NATURE OF CHARGE: *Dimels Capsules*, misbranding, Section 502 (k), the article was composed in whole or in part of insulin which was not from a batch for which a certificate or release had been issued pursuant to Section 506; Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that, when consumed according to the directions in the labeling, the article would not produce the effect of the hormones found in the Islands of Langerhans, which fact was material in view of the following representations on the labels: "Each capsule Contains Hormone Complexes as found in Isles Langerhans * * * Dosage—One capsule three times daily."

Further misbranding, Section 502 (a), the statements on the labels, "To be taken only upon advice of a physician. Its use otherwise may be dangerous. To be used only in uncomplicated and incipient diabetes," were false and misleading since they represented and suggested that the article, when taken as directed, would be physiologically active and would be dangerous unless taken upon the advice of a physician, and that, when taken as directed, it would be of value in the treatment of uncomplicated and incipient diabetes. The article, when taken as directed, was inert and physiologically inactive, and whether taken upon the advice of a physician or otherwise, it would not be dangerous and it would not be of value in the treatment of uncomplicated and incipient diabetes.

Aditis Capsules, misbranding, Section 502 (j), the article contained barium iodide and thyroid in amounts which would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the following directions from the labeling: "Dose—One to three capsules daily."

DISPOSITION: On May 23 and 24, 1944, the case was tried to a jury and a verdict of guilty was returned with respect to both defendants on all counts. On May 29, 1944, a motion for a new trial was filed on behalf of the defendants, which motion was denied on June 19, 1945. On June 28, 1945, the court imposed a fine of $100 and costs.

1555. Misbranding of Lax Thyroid Tablets. U. S. v. Edward S. Hidden (Carolina Chemical Co.). Plea of guilty. Fine, $500. Sentence of 1 year imprisonment suspended; defendant placed on probation for 5 years, conditioned upon payment of fine. (F. D. C. No. 14262. Sample Nos. 68126–F, 68501–F.)

INFORMATION FILED: February 6, 1945, Eastern District of South Carolina, against Edward S. Hidden, trading as the Carolina Chemical Co., Charleston, S. C.

ALLEGED SHIPMENT: On or about May 20 and June 30, 1944, from the State of South Carolina into the State of Ohio.

PRODUCT: The *Lax Thyroid Tablets* consisted of white and pink tablets in one shipment and light-colored and pink tablets in the other shipment. The tablets were packaged in envelopes in which were enclosed certain mimeographed sheets entitled "Lax Thyroid Tablets."

Analyses showed that each of the white and light-colored tablets contained approximately ½ grain of thyroid, and that each of the pink tablets contained plant drugs, including the laxative drug aloin.

NATURE OF CHARGE: White and light-colored tablets, misbranding, Section 502 (j), the tablets, by reason of the fact that each contained approximately ½ grain of thyroid, would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: (Envelopes containing the light-colored tablets) "Thyroid Tablets * * * Directions: One tablet at bedtime or one tablet before meals"; (mimeographed sheets accompanying the white and light-colored tablets) "Take one Lax Thyroid Tablet at bedtime. If you want to increase dosage you may take one before each meal. * * * Lax Thyroid Tablets are intended to be used as a week-by-week treatment. Do not expect extraordinary results from taking one packing. * * * Loss of weight with Lax Thyroid Tablets does not usually start at once. It may take a few days or even a few weeks to get things started in the right direction. * * * It takes a little time to experience the benefits of this treatment." Further misbranding, Section 502 (a), certain statements in the mimeographed sheets were false and misleading since they represented and created the impression that the tablets would be a safe and appropriate remedy for the treatment of obesity,

and that the use of the tablets would result in greater vitality and a general feeling of well-being in the user. The article would not be a safe and appropriate remedy for obesity, but was a dangerous drug, and its use would not result in greater vitality and a general feeling of well-being in the user.

All tablets, misbranding, Section 502 (b) (1), the labels on the envelopes containing the tablets bore no statement containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the labels bore no statement of the quantity of the contents of the envelopes; and, Section 502 (e) (2), the labels of the tablets failed to bear the common or usual name of each active ingredient, and, in the case of the light-colored tablets, the label failed to bear the name of one of the ingredients, thyroid, and the quantity or proportion of thyroid contained in the tablets.

The information also alleged that an article known as *Vitalex Tablets* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 18, 1945. A plea of guilty having been entered, the court imposed a fine of $500 covering both violations, and sentenced the defendant to imprisonment for 1 year. The jail sentence was suspended and the defendant was placed on probation for 5 years, conditioned upon the payment of the fine.

1556. Misbranding of N. M. Tablets, C. C. Pills, and N. K. Tablets. U. S. v. Maxwell Zedd (Zedd's Cut Rate Drug Stores). Plea of nolo contedere. Fine, $150. (F. D. C. No. 14236. Sample Nos. 53242–F, 53277–F, 53278–F.)

INFORMATION FILED: May 8, 1945, Eastern District of Virginia, against Maxwell Zedd, trading as Zedd's Cut Rate Drug Stores, at Norfolk, Va.; charging that the defendant, while holding the tablets and pills for sale after shipment in interstate commerce, had removed, on or about November 23, 1943, and February 10, 1944, a number of the tablets and pills from the containers in which they had been shipped and had repacked them into boxes and envelopes labeled as hereinafter described, which acts of removal and repacking resulted in the misbranding of the articles.

PRODUCT: Analyses disclosed that the *N. M. Tablets* consisted essentially of extracts of damiana and nux vomica, zinc phosphide, and starch, coated with calcium carbonate and sugar, and colored red; that the *C. C. Pills* contained calomel, compound extract of colocynth, resin of jalap, and gamboge; and that the *N. K. Tablets* consisted of approximately 1 grain of methylene blue, cubeb, santal oil, and possibly other extractives.

LABEL IN PART: (Envelopes) "C. C. Pills 10¢"; (boxes) "N. M. [or "N. K."] Tablets One three times a day Zedd's Cut Rate Drug Stores * * * Norfolk, Va."

NATURE OF CHARGE: *N. M. Tablets*, misbranding, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling, by reason of the presence of zinc phosphide, nux vomica, and cantharides; Section 502 (b) (2), its label bore no statement of the quantity of the contents; and, Section 502 (e), its label failed to bear the common or usual name of each active ingredient, including the name and quantity or proportion of any strychnine.

C. C. Pills, misbranding, Section 502 (b) (1) (2), the envelopes containing 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), the label failed to bear the common or usual name of each active ingredient, including the name and proportion of calomel, a derivative of mercury; Section 502 (f) (1), the envelopes bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the article (a laxative) bore no warnings against use in those pathological conditions, or by children, where its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users.

N. K. Tablets, misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e), the label did not bear the common or usual name of each active ingredient; Section 502 (f) (2), the article, by reason of the presence of methylene blue, santal oil, and cubeb, should have borne, but failed to bear, a label warning that its use should be discontinued if disturbance of the stomach or bowels, or skin rashes, were noticed, which warning was necessary for the protection of users.