

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs bore no label containing a statement of the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), they bore no labeling containing directions for use.

Further misbranding, Section 502 (e) (1), the container of the repackaged *Benadryl capsules* bore no label containing the common or usual name of the drug; and, Section 502 (f) (2), the container of the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: September 30, 1949. Pleas of nolo contendere having been entered, the court placed the defendants on probation for 1 year.

3003. Adulteration and misbranding of Geo-Mineral. U. S. v. 672 Bottles * * *.
(F. D. C. No. 27227. Sample No. 51436-K.)

LIBEL FILED: May 18, 1949, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 15, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 672 3-ounce bottles of *Geo-Mineral* at Anderson, Ind. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: August 8, 1949. Default decree of forfeiture and destruction.

3004. Misbranding of Gall-Klenz. U. S. v. 27 Gallons * * *. (F. D. C. No. 27779. Sample Nos. 16285-K, 42343-K.)

LIBEL FILED: August 29, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about April 20, May 16, and June 18, 1949, from Des Moines, Iowa.

PRODUCT: 27 gallons of a drug, some of which had been repackaged into 288 2-ounce and 6-ounce bottles labeled "Gall-Klenz," at Detroit, Mich., in possession of the F. A. R. Chemical Co.

Examination of the product showed that it contained alcohol, sodium salicylate, phenolphthalein, bile extract, sodium oleate, menthol, and aromatics.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, a circular entitled "Dear Friend" and leaflets entitled "Valuable Knowledge Everyone Should Know," "Bowel-

Klenz," and "Directions for Taking Gall-Klenz," were false and misleading since the article would not be effective for the purposes stated and implied in the labeling; since it did not conform to all food and drug laws; since it contained drugs; since it was not harmless; and since it was capable of causing the laxative habit. The statements represented and suggested that the article conformed with all food and drug laws; that it contained no drugs; that it was a harmless non-habit-forming liquid; that it would be efficacious in the treatment of liver and gall disorders, such as gallstones, stomach and bowel distress, indigestion, and gas; that it would restore the liver to its natural healthy state; that it would stimulate a flow of pure bile; that it would restore the stomach and other dependent organs to a normal activity; that it would enable one to regain good health; and that it would be efficacious in the treatment of pains in the side, around the waist line, and in the region of the heart or appendix, gallstones, gas, colic, indigestion, belching, sourness, dyspepsia, biliousness, lack of appetite, nausea, vomiting of bile, coated tongue, duodenal ulcers, heavy distressed feeling in pit of stomach, diarrhea, piles, gas in the intestines, bloating, intestinal indigestion, pains or signs of appendicitis which often prove to be caused from gallstone or gall bladder origin, heartburn, sick, nervous, or bilious headache, bad complexion, jaundice, yellow, sallow, or greenish skin, blues and despondency, dizzy fainting spells, lack of pep, cold sweats, anemia, nervousness, high blood pressure, arthritis, diabetes, and some kidney pains.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration as are necessary for the protection of users, since the label statement "Gall-Klenz contains a laxative, and all laxatives may become habit forming" was contradicted by the statement, "Gall-Klenz is a harmless, non-habit forming * * * liquid," in one of the leaflets. The labeling did not inform the purchaser that the article if taken as directed in such labeling, namely, "The average condition * * * has shown to require from three to nine months for most lasting results" and "The treatment should be continued even after the symptoms disappear, that the disruptions caused by these disorders may be properly corrected," may result in dependence upon laxatives to move the bowels. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: October 10, 1949. Default decree of condemnation and destruction.

3005. Misbranding of Cathartein Compound Tablets. U. S. v. 60,000 Tablets
* * *. (F. D. C. No. 27779. Sample Nos. 16281-K, 42340-K.)

LIBEL FILED: August 29, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about April 28, 1949, by the Standard Chemical Co., from Des Moines, Iowa.

PRODUCT: 60,000 *Cathartein Compound Tablets* at Detroit, Mich. Examination showed that the tablets contained belladonna alkaloids, phenolphthalein, cascara sagrada extract, podophyllin, aloin, and ginger oleoresin.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the conditions for which it was intended to be used.

DISPOSITION: October 11, 1949. Default decree of condemnation and destruction.