

4127. Misbranding of Bi-Lets tablets. U. S. v. 1 Bottle, etc. (F. D. C. No. 34877. Sample No. 57113-L.)

LABEL FILED: March 6, 1953, Southern District of Ohio.

ALLEGED SHIPMENT: On or about October 15, 1952, from Buffalo, N. Y.

PRODUCT: 1 bottle of *Bi-Lets tablets*, 3 cellophane envelopes containing 4 tablets, 500 empty boxes labeled, in part, "Bi-Lets," and 400 circulars entitled "Read This For Your Health's Sake!" at Cincinnati, Ohio, in the possession of Medical Laboratories.

RESULTS OF INVESTIGATION: The bottle containing the *Bi-Lets tablets* was shipped in interstate commerce as described above, and after receipt by Medical Laboratories, a portion of the tablets in the bottle was repackaged into small cellophane envelopes of 4 tablets each. The envelopes then were attached to the above-mentioned circular and distributed by the consignee as free samples. Upon request from customers desiring to purchase tablets, the consignee would repack the remaining tablets into the empty boxes.

LABEL, IN PART: (Box) "Bi-Lets For Your Health Distributed By Medical Laboratories Room 402—104 W. 4th Street Cincinnati 2, Ohio Contents 25 Tablets Directions: Take one (1) or one-half ($\frac{1}{2}$) Bi-Let at bedtime. In obstinate cases, take one (1) at bedtime and one (1) before breakfast. Caution: In any condition where there has been abdominal pain and vomiting you should see a physician. Formula: Extract cascara sagrada 2 gr., Phenolphthalein 1 gr., Aloin $\frac{1}{8}$ gr., Extract Nux Vomica $\frac{1}{8}$ gr. (Strychnine 0.009 gr.) Ovgall 1 gr."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "For Your Health" appearing on the box label and certain statements in the above-mentioned circular accompanying the article were false and misleading. The statements represented and suggested that the article would be necessary "For Your Health"; that disorders of the liver, gallbladder, and intestinal tract cause constipation and other ailments; and that the article was an adequate and effective treatment for such conditions and for overindulgence. The article would not be necessary "For Your Health," and it was not an adequate and effective treatment for the conditions stated and implied, including overindulgence.

Further misbranding, Section 502 (f) (1) and (2), the labeling of the article, namely, the box labeling, failed to bear adequate directions for use; and the box labeling and the above-mentioned circular failed to bear such adequate warnings against use in those pathological conditions or by children where its use may 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. The box label did not bear indications for use of the article; and the box label and the circular did not bear adequate warnings against use of the article when symptoms of appendicitis were present, where a skin rash would appear, and against frequent or continued use to prevent formation of the laxative habit. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 20, 1953. Default decree of condemnation and destruction.