sodium capsules were dispensed upon request for refills of written prescriptions for such drugs without obtaining authorization from the prescriber. The corporation and Paul Jones, Sr., were charged with causing the acts of dispensing in each of the four counts of the information, and Paul Jones, Jr., was joined as a defendant in three of the counts. Such acts of dispensing were contrary to the provisions of Section 503 (b) 1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: October 1, 1953. Pleas of guilty having been entered, the court imposed a fine of $1,500 against the defendants jointly and placed Paul Jones, Sr., on probation for 18 months.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4209. Adulteration and misbranding of various drugs. U. S. v. 71 Bottles, etc. (F. D. C. No. 34477. Sample Nos. 41211–L to 41219–L, incl.)

LIBEL FILED: January 16, 1953, Western District of Washington.

ALLEGED SHIPMENT: On various dates after August 4, 1951, from points outside of the State of Washington.

PRODUCT: 71 bottles, each containing 1,000 tablets, of *Dex-Amo tablets;* 2 bottles, each containing 500 tablets, and 13 bottles, each containing 1,000 tablets, of *Paba-Sal tablets;* 13 bottles, each containing 1,000 capsules, of *Dasil Evronal capsules;* 4 bottles, each containing 1,000 2½-milligram tablets, and 5 bottles, each containing 1,000 5-milligram tablets, of *Desoxyephedrine hydrochloride tablets;* 29 unlabeled bottles, each containing 1,000 tablets, and 1 unlabeled bottle, containing 2,500 tablets, of a *drug presumed to be dextro-amphetamine sulfate tablets;* 3 bottles, each containing 1,000 tablets, of *amphetamine sulfate tablets;* 2 bottles, each containing 1,000 tablets, of *Dasil veratrum compound tablets;* and 11 bottles, each containing 1,000 tablets, of a *mixture of phenobarbital, aminophylline, and rutin,* at Seattle, Wash.

LABEL, IN PART: "No. 146 Dex-Amo Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.) Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 137 Paba-Sal Each tablet contains Para-Aminobenzoic Acid (5 gr.) 0.3 gm. (as the Sodium Salt) Sodium Salicylate (5 gr.) 0.3 gm. Enteric Coated Distributed by Palmer & Co. Seattle, Wash. Average Adult Dose: Two tablets three times daily or as directed by physician"; "Dasil Evronal 1½ gr. Each capsule contains: Sodium Allyl-Isopropyl-Barbiturate . . . 1½ gr. (Sodium Aprobarbital) Palmer & Co. Distributors * * * Caution: To be dispensed only by or on the prescription of a physician"; "No. 125 Each tablet contains: d-Desoxyephedrine Hydrochloride 2.5 mgm. Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician"; "No. 150 Each tablet contains: d-Desoxyephedrine Hydrochloride 5 mgm. Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician"; " 5 Mg. Each Racemic Amphetamine Sulfate * * * Caution: To be dispensed only by or on the prescription of a physician Distributed By Palmer & Co. Seattle, Wash."; "Dasil Veratrum Compound Tablets Each tablet contains: Veratrum Viride ¾ gr. Phenobarbital ¼ gr. Sodium Nitrite 1 gr. Palmer & Co. Distributors"; and "No. 108 Each tablet contains: Phenobarbital . . . 15 mg. Aminophylline . . . 100 mg. Rutin . . . 20 mg. Warning: May be Habit Forming Distributed by Palmer & Co. Seattle, Wash. Caution: To be dispensed only by or on the prescription of a physician."

NATURE OF CHARGE: *Dex-Amo tablets.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, (on label) "Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.)," since each tablet contained less than the stated amount of such ingredients. Misbranding, Section 502 (a), the label statements "Each tablet contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital NF ½ gr. (32 mg.)" were false and misleading as applied to the article, which contained less than the declared amounts of dextro-amphetamine sulfate and amobarbital; and, Section 502 (b) (1), the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory. Further misbranding, Section 502 (d), the article contained amobarbital, 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 article failed to bear the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Paba-Sal tablets. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purpose for which the article was to be used.

Dasil Evronal capsules. Misbranding, Section 503 (b) (4), the article was a habit-forming drug to which Section 502 (d) applied, and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Desoxyephedrine hydrochloride tablets (2½-milligram and 5-milligram tablets), and *amphetamine sulfate tablets.* Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory; and, Section 503 (b) (4), the articles were drugs which, because of toxicity and other potentiality for harmful effect and the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Drug presumed to be dextro-amphetamine sulfate tablets. Misbranding, Section 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article failed to bear a label containing the quantity or proportion of its active ingredient, dextro-amphetamine; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 503 (b) (4), the article was a drug which, because of toxicity and other potentiality for harmful effect and the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Dasil veratrum compound tablets. Misbranding, Section 502 (d), the article contained phenobarbital, 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 article failed to bear in juxtaposition with the name, and quantity or proportion of such derivative the statement "Warning—May be habit forming." Further misbranding, Section 502 (a), the label designation "Veratrum Compound Tablets" was misleading as applied to the article, which contained in addition to veratrum other potent ingredients.

Tablets containing a mixture of phenobarbital, aminophylline, and rutin. Misbranding, Section 502 (d), the article contained phenobarbital, 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 article failed to bear in juxtaposition with the name, and quantity or proportion of such derivative the statement "Warning—May be habit forming." Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the place of business of the manufacturer, packer, or distributor, since the name of the city, Seattle, Wash., which appeared on the label unaccompanied by a street address, did not reveal the firm's place of business, and the firm's street address was not shown in the current city directory or telephone directory; and, Section 503 (b) (4), the article was a habit-forming drug to which Section 502 (d) applied, and the label of the article failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The *Dex-Amo tablets* were alleged to be adulterated and misbranded and the *Paba-Sal tablets* and the *Dasil veratrum compound tablets* were alleged to be misbranded as described above when introduced into and while in interstate commerce. The other drugs involved were alleged to be misbranded under Section 503 (b) (4), as stated above, while held for sale after shipment in interstate commerce. The 2½-milligram and the 5-milligram *desoxyephedrine hydrochloride tablets, amphetamine sulfate tablets, drug presumed to be dextro-amphetamine sulfate tablets,* and *tablets containing a mixture of phenobarbital, aminophylline, and rutin* also were alleged to be misbranded under other sections of the Act, as stated above, when introduced into and while in interstate commerce.

DISPOSITION: July 24, 1953. Default decree of condemnation and destruction.

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

4210. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Alan W. Saul (Saul's Pharmacy). Plea of nolo contendere. Fine, $450. (F. D. C. No. 33724. Sample Nos. 3516–L to 3518–L, incl.)

INFORMATION FILED: July 22, 1953, Eastern District of Virginia, against Alan W. Saul, trading as Saul's Pharmacy, Norfolk, Va.

ALLEGED VIOLATION: On or about February 20 and 27 and March 7, 1952, while a number of *dextro-amphetamine sulfate tablets* were being held for sale at Saul's Pharmacy after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), the label of the article failed to bear the com-

*See also No. 4209.