

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and, the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions for use "One tablet at bedtime" and "One tablet three times a day after meals," borne on the labeling of the repackaged tablets, were not adequate directions for use.

DISPOSITION: November 15, 1950. Pleas of guilty having been entered, the court imposed a fine of \$20 against each defendant.

✓ 3288. Misbranding of cancer cure. U. S. v. 2 Bottles, etc. (F. D. C. No. 29080. Sample No. 49689-K.)

LABEL FILED: April 19, 1950, District of Colorado.

ALLEGED SHIPMENT: The Hoxsey Cancer Clinic shipped from Dallas, Tex., to Denver, Colo., on or about March 28, 1950, two pint bottles of a product labeled, in part: "From Hoxsey Cancer Clinic, 4507 Gaston Ave., Dallas, Texas. To Regular Concentrate add enough water to make 1 Gal. Shake Well." Linwood E. Downs transported from the Hoxsey Cancer Clinic, Dallas, Tex., to Denver, Colo., during or about September 1948, 1 unlabeled jar containing approximately 2 ounces of a yellow powder.

Approximately 90 booklets which related to the drug and which were entitled "Hoxsey Cancer Clinic Specializing in Cancer" were shipped also from Dallas Tex., from the Hoxsey Cancer Clinic.

PRODUCT: Analysis of a sample of the "Regular Concentrate" showed that it was a dark brown, opaque liquid having a bitter taste suggesting cascara, and having the odor and taste of licorice, and that it consisted essentially of an aqueous solution of potassium iodide, licorice, and other plant extractives, including (probably) cascara.

Examination of the yellow powder showed that it consisted principally of arsenious sulfide, arsenious oxide, and aluminum silicate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the above-mentioned booklets, contained statements which represented and suggested that the articles were effective in the treatment and cure of cancer, whereas the articles were not effective for such purposes; and, Section 502 (f) (2), the labeling of the yellow powder failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, or application, in such manner and form as are necessary for the protection of the user. The articles were misbranded when introduced into, and while in, interstate commerce, and while held for sale after receipt in interstate commerce.

DISPOSITION: June 1, 1950. Default decree of condemnation. The court ordered that the articles of drugs and booklets be released to the Food and Drug Administration.