2308. Misbranding of Schoell's 202 Treatment. U. S. v. Arthur Schoell (Schoell Manufacturing Co.). Plea of nolo contendere. Fine, $250. (F. D. C. No. 23229. Sample No. 19590-H.)

INFORMATION FILED: October 2, 1947, Northern District of California, against Arthur Schoell, trading as the Schoell Manufacturing Co., Los Gatos, Calif.

ALLEGED SHIPMENT: On or about August 13, 1946, from the State of California into the State of Minnesota.

PRODUCT: Examination showed that the treatment consisted of 20 capsules, each of which contained aloin, manganese dioxide, oil of cassia, apiol green, and capsicum; and of two suppositories which contained potassium alum, tannin, sodium chloride, sodium borate, and magnesium sulfate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label, and in a leaflet entitled "Schoell's 202 Treatment" which was enclosed with the article, were false and misleading. These statements represented and suggested that the article would be efficacious in the treatment of unnatural irregularities due to colds and other minor causes, and that it would be efficacious in the treatment of painful, irregular, and unnatural delayed menstruations. The article would not be efficacious for the purposes so represented.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, since the capsules were a laxative and the labeling failed to bear a warning that they should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present.

DISPOSITION: October 31, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $250.

2309. Misbranding of ephedrine and amytal pulvules. U. S. v. Cohen Drug Co., Inc., and Saul Cohen. Pleas of nolo contendere. Fine, $1,800 against corporation. Indictment dismissed with respect to individual. (F. D. C. No. 21474. Sample Nos. 42232-H, 42233-H, 42235-H, 42237-H, 42240-H, 42242-H, 42618-H to 42620-H, incl.)

INDICTMENT RETURNED: April 9, 1947, Southern District of West Virginia, against the Cohen Drug Company, Inc., Charleston, W. Va., and Saul Cohen.

ALLEGED SHIPMENT: Between the approximate dates of March 15 and May 21, 1946, from the State of Ohio into the State of West Virginia.

LABEL, WHEN SHIPPED: "Pulvules No. 44 Ephedrine and Amytal * * * Warning—May be Habit Forming. Caution—To be used only by or on the prescription of a physician * * * Eli Lilly and Company Indianapolis, U. S. A."

ALLEGED VIOLATION: On or about July 2, 9, 16, and 17, 1946, and while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of the said "Pulvules" (capsules) to be removed from the bottles bearing the labels described above, to be repackaged into boxes and labeled "Ephedrine and Amytal," and to be sold without a prescription.

NATURE OF CHARGE: That the defendant caused the drug to be misbranded, as follows: Section 502 (d), the product was a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been designated by the regulations as habit forming, and its label failed to bear a statement containing the name and quantity or proportion of the chemical derivative of barbituric acid and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; Section 502 (f) (1), the labeling failed to bear adequate directions for use; and, Section 502 (f) (2), it failed to bear adequate warnings against use in those pathological conditions, and by children, where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 5, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $200 on each of the 9 counts against the corporation and ordered the action against the individual dismissed.