misleading, since the article did not constitute an adequate treatment for coughs from all causes. It was alleged to be misbranded further in that the statement in the directions, "Coldlax contains no habit forming drugs" was false and misleading, since it contained aromatic fluidextract of cascara sagrada by reason of which frequent or continued use of the article might cause dependence upon laxatives to move the bowels; in that the label failed to bear the common or usual name of each active ingredient, since "Alkaloids" is not the common or usual name of any constituent of the preparation, and the names of other constituents were given in abbreviated form; and in that its labeling failed to bear adequate directions for use, since the directions given did not limit the period of time over which the article might appropriately be consumed.

The Heads-Up and Coldlax were alleged to be misbranded further in that their labeling failed to bear adequate warnings against use in those pathological conditions and by children where use might be dangerous to health and against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the labeling failed to bear a warning that the articles should not be used in cases of nausea, vomiting, abdominal pain, and other symptoms of appendicitis and did not warn that frequent or continued use of the articles might result in dependence upon laxatives to move the bowels.

On April 21, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

447. Misbranding of Laxrid. U. S. v. 72 10-Ounce Packages and 33 4-Ounce Packages of Lawrence Mack's Laxrid. Default decree of condemnation and destruction. (F. D. C. No. 3825. Sample No. 52201-E.)

The labeling of this product failed to bear adequate directions for use, and it also contained false statements regarding its ingredients, its efficacy as a weight reducer, and its therapeutic qualities.

On February 20, 1941, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped by Lawrence Mack, Inc., from Detroit, Mich., on or about January 6, 1941; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted essentially of Epsom salt, Glauber's salt, sodium bicarbonate, tartaric acid, citric acid, and small quantities of sodium phosphate, potassium and sodium chlorides, saccharin, and peppermint oil.

The article was alleged to be misbranded: (1) In that its label failed to bear adequate directions for use since those given were not suitable for a laxative. (2) In that the following statements in the label (carton and circular) "Report of Laboratory Test of Lawrence Mack's Laxrid. 'We have tested a sample of Lawrence Mack's Laxrid and find that it is entirely free from any of the poisonous