

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

5447. Elip tablets. (F.D.C. No. 34887. S. Nos. 37-389/90 L.)

QUANTITY: 39 bags, 1,200 tablets each, at Baldwin, N.Y., in possession of Baldwin Laboratories, and 94 12-tablet vials at Baldwin, N.Y., in possession of Elip Distributing Co.

SHIPPED: 6-6-52, from East Newark, N.J.

LABEL IN PART: (Bag) "Elip Tablet"; (vial) "Elip Tablets * * * Active Ingredients: Potassium Bitartrate, Sulfur, Rhubarb."

ACCOMPANYING LABELING: Window sign bearing the words "Elip For Piles" and counter display placards bearing the words "An Internal Preparation For The Relief of Piles."

RESULTS OF INVESTIGATION: The tablets in the bags represented the remainder of a bulk shipment which had been made to Baldwin Laboratories at Baldwin, N.Y., from East Newark, N.J.; and the tablets in the vials represented a portion of such bulk shipment which had been sold by Baldwin Laboratories to Elip Distributing Co. and repackaged into vials by that company.

The above-described window sign was on display in the window of Baldwin Laboratories, and the counter display placard was used by the Elip Distributing Co. in preparing the vials of tablets for sale. The vials were attached to the placards in units of six.

LIBELED: 3-20-53, E. Dist. N.Y.; amended libel 1-10-55.

CHARGE: 502(a)—while held for sale, the labeling of the article in the bags and vials contained false and misleading representations that the article was an adequate and effective treatment for piles and the discomfort and itching of rectal irritation caused by piles; and 502(f) (2)—the labeling of the article failed to bear a warning against its use for bleeding piles.

DISPOSITION: The Elip Distributing Co. and Ira Lichtenstein, t/a Baldwin Laboratories, claimants, filed an answer to the original libel, denying that the article was misbranded as alleged. Interrogatories were served by the Government upon the claimants on 10-20-53; and the claimants, without answering the interrogatories, made a motion for summary judgment. The matter was argued before the court on 1-13-54, and on 2-11-54 the court handed down the following decision in denial of the motion:

BYERS, District Judge: "This is a claimant's motion in a condemnation proceeding under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301, et seq.) for summary judgment.

"The basis of the motion is a holding by the U.S. Post Office Department that the subject matter of the libel was not falsely and fraudulently labeled.

"Fraud is not alleged in the libel, nor was such an allegation requisite under the law. *U.S. v. 5 cases, etc.*, 156 Fed (2) 493 Cf. *U.S. v. Dotterweich*, 320 U.S. 277.

"It is clear that such a departmental holding is not *res judicata*.

"Motion denied. Settle order."

Following the decision, the claimants filed answers to the interrogatories. The amended libel was filed, to which the claimants filed an answer, denying that the article was misbranded; they again advanced the defense of *res judicata* based upon the prior Post Office proceedings. The Government moved to strike the allegations in the answer relating to the *res judicata* defense; and on 9-6-55, the court granted the Government's motion to strike.

The case came on for trial before the court without a jury on 12-18-56; and at the conclusion of the trial, the case was taken under advisement by the court. On 4-5-57, the court handed down the following opinion (150 F. Supp. 648):

BRUCHHAUSEN, *District Judge*: "The libelant instituted this action to condemn a quantity of drugs and advertising material, upon the ground that the drugs were misbranded or mislabelled, in violation of the Pure Food and Drug Act.

"The purpose of the law is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. It was enacted to make self-medication safer and more effective, and to require that drugs moving in interstate commerce be properly labeled so that their use as prescribed may not be dangerous to the health of the user.' *United States v. 62 Packages, etc.*, 48 F. Supp. 878, 887, affirmed 142 F. 2d 107, certiorari denied 323 U.S. 731.

"The term 'labeling' applies to the matter printed or written upon the article itself, and upon the containers or wrappers accompanying it (21 U.S.C. 321(m)). A drug is deemed misbranded 'if its labeling is false or misleading in any particular' also if the labeling fails to include adequate warnings as to its use (21 U.S.C. 352(a)(f)).

"It is not disputed that the claimant Ira Lichtenstein, doing business as Baldwin Laboratories, conceived the formula for the drugs or tablets in question; that the formula consisted of a mixture of flowers of sulphur, rhubarb root and cream of tartar; that the said claimant engaged Jabert Pharmacal Company, Inc. to manufacture the tablets, and that the said claimant contracted with the claimant Elip Distributing Corporation to market them, including packaging and advertising.

"The contention is that in the process of marketing the tablets, the claimants deceived the public in asserting that the tablets would relieve the ailment, known as 'Piles.'

"It is interesting to note that the manufacturer made no such assertion. Its label on the gross shipment to the distributors made no mention of such ailment but designated the tablets as 'laxatives.' The distributors did not use that label but prepared a different label, inserted it in each package or vial of 12 tablets, reading, in part:

Elip Tablets—A palliative treatment for discomfort and itching of rectal irritation caused by piles.

"The counter display cards contained the statement:

An internal preparation for the relief of piles. Price 62. Elip Reg. U.S. Pat. Off.

"A neon sign in the window of Baldwin Laboratories read: 'Elip for Piles.'

"During the trial, the claimants stipulated that the labeling should contain a warning against using the tablets for bleeding piles.

"'Elip,' the designation used by the claimants in promoting the product is 'pile' spelled backwards.

"The three medical experts produced by the Government, expert proctologists, testified that Elip tablets are laxatives and not particularly mild and that the only complete cure for piles is surgery.

"The claimant Lichtenstein, a pharmacist, admitted that surgery was the only known complete cure for piles, but denied that Elip was held out as a cure. He said that he conceived the tablet as a mild laxative softening the digested matter passing over the pile area, and containing an astringent for washing the affected area.

"Either he or his medical witness also asserted the qualities of the tablets were such that the laxative did not operate until it reached the large intestine, thus guaranteeing a complete movement and that there were certain germ killing qualities in the drug.

"Apparently no certain medication has been discovered to date which will cure piles nor are the specific causes known. They are known as hemorrhoids in medical terminology, and consist of swollen veins in the lower end of the large intestine, or anus, brought on by such causes as constipation, infection, overstraining, heredity, childbirth, tension, worry and diet.

"If they protrude, they are known as external as distinguished from internal hemorrhoids, and when dilated they are very painful. Very often they bleed. Temporary relief comes with the lessening of congestion. Sometimes, as with common colds, piles cure themselves.

"A controlled experiment was conducted at Bellevue Hospital by Dr. Max P. Cowett, a distinguished proctologist. He testified that twenty-eight patients, interspersed between hospital and clinic patients were treated with Elip tablets for a period of almost four months. An additional twenty were given placebos in the form of milk sugar tablets. The results were uncomplimentary to Elip. Several of those using the tablets grew worse, or complained of abdominal cramps, with increased bowel movements, and tenesmus, or bowel frustration. The experiment with some patients had to be discontinued. Several required either surgery or sclerosing. None of the patients on either the Elip or the placebo benefited during the treatment.

"Various newspaper and periodical advertisements were submitted in evidence as proof of the intent of the labels, although not as evidence of the labeling itself. Such evidence is competent. *Colgrove v. United States*, 9 Cir., 176 F. 2d 614, certiorari denied 338 U.S. 911; *Research Laboratories v. United States*, 167 F. 2d 410, certiorari denied 335 U.S. 843; *United States v. Vitamin Industries, Inc.*, D.C. Nebr., 130 F. Supp. 755.

"In newspaper advertising and throwaways, the claimant made claims for the tablets such as: 'Piles checked in 72 hours with tablets * * * in 72 hours the bleeding stopped * * * Elip brings sure relief from pile misery * * * the only internal pile remedy.'

"It is plain that the claimants entered into a campaign of 'bait advertising.' A product, manufactured as a laxative, without any changes by the promoters, is held out to the unsuspecting public as a remedy for another condition, piles. The recklessness of the claimants and their utter disregard of those whom they catered to is evidenced by their admission that the tablets could not aid anyone afflicted with bleeding piles. That the element of large profit was not absent from this enterprise is inferable. The tablets cost the claimants about one-tenth of a cent each and were sold by the claimants at \$2 per package of 12 tablets. It is fairly apparent that if the claimants had informed the purchasers that the product was nothing more than a laxative, they would have been obliged to compete with the large number of producers of that article and would not have interested the pile sufferers.

"A decree is directed for the relief demanded in the libel."

In accordance with the above opinion, judgment of condemnation was entered on 6-10-57, and the product was ordered destroyed.

5448. Multizyme. (F.D.C. No. 40552. S. No. 74-325 M.)

QUANTITY: 777 unlabeled 8-oz. btls. and 1,596 unlabeled 4-oz. btls. at Seattle, Wash., in possession of Enzymes Products Co., Inc.

SHIPPED: 2-8-57 and 2-13-57, from Anaheim, Calif., by Ward Erickson.

ACCOMPANYING LABELING: Loose labels designated as "Multizyme Formula W.E. 8 ["or 4"] fl. ozs.," leaflets designated as "The Revolutionary New Multizyme * * * Put your Health in Balance," and order cards designated as "Multizyme * * * Special Trial Offer."

RESULTS OF INVESTIGATION: The accompanying labeling of the article was printed locally for the consignee.

LIBELED: 8-12-57, W. Dist. Washington; amended libel 8-14-57.