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

3921. Misbranding of methamphetamine hydrochloride tablets, pentobarbital sodium capsules, Tricombisul tablets, thyroid tablets, and Amytal Sodium capsules. U. S. v. Andrew J. Kennedy (Kennedy Drugs), and Paul J. Argust. Pleas of guilty. Fine of $400 against Defendant Kennedy and $200 against Defendant Argust. (F. D. C. No. 33712. Sample Nos. 17021–L, 17048–L, 17325–L, 17563–L, 17567–L.)

INFORMATION FILED: January 13, 1953, Southern District of California, against Andrew J. Kennedy, trading as Kennedy Drugs, Los Angeles, Calif., and Paul J. Argust, a pharmacist employed by Mr. Kennedy.

ALLEGED VIOLATION: On or about May 4, 7, 9, and 11, 1951, and April 22, 1952, while a number of *methamphetamine hydrochloride tablets*, *pentobarbital sodium capsules*, *Tricombisul tablets*, *thyroid tablets*, and *Amytal Sodium capsules* were being held for sale at Kennedy Drugs, after shipment in interstate commerce, various quantities of such drugs were repacked and dispensed without a prescription of a physician, which acts resulted in the repackaged drugs being misbranded.

Defendant Kennedy was charged with causing the repacking and dispensing of the *pentobarbital sodium capsules*, *Tricombisul tablets*, and *Amytal Sodium capsules;* Defendant Argust was charged with causing such acts to be done with respect to the *methamphetamine hydrochloride tablets;* and both of the defendants were charged with causing the repacking and dispensing of the *thyroid tablets*.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* and *Amytal Sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of such repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *thyroid tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the label of the *methamphetamine hydrochloride tablets* and the *Tricombisul tablets* failed to bear the common or usual name of each active ingredient of such drugs; and, Section 502 (f) (2), the labeling of the repackaged *methamphetamine hydrochloride tablets* and *Tricombisul tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 2, 1953. Pleas of guilty having been entered by the defendants, the court fined Defendant Kennedy $400 and Defendant Argust $200.