

**617. Misbranding of Lacto-Kelpol, Evitades, and chaulmoogra oil. U. S. v. 33 Bottles of Lacto-Kelpol, 10 Bottles of Evitades, and 19 Packages of Chaulmoogra Oil. Default decree of condemnation and destruction. (F. D. C. Nos. 4333 to 4335, incl. Sample Nos. 55412-E, 55413-E, 55415-E.)**

The labeling of the Lacto-Kelpol failed to bear adequate directions for use, and that of all three products contained false and misleading claims.

On April 23, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named products at Seattle, Wash., which had been consigned by Seal-Ins Laboratories, Inc., alleging that they had been shipped on or about August 15 and October 4, 1940, and January 4, 1941, from Los Angeles, Calif.; and charging that they were misbranded.

Analyses of samples of the articles showed that the Lacto-Kelpol consisted essentially of an emulsion of mineral oil, agar agar, lactic acid (approximately 1 percent), and water; that the Evitades tablets contained extracts of plant drugs; and that the chaulmoogra oil was labeled properly as to its identity.

The Lacto-Kelpol was alleged to be misbranded (1) in that the bottle label and carton failed to bear adequate directions for use by children, since the directions were indefinite as to quantity; (2) in that its name, "Lacto-Kelpol Lactic Acid Emulsion," was false and misleading since it owed its therapeutic value to ingredients other than lactic acid, and kelp was not one of its ingredients; and (3) in that representations in an accompanying circular that it would be of value in the treatment of certain types of diarrhea, colitis, dysentery, and constipation, were false and misleading since it would not be effective for such purposes.

Evitades was alleged to be misbranded in that the following statements in an accompanying circular, "Evitades is mild in sedative action. Useful in treating insomnia; also, nervous disturbances of the menstrual period," were false and misleading since it would not be efficacious for the purposes recommended.

The chaulmoogra oil was alleged to be misbranded in that statements in an accompanying circular representing that it was a preventive and appropriate treatment for various types of arthritis were false and misleading since it would not be efficacious for such purposes.

On June 17, 1941, no claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

**618. Misbranding of Real-Lax Chewing Laxative. U. S. v. 104 Dozen Packages of Real-Lax Chewing Laxative. Default decree of condemnation and destruction. (F. D. C. No. 5996. Sample No. 72101-E.)**

This product was a peppermint-flavored gum containing phenolphthalein, and its labeling failed to bear such adequate warnings as are necessary for the protection of users.

On October 8, 1941, the United States attorney for the Southern District of California filed a libel against 104 dozen packages of the above-named product at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about July 10 and August 7, 1941, by the Pennsylvania Drug Products Corporation from Pittsburgh, Pa.; and charging that it was misbranded.

The article was alleged to be misbranded in that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health or against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the labeling failed to bear a warning against use when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present and against frequent or continued use which might result in dependence upon laxatives.

On October 28, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**619. Misbranding of Vinco Herb Tablets. U. S. v. 208 Small Boxes and 22 Large Boxes of Vinco Herb Tablets. Default decree of condemnation and destruction. (F. D. C. No. 5202. Sample Nos. 42425-E, 42426-E.)**

The labeling of this product failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users and also bore false and misleading curative and therapeutic claims. Both sizes of packages were substantially larger than was necessary to hold the contents. The labeling of the small packages failed to bear certain mandatory labeling statements in such manner that they might be read and understood under ordinary conditions of purchase and use.

On July 22, 1941, the United States attorney for the Western District of Pennsylvania filed a libel against the above-named product at Pittsburgh, Pa., alleging that the article had been shipped on or about October 28, 1940, by the Vinco Herb Co. from Dayton, Ohio; and charging that it was misbranded.

Analysis showed that the article consisted essentially of aloe and extracts of plant drugs including capsicum and an emodin-bearing drug. The tablets in the small packages occupied 26 percent of their capacity and the tablets in the large packages occupied 42½ percent of their capacity.

The article in both sized packages was alleged to be misbranded (1) in that the labeling failed to bear adequate directions for use since the directions provided for taking the tablets over a period of 10 days, whereas a laxative should be taken only occasionally; (2) in that the labeling failed to bear adequate warnings against use by young children where its use might be dangerous to health or against unsafe dosage or duration of administration as are necessary for the protection of users since the product was essentially a laxative and there was no warning that frequent or continued use might result in dependence on laxatives; (3) in that statements in the labeling representing that it was an appropriate treatment for coated tongue, flatulence, sour stomach, simple headache, acid indigestion, listlessness, lazy feeling, bad breath, sluggishness, dull eyes, and sallow skin and that it would make life happy and enjoyable and would provide a clean, healthy condition of the mind and body, were false and misleading since it was a laxative and the various disease conditions for which it was recommended may be due to causes other than constipation; and (4) in that its containers were so made, formed, or filled as to be misleading.

The product in the small packages was alleged to be misbranded further (1) in that the name and address of the manufacturer, the declaration of the quantity of the contents, and the statement of the ingredients required by or under authority of law to appear on the labeling were not placed on the label with such conspicuousness and in such terms as to make them likely to be read by the ordinary individual under customary conditions of purchase and use since all these statements appeared on the bottom of the box; and (2) in that certain statements appeared in several foreign languages upon the box and certain statements and other information required by or under authority of law did not appear on the box in these foreign languages.

On August 22, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**C20. Misbranding of quinine sulfate. U. S. v. 1,056 Bottles of Quinine Sulfate. Default decree of condemnation and destruction. (F. D. C. No. 4398. Sample No. 50227-E.)**

The labeling of this product failed to bear adequate directions for use, and its containers were filled only to approximately one-half of their capacity.

On April 19, 1941, the United States attorney for the Eastern District of Virginia filed a libel against 1,056 bottles of quinine sulfate at Richmond, Va., alleging that the article had been shipped in interstate commerce on or about March 29, 1941, by the Carroll Chemical Corporation from Baltimore, Md.; and charging that it was misbranded. It was labeled in part: "National Brand Quinine Sulphate \* \* \* ½ Oz."

The article was alleged to be misbranded in that the labeling did not bear adequate directions for use; and in that its container was so made, formed, or filled as to be misleading.

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

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH  
OFFICIAL OR OWN STANDARDS**

**621. Adulteration and misbranding of Russian oil and citrate of magnesia. U. S. v. James J. Kaplan (Diamond Drug & Magnesia Co.). Plea of guilty. Fine, \$30. (F. D. C. No. 2841. Sample Nos. S7090-D, 2247-E, 2261-E.)**

The mineral oil was represented to be U. S. P. mineral oil, i. e., heavy mineral oil; whereas it was light mineral oil. The citrate of magnesia contained less magnesium citrate and less citric acid than the amounts specified by the United States Pharmacopoeia.

On October 28, 1940, the United States attorney for the District of Massachusetts filed an information against James J. Kaplan, trading as the Diamond