

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

**340. Misbranding of Fru-Lax. U. S. v. 3 Cans and 20 Cans of Fru-Lax. Default decree of condemnation and destruction. (F. D. C. No. 2436. Sample No. 30048-E.)**

The labeling of this product bore false and misleading representations regarding its efficacy in the treatment of the conditions indicated hereinafter and failed to bear the names of the active ingredients and adequate directions for use, and such adequate warnings as are necessary for the protection of users.

On July 29, 1940, the United States attorney for the Eastern District of Wisconsin filed a libel (amended August 16, 1940) against 3 3-ounce cans and 20 12-ounce cans of Fru-Lax at Racine, Wis., alleging that the article had been shipped in interstate commerce on or about April 8 and July 9, 1940, by the Fru-Lax Co. from Chicago, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of purging cassia tissues, senna-leaf tissues, and carob-bean tissues.

The article was alleged to be misbranded in that representations in the labeling that it was not habit-forming; that it would restore and enable one to regain health; would relieve ailments caused by poisons absorbed from the bowels; that it was efficacious in the treatment of rheumatism, neuritis, stomach trouble, gall-bladder trouble, headaches, catarrh, skin trouble, excessive gas, colds, piles, high blood pressure; that it was of value in reducing; was an ideal neutralizer, would help make the body disease-proof; and that it possessed the rejuvenating and restorative properties implied in the statements "Return to Nature \* \* \* Don't feel 'old at 40'," were false and misleading since the use of the article might result in the laxative habit, and it would not be efficacious for the purposes for which it was so recommended. It was alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients; in that the label did not bear adequate directions for use; and in that the label did not bear such 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 October 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**341. Misbranding of Maurice Le Bell's Formula No. 7. U. S. v. 143 Bottles of Maurice Le Bell's Formula No. 7. Default decree of condemnation and destruction. (F. D. C. No. 3297. Sample Nos. 30415-E, 30417-E.)**

The label of this product contained false and misleading representations regarding its efficacy for the conditions indicated below. Furthermore, its labeling failed to bear adequate directions for use.

On November 4, 1940, the United States attorney for the Northern District of Illinois filed a libel against 143 bottles of the above-named product at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about September 11, 1940, by Hollywood Formulas, Inc., from Los Angeles, Calif.; and charging that it was misbranded.

Analysis showed that the article consisted of tablets containing Irish moss, rhubarb root, seaweed such as *Laminaria*, parsley leaf, cranberry fruit, and leaves resembling celery.

The article was alleged to be misbranded in that the following statements in the labeling were false and misleading, since the article was not efficacious for the purposes recommended therein: (Bottle) "As Recommended by Hollywood's Famous Dr. Maurice Le Bell, D. C. Reducing Specialist"; (booklet) "The Reducing Method of Dr. Maurice LeBell, D. C. to be Used in Connection with Formula No. 7 \* \* \* Important \* \* \* The instructions contained in this booklet are a vital part of your reducing program, and should be studied carefully. They are a simplified form of the famous reducing method used by Dr. Maurice LeBell, D. C., in his many years of private practice. \* \* \* Best results are obtained by following these instructions carefully \* \* \* We suggest that you take a full length front and profile snapshot of yourself today. Many people have reported a second picture taken at the end of their supply of Formula showed most gratifying results." It was alleged to be misbranded further in that the directions for use appearing on the bottle and in the booklet. "Take 8 tablets daily, 3 before breakfast and dinner and 2 before retiring. (See exercise and diet booklet.)

Decrease dosage in accordance with degrees of laxation required," were inappropriate for the article, since they suggested frequent and continuous consumption and were therefore inadequate.

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

**342. Misbranding of Slendotabs. U. S. v. 80 Packages of Slendotabs. Default decree of condemnation and destruction. (F. D. C. No. 2532. Sample No. 16769-E.)**

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter. The article contained strychnine, which fact was not declared on the label. Its labeling also failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users.

On or about August 16, 1940, the United States attorney for the Western District of Missouri filed a libel against 80 packages of Slendotabs at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about May 18, 1940, by Keneco Products from Elmira, N. Y.; and charging that it was misbranded.

Analysis showed that each tablet of the article contained approximately  $\frac{1}{2}$  grain of phenolphthalein, a resinous drug such as leptandra resin, compounds of iodine equivalent to 0.088 grain of iodine per tablet, and alkaloidal material including strychnine.

The article was alleged to be misbranded (1) in that its labeling represented that it would be efficacious in reducing excessive fat, that it was a scientifically balanced weight reduction method, and would help eliminate waste matter and accumulated poisons from the body, which representations were false and misleading since the article would not constitute an adequate or appropriate treatment for such purposes; (2) in that the labeling was misleading in that it failed to reveal that the article contained strychnine, a material fact in the light of the statement on the carton that the active ingredients were phenolphthalein, calcium iodized, and leptandrin. It was alleged to be misbranded further in that its label failed to bear a statement of the presence of and quantity of strychnine contained therein; in that its labeling failed to bear adequate directions for use, since the directions on the carton, "Take one or two tablets immediately before each meal, three times a day. For best results, take tablets regularly and faithfully, as directed. As these tablets are laxative, not more than six tablets should be taken in 24 hours," and the directions in the leaflet were not appropriate for an article of such composition and was therefore inadequate. It was alleged to be misbranded further in that the labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health and against unsafe dosage or methods 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 of the danger involved in the use of the article in cases of appendicitis, nor did it warn that frequent or continued use might result in dependence upon laxatives, nor did the label reveal the fact the the use of the article might result in skin eruptions.

On October 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**343. Misbranding of Venus Tablets. U. S. v. 66 Cartons and 80 Cartons of Venus Tablets. Default decrees of condemnation and destruction. (F. D. C. Nos. 2265, 4094. Sample Nos. 30305-E, 31965-E.)**

The labeling of this product bore false and misleading representations regarding its efficacy in the conditions indicated hereinafter and failed to bear adequate directions for its use and such adequate warnings as are necessary for the protection of users. It was also deceptively packaged.

On June 25, 1940, and April 10, 1941, the United States attorney for the Northern District of Illinois filed libels against 146 cartons of Venus Tablets at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about May 6 and September 22, 1940, by the Thoro Sales Service from Los Angeles, Calif.; and charging that it was misbranded.

Each carton contained a bottle labeled "Venus Tablets" and an envelope labeled "Sample Tablets V-76 Laxative Tablets." Analyses showed that the Venus Tablets contained rhubarb root, kelp, Irish moss, and green leafy material; and that the V-76 Tablets contained dried rhubarb root, cranberries, and green leafy mate-