

3448. Misbranding of pentobarbital sodium capsules. U. S. v. Weaverton L. Fadely (Fadely's Drug Store No. 1) and D. Murray Hayden. Pleas of guilty. Fine of \$500 against Defendant Fadely and \$250 against Defendant Hayden. (F. D. C. No. 30047. Sample Nos. 53787-K, 53857-K.)

LIBEL FILED: April 18, 1951, Northern District of Alabama, against Weaverton L. Fadely, trading as Fadely's Drug Store No. 1, Birmingham, Ala., and D. Murray Hayden, pharmacist.

INTERSTATE SHIPMENT: From the States of New Jersey and Illinois into the State of Alabama, of quantities of *pentobarbital sodium capsules*.

ALLEGED VIOLATION: On or about October 5 and November 1, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repacked and sold without a prescription, which acts resulted in the repackaged drug being misbranded. Weaverton L. Fadely, as owner of the store was charged in both counts of the information, and D. Murray Hayden was joined as a defendant in count 2 and charged with the sale involved in that count.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: May 4, 1951. Pleas of guilty having been entered, the court imposed a fine of \$500 against Defendant Fadely and \$250 against Defendant Hayden.

3449. Misbranding of Eden Creme. U. S. v. 1,601 Jars * * *. (F. D. C. No. 29066. Sample No. 58673-K.)

LIBEL FILED: April 17, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about January 26, 1950, by Captivante Labs., Inc., from New York, N. Y.

PRODUCT: 1,601 jars of *Eden Creme* at Venice, Calif. Examination showed that the product was a soft cream containing approximately the declared amount of estrogenic hormones.

LABEL, IN PART: "Eden Creme * * * Approximately 30,000 International Units of Estrogens (substantially Estrones with traces of Equilin, Hippulin, Estradiol and Equilin) in this jar. This jar should last during a 30-day consecutive period. Net contents not less than 2 ozs. Distributors House of Eden, 6411 Hollywood Blvd. Hollywood 28, Calif."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling did not specify any condition for which the article was to be used and did not state the structure or function of the body that the article was intended to affect.

DISPOSITION: May 21, 1951. The House of Eden, claimant, having filed an answer denying that the product was a drug and that it was misbranded as alleged in the libel, but subsequently having withdrawn its claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

3450. Adulteration and misbranding of first aid kits. U. S. v. 97 Kits * * *
(F. D. C. No. 30746. Sample No. 5007-L.)

LIBEL FILED: March 14, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about August 2, 1950, by the Kiffe Sales Co., from New York, N. Y.

PRODUCT: 97 *first aid kits*, each kit containing a plastic tube of 6 5 mg. amphetamine sulfate tablets, a plastic tube of 8 wound tablets, a plastic tube of 12 atabrine tablets, and a glass vial of iodine, at Boston, Mass.

Examination showed that many of the items were undergoing deterioration. The kits were made up for the use of the Armed Services during the last war and were quite old.

NATURE OF CHARGE: Adulteration. Section 501 (d), a substance containing isopropyl alcohol had been substituted for Iodine Tincture U. S. P., which does not contain isopropyl alcohol.

Misbranding, Section 502 (b) (2), the labels of the tablets in the kits failed to bear accurate statements of the quantity of the contents; Section 502 (e) (1), the label of the wound tablets failed to bear the common or usual name of the drug, namely, sulfadiazine; and, Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use.

DISPOSITION: April 23, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3451. Adulteration and misbranding of epinephrine bitartrate tablets. U. S. v. Graham Chemical Co. and Dr. Samuel D. Goldberg. Pleas of nolo contendere. Fine of \$2 against company and \$50 against individual.
(F. D. C. No. 28106. Sample Nos. 11257-K, 11295-K.)

INFORMATION FILED: May 17, 1951, Eastern District of New York, against the Graham Chemical Co., a partnership, Jamaica, N. Y., and Dr. Samuel D. Goldberg, a partner.

ALLEGED VIOLATION: On or about July 24, 1947, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, a guaranty to the effect that all articles comprising each shipment or other delivery made by the company to the holder of the guaranty would be neither adulterated nor misbranded within the meaning of the law.

On or about October 29, 1948, and February 24, 1949, the defendants shipped under the guaranty to Long Island City, N. Y., two lots of *epinephrine bitartrate tablets*. As originally filed, the information charged that both shipments of the drug were adulterated and misbranded, but the adulteration charge was dismissed with respect to the shipment of October 29, 1948, and the misbranding charge was dismissed with respect to the shipment of February 24, 1949.

*See also No. 3450.