

**FEDERAL SECURITY AGENCY**

**FOOD AND DRUG ADMINISTRATION**

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,  
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

801-850

**DRUGS AND DEVICES**

The cases reported herewith were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER,

*Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., October 7, 1943.

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**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS**

**801. Misbranding of Dr. Shreves' S-and-L Pills and Dr. Shreves' Anti-Gall-Stone Remedy. U. S. v. Ralph V. Toland (Dr. Shreves' Medicine Co.). Plea of guilty. Fine, \$50 and costs. (F. & D. No. 4117. Sample Nos. 15549-E, 30909-E.)**

On July 31, 1941, the United States attorney for the Southern District of Iowa filed an information against Ralph V. Toland, trading as Dr. Shreves' Medicine Co., Newton, Iowa, alleging shipment on or about June 19, 1940, from the State of Iowa into the State of Arkansas of a number of boxes of Dr. Shreves' S-and-L Pills which were misbranded, and on or about May 11, 1940, from the State of Iowa into the State of Indiana of a number of packages, each containing a bottle of Dr. Shreves' Anti-Gall-Stone Remedy, and an envelope containing a number of Dr. Shreves' S-and-L Pills which were also misbranded.

Analysis of a sample of the pills showed that they contained plant material, including a laxative plant drug, and metallic mercury with chalk, the two samples containing 0.62 grain and 0.68 grain respectively of mercury. Analysis of a sample of the gallstone remedy showed that it consisted essentially of lime water containing a white sediment and flavored with sassafras.

The pills were alleged to be misbranded in that they would be dangerous to health when used in the dosage or with the frequency or duration prescribed,

<sup>1</sup> For substitution of a drug and its sale under the name of another drug, see No. 820; omission of name and place of business of manufacturer, packer, or distributor, No. 845; omission of accurate statement of quantity of contents, Nos. 805, 809, 845; inconspicuousness of quantity of contents and active ingredients statements, Nos. 840, 849; omission of, or unsatisfactory, active ingredient statement, Nos. 809, 828, 839, 844, 845; deceptive packaging, No. 805.

recommended, or suggested in the labeling, (box and envelope) "Directions—One to three pills every night until the bowels move freely," and (circular enclosed in envelope) "Directions—Dose—One to three pills. For occasional Constipation, Biliousness and Sour Stomach, take two or three pills at bedtime, then follow with two pills every night until completely restored," since they contained mercury, a cumulative toxic substance. The pills which were shipped separately were alleged to be misbranded in that certain statements in the labeling, which represented that they would be efficacious as a treatment for biliousness and sour stomach, catarrh of the stomach or bowels, dizziness, nausea, diarrhea, or dysentery, would promote digestion and assimilation, and would restore tone to the system, were false and misleading since they would not be efficacious for such purposes. The combination Anti-Gall-Stone Remedy and Pills was alleged to be misbranded in that certain statements in the labeling which represented and suggested that it would be efficacious as a gallstone remedy, would produce a chemical change in the gall, would alter the secretions of the gall bladder, liver, kidneys, and bladder, would place the system in better condition and would maintain the stomach and intestines in a healthy condition, would overcome chronic constipation, would clean the alimentary canal, would prevent injury to the system by disease germs in the stomach and bowels, and would cleanse the system by removing poisons, would be efficacious in the treatment of biliousness, sour stomach, catarrh of the stomach or bowels, dizziness, nausea, diarrhea or dysentery, would promote digestion and assimilation and would restore tone to the system, were false and misleading since the combination would not be efficacious for such purposes.

On July 11, 1942, the defendant entered a plea of guilty and the court imposed a fine of \$50 and costs.

**802. Misbranding of UtraJel. U. S. v. 59 Boxes of UtraJel Regular and 8 Boxes of UtraJel Mild. Default decree of condemnation and destruction. (F. D. C. No. 7490. Sample Nos. 92548-E, 92549-E.)**

On May 12, 1942, the United States attorney for the Southern District of California filed a libel against 58 boxes of UtraJel Regular and 8 boxes of UtraJel Mild, at Los Angeles, Calif., alleging that the articles had been shipped in interstate commerce on or about April 18, 1942, by the Pynosol Laboratories, Inc., from Chicago, Ill.

Analysis of a sample of the UtraJel Regular showed that it consisted essentially of soap, water, oil of pine, and combined iodine. Analysis of a sample of the UtraJel Mild showed that it consisted essentially of soap, water, and oil of pine.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling since they might result in injury to the parts to which applied and to other organs of the body. The dosage recommendations were in part as follows: "As a Uterine Evacuant \* \* \* Prepare field, gently insert sterilized applicator into the internal os and pass it carefully along the canal and into the mouth of the uterus remembering the position of the uterus as determined by previous bimanual examination. In all cases treatment should be administered very slowly to eliminate as much, the possibility of shock and excessive cramping. Dosage: 2 to 5cc first month, 8-10cc second month, 12-15cc third month and 20-22cc for farther advanced cases. Note: in some cases it may be necessary to increase dosage slightly, depending entirely on individual case \* \* \* When no response is obtained after treatment, it is due either to uterine inertia or insufficient dosage. A great number of cases respond to a second treatment \* \* \* The same procedure should be followed if portions of placenta are retained."

They were alleged to be misbranded further in that the following statements "Cervical Infections and Cervical Erosions (Minor) \* \* \* Infections of the Cervical Canal (Minor) \* \* \* Cystic Cervix," were false and misleading since the articles would not be effective treatments for the conditions mentioned, and in that the statements "UtraJel \* \* \* As a Uterine Evacuant \* \* \* UtraJel has been used successfully for induction of labor in full term deliveries, and for the expulsion of either entire or parts of placenta," were false and misleading since they represented and suggested that the articles were safe and appropriate for introduction into the uterine cavity, whereas they were not safe and appropriate for such use but were unsafe and dangerous and were capable of producing serious or even fatal consequences.

On August 10, 1942, no claimant having appeared judgment of condemnation was entered and the products were ordered destroyed.