

"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

and harmful substances listed below: Alkaloids...None Narcotics...None Phenolic Substances...None Alcohols...None Veronal, Barbital, and similar compounds...None Metallic Poisons...None (Salts of lead, arsenic, antimony, mercury, tin, bismuth and barium) Di-nitrophenol...None Plant Tissues...None (Pokeweed, bladder wrack, etc.) Thyroid Extract...None," were false and misleading since they gave the impression that the article contained no deleterious substances. (3) In that statements in the booklet entitled "How I Reduced," representing that its use would "Do Away With Excess Weight," relieve constipation, that reduction of weight gained by its use usually was permanent; that it would remove heaviness in body, take away that bloated, sluggish feeling; would enable the user to get up full of vim, vigor, and vitality; and that it would relieve gas and acids, were false and misleading since it would not be efficacious for such purposes.

On April 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**448. Misbranding of mineral oil. U. S. v. 1,122 Bottles of Mineral Oil. Consent decree of condemnation. Product ordered released under bond for re-labeling. (F. D. C. No. 4859. Sample Nos. 56418-E, 56419-E.)**

This product was light mineral oil and not heavy mineral oil as suggested by its labeling. Moreover, its labeling failed to bear such warnings as are necessary for the protection of users.

On June 2, 1941, the United States attorney for the Eastern District of New York filed a libel against 1,122 bottles of mineral oil at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce within the period from on or about March 9 to on or about May 3, 1940, by Purex Products, Inc., from Boston, Mass.; and charging that it was misbranded. The article was labeled in part: "PuRex Russian Mineral Oil Light."

The article was alleged to be misbranded in that the designation "Russian Mineral Oil" (in comparatively large type) and the word "Light" (in comparatively small type) borne on the label were misleading, since the term "Russian Mineral Oil" is associated in the minds of purchasers with an oil having a kinematic viscosity, which is substantially higher than that of the article.

It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against unsafe methods of administration in such manner and form as are necessary for the protection of users, since the labeling carried no warning against its administration directly before or after meals.

On June 24, 1941, Purex Products, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled to comply with the law.

**449. Adulteration and misbranding of solution of citrate of magnesia. U. S. v. 137 Bottles of Solution of Citrate of Magnesia. Default decree of condemnation and destruction. (F. D. C. No. 3402. Sample No. 20499-E.)**

This product contained less magnesium citrate and less citric acid than the amounts required by the United States Pharmacopoeia. Its labeling also failed to bear a statement of the quantity of the contents or a warning against its use in those pathological conditions where its use might be dangerous to health.

On November 23, 1940, the United States attorney for the Southern District of Georgia filed a libel against 137 bottles of the above-named product at Augusta, Ga., alleging that it had been shipped in interstate commerce on or about September 10, 1940, by the McMillan Drug Co. from Columbia, S. C.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that it purported to be or was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the standard set forth therein.

It was alleged to be misbranded in that it was a drug in package form and the label failed to bear an accurate statement of the quantity of contents; and in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health as might be necessary for the protection of users.

On January 1, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.