

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4541-4560

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from the standard set forth in such compendium; Section 501 (c), the strength of the article differed from that which it purported and was represented to possess; and, Section 501 (d) (2), a substance had been substituted in whole or in part for the article.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

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

4541. Alpha-estradiol tablets. (F. D. C. No. 33749. S. No. 23-101 L.)

INFORMATION FILED: 1-21-53, S. Dist. N. Y., against Cedardale Drug Co., Inc., New York, N. Y., and Sol Lederman, president and treasurer.

SHIPPED: 4-4-50, from New York to New Jersey.

CHARGE: 502 (b) (1) and (2)—the tablets failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the tablets failed to bear a label containing the common or usual name of each active ingredient; and, 502 (f) (1)—the labeling of the tablets failed to bear adequate directions for use.

PLEA: Not guilty.

DISPOSITION: On 8-16-54, the case came on for trial before the court without a jury, and at the conclusion of the trial the court rendered a verdict of guilty. On 9-21-54, the court fined each defendant \$1,000.

4542. Pentobarbital sodium capsules. (F. D. C. No. 34854. S. Nos. 2-193/5 L.)

INFORMATION FILED: 7-22-53, E. Dist. Va., against Cradock Pharmacy, Inc., Cradock, Va.

SHIPPED: Between 12-17-51 and 1-3-52, from Virginia to Florida.

CHARGE: 502 (b) (1) and (2)—the article failed to bear a label when shipped containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (d)—the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and, 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

*See also No. 4560.