Agency, after investigation, to be and by regulations designated as, habit forming, and the label of the repackaged pulvules failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the boxes containing the repackaged pulvules bore no labeling containing directions for use.

DISPOSITION: December 14, 1948. A plea of guilty having been entered, the court imposed a fine of $300.

**2695. Misbranding of amytal and acetyl-salicylic acid capsules, nembutal sodium capsules, and benadryl hydrochloride capsules. U. S. v. Richard C. Miller (Miller's Rexall Drug Store). Plea of nolo contendere. Fine, $500.** (F. D. C. No. 25327. Sample Nos. 26395–K, 27008–K, 27022–K.)

INFORMATION FILED: December 4, 1948, Eastern District of Missouri, against Richard C. Miller, trading as Miller's Rexall Drug Store, Macon, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of June 20, 1947, and March 9, 1948, from the States of Indiana, Illinois, and Michigan, into the State of Missouri.

LABEL, WHEN SHIPPED: "Pulvules Amytal and Acetyl-Salicylic Acid [or "Capsules Nembutal Sodium" or "Kapseals Benadryl Hydrochloride"] * * * Caution—To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 15, 24, and 26, 1948, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the articles to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. The repackaged capsules were labeled "Aspirin & Amytal," "Nembutal," and "Benadryl."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the labels of the repackaged capsules bore no statement containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no statement of the quantity of the contents; Section 502 (d), the capsules of the articles other than the *benadryl hydrochloride capsules* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as, habit forming, and the labels of the repackaged capsules of such articles failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the boxes containing the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: May 23, 1949. A plea of nolo contendere having been entered, the court imposed a fine of $500.

**2696. Misbranding of Dr. Miller's Nosoil, Dr. Miller's Laxative Herbs, Dr. Miller's Deterg-All, Dr. Miller's Aspirin, Dr. Miller's Cascara Compound, and Dr. Miller's Laxative Pills. U. S. v. National Chemical Co. and William H. Dalton and Orland M. Dalton. Pleas of guilty. Fines of $40 against company and $17.50 against each individual, together with costs.** (F. D. C. No. 25576. Sample Nos. 18760–K to 18762–K, incl., 18764–K, 18766–K, 18774–K.)

INFORMATION FILED: December 21, 1948, Southern District of Iowa, against the National Chemical Co., a corporation, Burlington, Iowa, and William H. Dalton, president, and Orland M. Dalton, secretary-treasurer.

ALLEGED SHIPMENT: Between the approximate dates of October 15, 1947, and January 3, 1948, from the State of Iowa into the State of Ohio.

LABEL, IN PART: "Dr. Miller's Nosoil For Nose and Throat," "Dr. Miller's Laxative Herbs," "Dr. Miller's * * * Deterg-All Mouth Wash & Throat Gargle," "Dr. Miller's * * * Aspirin," "Dr. Miller's Sugar Coated Cascara Compound," and "Dr. Miller's Laxative Pills."

NATURE OF CHARGE: *Dr. Miller's Nosoil.* Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of nose colds, hay fever, chronic sinus disease, and acute earache, whereas it would not be efficacious for such purposes; Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 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 since the ingredient phenol, which was declared on the label, was not declared by its common or usual name, carbolic acid; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the article contained oil as a vehicle or base and was for use as nose drops, and its labeling failed to warn that frequent or excessive use of the preparation may cause injury to the lungs and that the preparation should not be used at all in infants and younger children except on competent advice.

*Dr. Miller's Deterg-All.* Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of sore mouth, pyorrhea, tonsillitis, and respiratory diseases, and in the treatment and prevention of many contagious diseases which find their way into the body by way of the mouth and throat, whereas it would not be efficacious for such purposes.

*Dr. Miller's Aspirin.* Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of neuritis, lumbago, sciatica, acute colds, tonsillitis and allied conditions, and any aching of the body of nerve and muscular origin, whereas it would not be efficacious for such purposes.

*Dr. Miller's Cascara Compound.* Misbranding, Section 502 (a), the label designation "Cascara Compound" was misleading since it represented and suggested that the laxative action of the article was derived solely from cascara, whereas the laxative action of the article was derived in part from other active laxative ingredients, aloin and podophyllin.

*Dr. Miller's Laxative Pills.* Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium; it

was fabricated from two or more ingredients; and it contained strychnine and calomel; and the label of the article did not bear the name and quantity or proportion of strychnine contained in the article, a statement showing the substance from which the ingredient calomel was derived, and the fact that the ingredient was derived from mercury.

Further misbranding, Section 502 (b) (2), the labels on the *Dr. Miller's Nosoil*, the *Dr. Miller's Laxative Herbs*, and the *Dr. Miller's Aspirin* bore no statement of the quantity of the contents; the *Dr. Miller's Cascara Compound* and the *Dr. Miller's Laxative Pills* were not designated solely by names recognized in an official compendium, were fabricated from two or more ingredients, and contained the alkaloids atropine, hyoscine, and hyoscyamine as constituents of belladonna; and the labels of the articles did not bear the name and quantity or proportion of such alkaloids nor in lieu thereof, the quantity or proportion of total alkaloids contained in the articles as constituents of belladonna.

Further misbranding, Section 502 (f) (2), the *Dr. Miller's Laxative Herbs*, the *Dr. Miller's Cascara Compound*, and the *Dr. Miller's Laxative Pills* were laxatives and the labeling failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form as are necessary for the protection of users, since their labeling failed to bear warnings that they should not be used in the presence of abdominal pain (stomach ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis; and the labeling of such articles failed also to bear adequate warnings against unsafe dosage and duration of administration, since their labeling failed to warn that frequent or continued use of the articles might result in dependence on laxatives to move the bowels.

DISPOSITION: April 18, 1949. Pleas of guilty having been entered, the court imposed fines of $40 against the company and $17.50 against each individual, together with costs.

2697. **Misbranding of Menestrex Capsules. U. S. v. 105 Bottles * * * (and 3 other seizure actions).** (F. D. C. Nos. 24765, 25792, 25977, 25978. Sample Nos. 260-K, 999-K, 1317-K, 1318-K.)

LIBELS FILED: On or about May 12, October 26, and November 4 and 5, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about August 28 and September 5 and 6, 1947, and August 20 and September 8, 1948, by the Rex Laboratory, from Nashville, Tenn.

PRODUCT: 128 12-capsule bottles and 55 25-capsule bottles of *Menestrex Capsules* at Atlanta, Ga. Examination showed that each capsule of the product consisted essentially of 4 grains of quinine sulfate and 0.6 grain of potassium permanganate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of a portion of the product were false and misleading since the product was not effective in the treatment of scanty or functionally difficult menstruation: "Menestrex * * * For easing distress in scanty or functionally difficult menstruation * * * Start taking about 3 days before expected menstruation * * * Not for use during pregnancy"; and, Section 502 (f) (1), the labeling of the remainder of the product failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: June 15 and December 17, 1948. Default decrees of condemnation and destruction.