NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3384. TB–1 tablets. U. S. v. 338 Bottles, etc. (F. D. C. No. 31055. Sample No. 17965–L.)

LIBEL FILED: April 11, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about April 5, 1951, by Stanley Lindo and Co., for account of the Strand Pharmacal Corp., Los Angeles, Calif., consigned to Bangkok, Thailand.

PRODUCT: 338 bottles, each containing 100 tablets, and 54 bottles, each containing 1,000 tablets, of *TB–1* at Long Beach, Calif.

LABEL, IN PART: "T–B RX Strand Brand of TB–1 Each tablet provides Para-Acetylamino Benzaldehyde Thiosemicarbazone 25 mg."

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 the article.

DISPOSITION: May 2, 1951. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3385. Adulteration and misbranding of Dr. Merrick's Ear Canker Creme. U. S. v. 69 Cartons * * *. (F. D. C. No. 30288. Sample No. 85882–K.)

LIBEL FILED: On or about December 6, 1950, Northern District of Texas.

ALLEGED SHIPMENT: On or about October 6, 1950, from Brookfield, Ill.

PRODUCT: 69 cartons, each containing 1 tube, of *Dr. Merrick's Ear Canker Creme* at Dallas, Tex.

LABEL, IN PART: (Carton) "Dr. Merrick's Ear Canker Creme Active Ingredients: Aureomycin, Tyrothricin, 2 Mercaptobenzothiazole, Bismuth Subnitrate, Bismuth Subgallate * * * Net Contents ½ Ounce."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess, namely (on display carton) "contains * * * aureomycin," (on retail carton) "Active Ingredients: Aureomycin," and (on leaflet enclosed in retail carton) "Aureomycin and Tyrothricin * * * By combining the two anti-biotics we obtain a very desirable synergistic action resulting in more effective curative action than when either Aureomycin or Tyrothricin is used separately," since the article contained an inconsequential trace, if any, of aureomycin.

Misbranding, Section 502 (a), the statements in the labeling of the article, which are quoted above in the adulteration charge, were false and misleading as applied to the article, which contained an inconsequential trace, if any, of aureomycin; and, Section 502 (l), the article purported to be and was represented as a drug composed in whole or in part of aureomycin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

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

DISPOSITION: April 4, 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

3386. Misbranding of pentobarbital sodium capsules. U. S. v. Bunting & Son, Inc. Plea of guilty. Fine, $800. (F. D. C. No. 29460. Sample Nos. 2936-K to 2939-K, incl.)

INFORMATION FILED: October 17, 1950, Eastern District of Tennessee, against Bunting & Son, Inc., Bristol, Tenn.

INTERSTATE SHIPMENT: From the States of Ohio and Illinois into the State of Tennessee, of quantities of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On or about August 8, 11, 15, and 22, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged and sold without a prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing 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 label of the repackaged capsules 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 capsules failed to bear adequate directions for use, in that the directions "One capsule at bedtime as needed for rest," borne on the labeling, were not adequate directions for use.

DISPOSITION: March 5, 1951. A plea of guilty having been entered, the court imposed a fine of $800 against the defendant.

3387. Misbranding of phenobarbital tablets. U. S. v. Nicholas Paris (Paris Drug Store). Plea of nolo contendere. Defendant fined $500 and placed on probation for 1 year. (F. D. C. No. 29993. Sample Nos. 49741-K, 49743-K, 75194-K.)

INFORMATION FILED: December 20, 1950, District of Colorado, against Nicholas Paris, trading as the Paris Drug Store, Denver, Colo.

INTERSTATE SHIPMENT: On or about February 28, 1950, from the State of Missouri into the State of Colorado, of a quantity of *phenobarbital tablets.*

ALLEGED VIOLATION: On or about April 3, 6, and 10, 1950, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the tablets to be repackaged and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged *phenobarbital 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 has been 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