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

2671. Misbranding of Uvursin. U. S. v. 53 Boxes * * *. (F. D. C. No. 26357. Sample No. 5391–K.)

LIBEL FILED: December 29, 1948, District of Rhode Island.

ALLEGED SHIPMENT: On or about September 16 and October 25, 1948, by the John J. Fulton Co., from San Francisco, Calif.

PRODUCT: 53 boxes, each containing 54 capsules, of *Uvursin* at Providence, R. I.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions which appeared in the labeling failed to reveal the disease or condition for which the article was to be taken.

DISPOSITION: March 2, 1949. Default decree of condemnation and destruction.

2672. Misbranding of Home Brand Laxative and Liver Tablets. U. S. v. 32 Cartons, etc. (F. D. C. No. 26459. Sample No. 44333–K.)

LIBEL FILED: February 7, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 28, 1946, from St. Louis, Mo.

PRODUCT: 32 cartons, each containing 36 tablets, and 564 cartons, each containing 12 tablets, of *Home Brand Laxative and Liver Tablets* at Columbus, Ohio, in the possession of Theodore A. Wegener. The article was shipped in bulk and repackaged by the consignee.

Analysis showed that the article consisted essentially of extracts of laxative plant drugs, such as cascara sagrada, aloe, and podophyllum.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions and diseases stated and implied: (carton) "Liver Tablets * * * Aids in cleansing the stomach purifying the liver and regulating the bowels * * * For chronic constipation" and (leaflet enclosed in carton) "Liver Tablets * * * The Efficient Treatment for Relieving Stomach, Liver and Bowel Complaints. H. B. Laxative and Liver Pills is an excellent remedy for treatment of Bad Breath, Sour Stomach, Bilious Headache, Diseases of the Liver and Chronic Constipation * * * harmless * * * to insure freedom from Headache, heavy Stomach and that dark brown taste and a constipated condition."

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the article failed to bear a warning against use of the article in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and it failed also to warn that frequent or continued use of the article may lead to dependence upon laxatives. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 1, 1949. Default decree of destruction.