

The article was alleged to be misbranded in that certain statements appearing in its labeling which represented and suggested that the article was not habit-forming, gave "pep," was effective in the treatment of stomach, liver, kidney, blood, nerve, and intestinal disorders, and was effective in the treatment of constipation, swollen limbs, and indigestion, were false and misleading since the article was capable of causing laxative-habit formation, did not give "pep," and was not effective in the treatment of the disorders and conditions above-described; and in that the statement appearing in its labeling, "Natur-Pep Tonic Is Prepared From Ingredients of Recognized Medicinal Value: Extract Cascara Sagrada, Iron Pyrophosphate, Strontium Salicylate, Oleum Coriander, Methyl Salicylate, Extract Gentian, Alcohol  $\frac{1}{2}$ %, Hexamethylenamine, Extract Glycyrrhiza, Magnesium Sulphate, Potassium Acetate, Sodium Salicylate, Oleum Anise, Glycerine," was misleading since such statement created the impression that the article provided significant quantities of all the ingredients named, whereas it did not provide significant quantities of such ingredients, but was essentially an Epsom salt laxative. It was alleged to be misbranded further in that its labeling failed to bear adequate directions for use since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and in that the labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, or adequate warnings against unsafe methods and duration of administration, in such manner and form as are necessary for the protection of users, since the labeling failed to bear a warning that a laxative should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and that frequent or continued use might result in dependence upon a laxative to move the bowels.

On December 16, 1942, no claimant having appeared, judgment was entered ordering that the product be destroyed.

**958. Misbranding of Ramazzotti. U. S. v. 3 Cases of Ramazzotti. Consent decree of condemnation. Product ordered released under bond for relabeling.**  
(F. D. C. No. 8615. Sample Nos. 17361-F, 18845-F.)

On or about October 22, 1942, the United States attorney for the District of Connecticut filed a libel against 3 cases, each containing 24 bottles, of Ramazzotti at Stamford, Conn., alleging that the article had been shipped in interstate commerce on or about July 24, 1942, by the Banfi Products Corporation from New York, N. Y.; and charging that it was misbranded.

Examination showed that the article contained extracts of plant drugs, including a laxative drug such as rhubarb, and 38.2 percent of alcohol.

The article was alleged to be misbranded in that the statement "originated by FLLI. RAMAZZOTTI, MILANO, ITALY" and various other statements in the Italian language, together with designs including the Papal seal and the State seal of Italy, appearing in the labeling, were false and misleading since they created the impression that the article was prepared in Milan, Italy, whereas it was manufactured in New York, N. Y.

The article was alleged to be misbranded further (1) in that the statements on the bottle label, "FAMOUS SINCE 1815," and on the bottle wrapper, "Used throughout the World since 1815," were false and misleading since the article had not been produced and marketed over the period since 1815; (2) in that the name of each active ingredient, including the name and quantity or proportion of alcohol contained in the article, required by law to be declared on the label, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, since the names of the active ingredients and the quantity or proportion of alcohol did not appear on the bottle wrapper and did not appear in the Italian language in any of the labeling; and (3) in that its labeling failed to bear adequate directions for use since the directions in English, "Dose:  $\frac{1}{2}$  to 1 oz. taken straight, in black coffee, or hot lemonade before or after meals, upon retiring or any time during the day," and the directions in Italian "puro e misto all'acqua, al seltz, alle acque minerali, al Vermouth e col caffè" (translation: "pure and mixed with water, seltzer, with mineral waters, with Vermouth and with coffee"), did not provide for a definite amount of frequency or duration of administration, but were indefinite and therefore not adequate.

It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein 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 the user, since its labeling bore no warning against use by children for whom, by reason of its large proportion of alcohol, it would be especially unsuitable; its labeling bore no warning against use in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis, whereas, by reason of its content of a laxative drug such as rhubarb, it would be dangerous when used in such circumstances; and it bore no warning against frequent or continued use which might result in the establishment of dependence upon laxatives to move the bowels.

On January 7, 1943, Banfi Products Corporation, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of and in form satisfactory to the Food and Drug Administration.

**959. Misbranding of Special SC Pink Tablets. U. S. v. 3 Drums of Special SC Pink Tablets. Product relabeled and ordered released to claimant. (F. D. C. No. 8428. Sample Nos. 4628-F to 4630-F, incl.)**

On September 29, 1942, the United States attorney for the Middle District of Tennessee filed a libel against 3 drums containing a total of approximately 140,000 Special SC Pink Tablets at Nashville, Tenn., alleging that the article had been shipped in interstate commerce on or about February 19, April 25, and June 23, 1942, by Charles H. Dietz, Inc., from St. Louis, Mo.; and charging that it was misbranded.

Analyses of samples showed that the article consisted essentially of acetanilid, potassium bromide, laxative plant drugs, and cinchonidine sulfate.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since there were no directions. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against use in those pathological conditions, or by children, wherein its use might be dangerous to health, in such manner and form as are necessary for the protection of users, since the article was a laxative and its labeling failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; that frequent or continued use of the article might result in dependence on a laxative; and that the article was not to be given to children. It was alleged to be misbranded further in that its labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users, since the labeling failed to warn that frequent or continued use of acetanilid might be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug, and that not more than the recommended dosage was to be taken.

On October 9, 1942, the product having been relabeled and the claimant, the Gattis Chemical Co., Nashville, Tenn., having paid costs of the proceedings, the product was ordered delivered to the claimant.

**DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH\***

**960. Adulteration of sulfanilamide tablets. U. S. v. 3,000 Bottles of Sulfanilamide Tablets. Consent decree of condemnation. Product ordered released under bond for segregation and destruction or reprocessing of the contaminated portion. (F. D. C. No. 8962. Sample No. 18441-F.)**

Examination of a sample of this product showed that most of the tablets were covered with live mold, a species of *Aspergillus*.

On December 9, 1942, the United States attorney for the Eastern District of New York filed a libel against 3,000 bottles, each containing 1,000 tablets, of sulfanilamide at Brooklyn, N. Y., alleging that the article had been shipped in interstate commerce on or about November 18, 1942, by the Maltbie Chemical Co., Newark, N. J.; and charging that it was adulterated in that it consisted in whole or in part of a filthy substance.

On December 26, 1942, the Maltbie Chemical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be sorted according to codes and the portion

\*For bacterial contamination see Nos. 970-977, 985, 986.