

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS¹**

704. Misbranding of Dickson's Laxative Rheumatic Diruatica. U. S. v. 15 Bottles of Dickson's Laxative Rheumatic Diruatica. Default decree of condemnation and destruction. (F. D. C. No. 6899. Sample No. 71670-E.)

The labeling of this product, in addition to failure to bear adequate directions for use and such adequate warnings as are necessary for the protection of users, also bore false and misleading curative and therapeutic claims.

On February 27, 1942, the United States attorney for the Eastern District of Arkansas filed a libel against the above-named drug product at Blytheville, Ark., alleging that it had been shipped in interstate commerce on or about November 7, 1941, by A. H. Dickson from Memphis, Tenn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of Epsom salt, methenamine, sodium salicylate, sodium benzoate, salicylic acid, methyl salicylate, and was colored with caramel.

The article was alleged to be misbranded: (1) In that the labeling did not bear adequate directions for use since there was no limitation as to duration of use and the statement "Dose—Tablespoonful four times a day in a glass of water" implied that it was to be taken continuously; whereas a laxative should be taken only occasionally. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or adequate warnings against duration of administration, in such manner and form as are necessary for the protection of users since it failed to bear a warning that the drug should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present and that frequent or continued use might result in dependence upon laxatives. (3) In that statements on the label, "Rheumatic Diruatica * * * Recommended for Rheumatic Urinary and Constipated Conditions," were false and misleading since they represented and suggested that it would be efficacious for rheumatic, urinary, and all constipated conditions; whereas it would not be efficacious for such conditions.

On May 4, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

705. Misbranding of Dromgooles Bitters. U. S. v. 13 Bottles and 7 Bottles of Dromgooles Bitters. Default decree of condemnation and destruction. (F. D. C. No. 7011. Sample Nos. 73185-E, 73186-E.)

The labeling of this product bore no directions for use and bore false and misleading representations regarding its curative and therapeutic efficacy. Furthermore, the designation "Bitters" was not appropriate for a drug of this type.

On March 16, 1942 the United States attorney for the Western District of Oklahoma filed a libel against 20 bottles of Dromgooles Bitters at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce on or about January 2, 1942, by the McCullough Drug Co. from Lawrenceburg, Ind.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of extracts of plant drugs including an alkaloid-bearing drug and a laxative drug, iron and ammonium citrate, alcohol, and water. It had an aromatic and astringent but not a bitter taste.

The article was alleged to be misbranded (1) in that its labeling failed to bear any directions for use; and (2) in that the statements on the labels, (both lots) "Bitters * * * Uterine Tonic, Sedative and Antispasmodic Aid in the relief of Periodic Pain and Distress" and (13 bottles) "Discontinue treatment when acute symptoms have subsided," were false and misleading since it was not a bitters, was not efficacious as a uterine tonic or sedative nor as an antispasmodic aid in the relief of periodic pain and distress, and (13 bottles) it would not be efficacious in the treatment of acute symptoms of such conditions.

On April 29, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

¹ See also No. 702 and soda in No. 720.