

Only Directions: 1 capsule after meals and 1 at bedtime. Contents 24 capsules * * * To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), the statement "containing * * * Emmenagogues" borne on the carton was false and misleading since the articles listed when used as directed, were not effective emmenagogues; and Section 502 (e) (2), the carton label failed to bear the common or usual name of each active ingredient contained in the article. The article was misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 27, 1953. The Kumfort Drug Products, trade name of the Lipton Drug Sales Co., having filed an answer to the libel but subsequently having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3955. Misbranding of Elip tablets. U. S. v. 58 Bags, etc. (F. D. C. No. 33229. Sample No. 37622-L.)

LIBEL FILED: May 8, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about February 11, 1952, from Newark, N. J.

PRODUCT: 58 1,200-tablet bags and 141 12-tablet boxes of *Elip tablets*, together with a number of empty boxes labeled, in part, "Elip Tablets," at Baldwin, N. Y., in the possession of the Baldwin Laboratories. Analysis showed that the product consisted of sulfur, rhubarb, and a tartrate.

RESULTS OF INVESTIGATION: The 58-bag lot represented the remaining portion of a bulk shipment of 120,000 tablets which had been shipped to the Baldwin Laboratories, and the 141-box lot represented tablets from the bulk shipment which had been repackaged by the Baldwin Laboratories.

LABEL, IN PART: (Box) "Elip Tablets Active Ingredients: Potassium Bitartrate, Sulfur and Emodin."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Elip Read Backwards Spells Pile" appearing on the box label was false and misleading since the statement represented and suggested that the article was an adequate and effective treatment for piles, whereas such was not the case; Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient since the label failed to declare the presence of rhubarb.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to warn that frequent or continued use, or use in accordance with the directions "Take 3 tablets with water the first night then 2 tablets every night thereafter," might result in the establishment of dependence upon laxatives to move the bowels.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 28, 1953. Default decree of condemnation and destruction.