

under tongue for absorption" and (uninserted page) "Directions for the male: 1 pellet under the tongue 4 times daily for a week or 10 days. 1 pellet under the tongue 3 times daily for a week or 10 days. 1 pellet under the tongue 2 times daily for a week or 10 days. 1 pellet under the tongue 1 time daily for a week or 10 days. * * * Directions for the female: Follow the same dosage as for the male until the first evidence of biological urge, or an itching sensation around the clitoris, then drop down to the next step, until 2 weeks after the beginning of the next menses period. Rest two days. On the third day give 1 pellet daily of Meta Lucyton until the beginning of the next menses, when you again give Meta Androstenedione in the same amount as given just before the 2 day rest."

DISPOSITION: October 26, 1949. Default decree of condemnation and destruction.

2952. Misbranding of Orange Blossom Suppositories. U. S. v. 35 Packages
* * *. (F. D. C. No. 27999. Sample No. 57010-K.)

LABEL FILED: September 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about August 24, 1949, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 35 packages each containing 6 *Orange Blossom Suppositories* at New York, N. Y. Examination showed that the suppositories consisted essentially of ammonium alum, approximately 50 percent, borax and siliceous material in a fatty base.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

DISPOSITION: January 16, 1950. Default decree of condemnation. The court ordered that a number of the suppositories be released to the Food and Drug Administration and that the remainder be destroyed.

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

2953. Misbranding of nembutal capsules, seconal sodium capsules, and Tuinal capsules. U. S. v. Benet's Pharmacies, Inc., and Harry Benet. Pleas of guilty. Fine, \$2,000. (F. D. C. No. 26706. Sample Nos. 18367-K, 18379-K, 18592-K, 18594-K, 18596-K, 19670-K, 19675-K, 19679-K, 19680-K, 19687-K, 19690-K to 19692-K, incl., 19696-K, 43834-K, 51222-K, 51312-K to 51315-K, incl.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Benet's Pharmacies, Inc., Cincinnati, Ohio, and Harry Benet, president and treasurer of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of May 6, 1948, and September 9, 1948, from the States of Illinois and Indiana into the State of Ohio, of quantities of *nembutal capsules*, *seconal sodium capsules* and *Tuinal capsules*.

ALLEGED VIOLATION: On or about October 18, 19, and 20, and November 16, 17, 18, 29, and 30, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of the drugs to be repacked and sold to various persons without a physician's prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The drugs when shipped in interstate commerce, were labeled with the prescription legend required by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged capsules of the drugs contained no statement of the quantity of the contents. Further misbranding, Section 502 (d), the capsules of the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as habit forming; and the label of the repackaged capsules of the drugs failed to bear the name and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Sections 502 (e) (1) and (2), the repackaged drugs were not designated solely by names recognized in an official compendium, and the labels of the *seconal sodium capsules* and *nembutal capsules* failed to bear the common or usual name of the drugs, namely, "seconal sodium" and "pentobarbital sodium," respectively; and the label of the repackaged *Tuinal capsules* failed to bear the common or usual name of each active ingredient, namely, "seconal sodium" and "amytal sodium." Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules of the drugs failed to bear adequate directions for use since the directions for use "One at bedtime as directed" and other directions similarly worded, borne on the labeling of the repackaged capsules, were not adequate directions for use.

DISPOSITION: October 5, 1949. Pleas of guilty having been entered, the court imposed against the defendants, jointly, a fine of \$100 on each of the twenty counts of the information.

2954. Misbranding of seconal sodium capsules, nembutal capsules, and Tuinal capsules. U. S. v. Alvin A. Bredemeyer (Madison Place Pharmacy). Plea of guilty. Fine, \$700. (F. D. C. No. 26720. Sample Nos. 19669-K, 19693-K, 19700-K, 43836-K, 43844-K to 43846-K, incl.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Alvin A. Bredemeyer, trading as the Madison Place Pharmacy, Cincinnati, Ohio.

INTERSTATE SHIPMENT: On or about May 13, 1947, from North Chicago, Ill., to Cincinnati, Ohio, of a quantity of *nembutal capsules*, and between the approximate dates of August 8, 1947, and September 29, 1948, from Indianapolis, Ind., into Cincinnati, Ohio, of quantities of *seconal sodium capsules* and *Tuinal capsules*.

ALLEGED VIOLATION: On or about October 18 and 19 and November 8, 18, 26, 29, and 30, 1948, while a number of the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. When the drugs were shipped in interstate commerce, they bore on their labels the prescription legend prescribed by the regulations.