

**1561. Misbranding of Nembutal Capsules and sodium phenobarbital capsules. U. S. v. H. Otis Fadal. Plea of guilty. Fine, \$600; sentence of 6 months in jail. Jail sentence suspended and defendant placed on probation for 2 years.** (F. D. C. No. 14237. Sample Nos. 60900-F, 61558-F, 61561-F.)

**INFORMATION FILED:** February 27, 1945, Western District of Texas, against H. Otis Fadal, a member of the partnership trading as Fadal's Square Drug Store, at Waco, Tex.

**INTERSTATE SHIPMENT:** Between the approximate dates of December 11, 1943, and April 12, 1944, from Chicago, Ill., and Kansas City, Mo., of quantities of *Nembutal Capsules* and *sodium phenobarbital capsules*.

**LABEL, WHEN SHIPPED:** "Capsules Nembutal \* \* \* (Pentobarbital Sodium, Abbott) Warning: May be habit forming 1½ grs. \* \* \* Caution: To be used only by or on the prescription of a physician or dentist \* \* \* Abbott Laboratories," or "Filled Capsules Phenobarbital Sodium 1½ Grs. (Barbituric Acid Derivative) Yellow Warning May Be Habit Forming Caution: To be used only by or on the prescription of a physician SE M CO The S. E. Massengill Co. \* \* \* Bristol, Tenn.-Va."

**NATURE OF CHARGE:** That, between the dates of April 10 and May 8, 1944, the defendant removed a number of capsules from one of the bottles labeled "Capsules Phenobarbital" and repacked the capsules into an unlabeled bottle; that, on or about May 8, 1944, the defendant removed from the unlabeled bottle a number of capsules, repacked them in an unlabeled envelope, and sold them without a prescription; and that, on May 9, 1944, the defendant removed a number of capsules from the unlabeled bottle, repacked them in an envelope labeled "Nembutal 1½ gr." and sold them without a prescription. The information also charged that, on or about May 9, 1944, the defendant removed from the bottle labeled "Capsules Nembutal" a quantity of capsules and repacked them in an envelope bearing the label "Nembutal 1½ gr."

The information charged further that the acts of the defendant resulted in the drugs being misbranded in the following respects: Section 502 (d), the drugs contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming, and the envelopes bore no labels containing the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (f) (1), the envelopes bore no labeling containing directions for use; Section 502 (f) (2), they bore no labeling containing warnings against use in those pathological conditions where the use of the drugs might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users; Section 502 (e), the envelopes containing the *phenobarbital capsules* failed to bear a label containing the common or usual name of the drug, "Sodium Phenobarbital"; and, Section 502 (a), the label statement "Nembutal," borne on one of the envelopes containing the *phenobarbital capsules*, was false and misleading.

**DISPOSITION:** March 1, 1945. A plea of guilty having been entered by the defendant, the court imposed a fine of \$600 and sentenced the defendant to serve 6 months in jail. The jail sentence was suspended, and the defendant was placed on probation for 2 years.

**1562. Misbranding of Col-Chex, Diarrhea and Flux Remedy, and Coldex. U. S. v. C. B. Drug Sales Co., Inc. Plea of guilty. Fine, \$100.** (F. D. C. No. 11332. Sample Nos. 35395-F to 35397-F, incl.)

**INFORMATION FILED:** February 14, 1944, Western District of North Carolina, against the C. B. Drug Sales Co., Inc., Charlotte, N. C.

**ALLEGED SHIPMENT:** Between the approximate dates of December 31, 1942, and March 11, 1943, from the State of North Carolina into the State of South Carolina.

**PRODUCT:** Analyses disclosed that the *Col-Chex* was composed of a mineral oil base containing camphor, menthol, oil of Eucalyptus, and ephedrine; that the *Diarrhea and Flux Remedy* was a mixture containing salol, chalk, sodium phenolsulfonate, bismuth salicylate, and plant material; and that the *Coldex* was a mixture containing 20.4 grains of sodium salicylate per fluid ounce and also containing menthol and camphor, emodin-bearing drugs, and other plant material.

**NATURE OF CHARGE:** *Col-Chex*, misbranding, Section 502 (a), the label statements, "Col-Chex for Nose & Throat \* \* \* Col-Chex is recommended as an aid in preventing colds and to check acute symptoms of trouble in nasal

passages. Repeat dosage every two hours until relieved," were false and misleading since the article would not be efficacious in the cure, mitigation, treatment, or prevention of colds nor in the treatment of all acute symptoms of trouble in the nasal and throat passages; and certain statements in an accompanying leaflet regarding another drug, *Coldex*, were false and misleading, since they represented and suggested that the other drug would be efficacious in the cure, mitigation, treatment, or prevention of colds, coughs, and flu, and that the use of the other drug would often save the whole family from a period of sickness, whereas the other drug would not be efficacious for those purposes.

*Diarrhea and Flux Remedy*, misbranding, Section 502 (a), the label statements, "Diarrhea and Flux Remedy An efficient Antiferment and intestinal antiseptic and astringent for the treatment of Diarrhea, Dysentery, Colitis and Flux," were false and misleading since the article would not be an efficacious remedy in the cure, mitigation, treatment, or prevention of diarrhea or flux and would not be an efficient antiferment or intestinal antiseptic or astringent for the treatment of diarrhea, dysentery, colitis, or flux.

*Coldex*, misbranding, Section 502 (a), the name "Coldex" was misleading in that it represented and implied that the article would be a competent treatment for colds, whereas it would not be a competent treatment for colds; and the label statement "For Relief of Colds" was false and misleading since the article would not be an effective treatment for the relief of colds. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that the directions, "Two Teaspoonfuls in Water Then one teaspoonful every three or four hours until bowels move freely. Thereafter three times a day until desired results are obtained," suggested continuous use of the article, whereas the article was a laxative, and frequent or continued use might result in dependence upon laxatives to move the bowels; and, Section 502 (f) (2), the labeling of the article failed to warn that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

**DISPOSITION:** April 9, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$100.

**1563. Alleged misbranding of Heron's Constipation Remedy and Liver Regulator and Heron's Pure Eucalyptus Oil. U. S. v. Norman C. Heron (N. C. Heron Co.). Motion to strike granted and demurrer sustained. Case appealed and subsequently dismissed upon the death of the defendant. (F. D. C. No. 11399. Sample Nos. 14862-F to 14864-F, incl., 36429-F, 36430-F, 39904-F.)**

**INDICTMENT RETURNED:** June 14, 1944, Southern District of California, against Norman C. Heron, trading as the N. C. Heron Co., Los Angeles, Calif.

**ALLEGED SHIPMENT:** Between the approximate dates of July 23 and August 26, 1943, from the State of California into the States of Oklahoma and Colorado.

**PRODUCT:** Analyses of samples disclosed that the *Constipation Remedy and Liver Regulator* consisted essentially of extracts of plant drugs including a laxative drug such as cascara sagrada; and that the *Heron's Pure Eucalyptus Oil* consisted of an oil of Eucalyptus.

**NATURE OF CHARGE:** *Constipation Remedy and Liver Regulator*, misbranding, Section 502 (a), the name of the article was false and misleading since it represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of all forms of constipation, and that it would be efficacious as a liver regulator, whereas the article would not be efficacious for the purposes claimed; and the label statements, "Harmless—Not Habit Forming," were false and misleading since the article might be harmful in the presence of appendicitis and might cause the formation of the laxative habit. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions on the label suggested frequent or continued use of the article, whereas it was a laxative and should not be used frequently or continuously; and, Section 502 (f) (2), the labeling failed to warn that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present, and that frequent or continued use might result in dependence upon laxatives to move the bowels.

*Eucalyptus oil*, misbranding, Section 502 (a), certain statements on the labels and in an accompanying circular were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, treatment, or prevention of colds, coughs, whooping cough, croup, consumption,