The article was alleged to be misbranded: (1) In that the directions (sample package) "Children One-quarter to one teaspoonful. Adults—One to two teaspoonfuls," and (remainder of product, bottle label) "Adjust dose to individual needs. And, taper off as action becomes normal. Children: According to age, one-quarter to one teaspoonful as needed. Adults: One to two teaspoonfuls night and morning until regulated," and (carton) "Dose: Children, 3 to 5 years, one-quarter teaspoonful; 5 to 9 years, one-half teaspoonful; 9 to 15, one teaspoonful. Adults, one to two teaspoonfuls night and morning until bowels act well," were not appropriate and were otherwise not adequate. (2) In that its labeling failed to bear adequate warnings against use in those pathological conditions or by children 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 the labeling did not inform the purchaser that its use was contraindicated in cases of appendicitis and that frequent or continued use might result in dependence upon laxatives to move the bowels. (3) In that the name "Prunlax" was false and misleading since the active laxative ingredients in the preparation were not derived from prunes; in that the statement on the bottle labels, "To further promote its helpful harmony with health processes of the body, no phenolphthalein, alcohol, or other disturbing drug is used in Prunlax," was false and misleading since Prunlax cannot be depended upon to act in helpful harmony with health processes of the body, and the statement would tend to create the impression that the article contained no potentially harmful or deleterious ingredients, when such was not the case; and in that representations in the labeling that it was a safe laxative which would correct constipation without habit formation and without the use of irritating drugs; that it was especially helpful in cases of biliousness, sour stomach, colic due to gas, and diarrhea due to improper diet; and that it would prevent the user from having dizzy spells, were false and misleading since it would not be safe under all conditions and would not be efficacious for the disease conditions mentioned. (4) In that the sample-sized package failed to bear a label containing the common or usual name of each of its active ingredients. (5) In that the sample-sized package failed to bear a label containing a statement of the quantity of contents.

On May 3, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

453. Misbranding of Rogers Headache Soda. U. S. v. 95 Dozen and 3½ Dozen Packages of Rogers Headache Soda. Default decree of condemnation and destruction. (F. D. C. No. 4000. Sample Nos. 39686-E, 39700-E.)

This product contained acetanilid and its label did not bear adequate directions for use and such adequate warnings as are necessary for the protection of users. It contained not more than 1.9 grains of acetanilid per powder, whereas it was labeled as containing 2½ grains of acetanilid per powder. Its principal ingredient was not soda as suggested by its name.

On March 20, 1941, the United States attorney for the Eastern District of Illinois filed a libel against 95 dozen 10-cent packages and 3½ dozen 25-cent packages of Rogers Headache Soda at Cairo, Ill., alleging that the article had been shipped in interstate commerce on or about November 7, 1940, and February 4, 1941, by the Rogers Drug Co. from Memphis, Tenn.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on the label, "Headache Soda—Each Powder Contains 2½ grs. Acetanilid," were false and misleading since they were incorrect. It was alleged to be misbranded further in that the label did not bear a statement of the quantity or proportion of acetanilid contained in the article; and in that the label did not bear adequate directions for use and 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, in such manner and form as are necessary for the protection of users.

On April 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.