

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3481. Misbranding of Histamist. U. S. v. 12 Cartons * * *. (F. D. C. No. 30929. Sample No. 18772-L.)

LIBEL FILED: April 18, 1951, Southern District of Iowa.

ALLEGED SHIPMENT: On or about January 23, 1951, by the Histamist Corp., from Chicago, Ill.

PRODUCT: 12 display cartons, each containing 12 plastic bottles, of *Histamist* at Des Moines, Iowa. Examination showed that the article was a solution containing methapyrilene hydrochloride and desoxyephedrine hydrochloride.

LABEL, IN PART: (Bottle) "Histamist An Antihistaminic and Decongestant nasal solution * * * 1 $\frac{3}{4}$ fl. oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the display carton of the article were false and misleading since the article was not an effective treatment for the conditions represented: "Histamist * * * for Head Colds - Sinus Misery * * * Helps resist infection * * * Check constant sore throats, infections, etc., from sinus drip Use Histamist for Direct relief * * * Do you have splitting sinus headaches? Smokers catarrh? Use Histamist for prompt relief * * * Do you have head colds, sinusitis * * * sinus headaches Use Histamist Check head cold and sinus misery in minutes Direct nasal sprays, for Direct relief."

Section 505 (a), the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: May 24, 1951. Default decree of condemnation and destruction.

3482. TB-1 powder. U. S. v. 2 Drums * * *. (F. D. C. No. 31157. Sample No. 24116-L.)

LIBEL FILED: May 29, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about May 14, 1951, A. E. Nydegger & Co., Inc., New York, N. Y., delivered the product for shipment from New York, N. Y., to Barcelona, Spain.

PRODUCT: 2 drums containing approximately 90 kilograms of *TB-1 powder* at New York, N. Y. Analysis showed that the product was para-acetyl-amino-benzaldehyde-thiosemicarbazone, commonly known as TB-1, a drug which has been used experimentally in the treatment of tuberculosis.

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: June 15, 1951. Default decree of condemnation and destruction.

3483. TB-1 tablets. U. S. v. 250 Bottles * * *. (F. D. C. No. 30895. Sample No. 24520-L.)

LIBEL FILED: April 4, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 21, 1951, the Hudson Shipping Co., Inc., introduced the product into interstate commerce at Brooklyn, N. Y., for the account of Gallard-Schlesinger Chemical Co., New York, N. Y., for shipment to Portuguese West Africa.

PRODUCT: 250 1000-tablet bottles of *TB-1* at Brooklyn, N. Y.

LABEL, IN PART: "TB1 (4 amino-acetyl-benzaldehyde thiosemicarbazone 50 mg. each) Gallard-Schlesinger Chemical Co., New York, N. Y."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: May 24, 1951. Default decree of condemnation and destruction.

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

DRUGS FOR HUMAN USE

3484. Misbranding of Seconal Sodium tablets and Benzedrine Sulfate tablets. U. S. v. Abraham S. Brown (Cumberland Drug). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 30560. Sample Nos. 79942-K to 79946-K, incl., 79962-K to 79966-K, incl.)

INFORMATION FILED: June 1, 1951, District of Massachusetts, against Abraham S. Brown, trading as the Cumberland Drug, Boston, Mass.

ALLEGED SHIPMENT: From the States of Indiana and Pennsylvania into the State of Massachusetts, of quantities of *Seconal Sodium tablets* and *Benzedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about June 15, 21, and 30, and July 7, 10, 14, 15, 19, 20, and 24, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use in that the directions "One tablet at bedtime as needed" appearing in the labeling of the repackaged *Seconal Sodium tablets*, and "One on arising ½ at noon," "as directed," and "One tablet on arising One tablet at noon" appearing in the labeling of the repackaged *Benzedrine Sulfate tablets* were not adequate directions for use; and, Section 502 (e) (1), the label of the repackaged *Benzedrine Sulfate tablets* failed to bear the common or usual name of the drug.

Further misbranding, Section 502 (d), the *Seconal Sodium tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designating 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."

DISPOSITION: June 12, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$300.

3485. Misbranding of Benzedrine Sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules. U. S. v. Linus D. Drury Corp. (Drury's Pharmacy), and Ralph E. Anderson. Pleas of nolo contendere. Fine of \$250 against corporation and \$50 against individual. (F. D. C. No.