

333. Misbranding of Utra Jel. U. S. v. 32 Tubes of Utra Jel. Default decree of condemnation and destruction. (F. D. C. No. 3196. Sample No. 14082-E.)

This product would be dangerous to health when used as directed in the labeling. It would not be efficacious for certain purposes for which it was recommended. It contained no free iodine as claimed, and the retail carton did not bear the common or usual names of the active ingredients.

On October 14, 1940, the United States attorney for the Eastern District of Pennsylvania filed a libel against 32 tubes of Utra Jel at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about August 15, 1940, by Pynosol Laboratories, Inc., from Chicago, Ill.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of water, soap, pine oil, and combined iodine. It contained no free iodine.

The article was alleged to be misbranded in that the following statement in the labeling was false and misleading since it was not efficacious for the said purposes: "For Specific and Non-Specific Infections of the Cervix and Cervical Canal." It was alleged to be misbranded further in that the following statement appearing in the labeling was false and misleading in that it was incorrect: (Tube) "Active Ingredients: 1% Iodine." It was alleged to be misbranded further in that its carton did not bear the common or usual names of the active ingredients; and in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely: (Carton) "1 to 5cc injected into cervical canal, and about 3-5cc applied on wool tampon to be left in position from 12 to 20 hours"; and (tube) "For Cervical and Intra-Uterine Use."

On November 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

334. Misbranding of Young's Preparation. U. S. v. 19 Packages of Young's Preparation. Default decree of condemnation and destruction. (F. D. C. No. 2233. Sample No. 20701-E.)

This product contained acetic acid and would be dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, which recommended it for the relief of itching skin and scalp and directed that it should be well-shaken and applied to afflicted parts two or three times a day, that if the parts were raw it should be diluted with water until it could be used full strength, and that it was natural for the product to sting when first applied.

On June 25, 1940, the United States attorney for the Southern District of Florida filed a libel against 19 packages of Young's Preparation at Jacksonville, Fla., alleging that the article had been shipped in interstate commerce on or about March 4, 1940, by O. L. Brunson from Waycross, Ga.; and charging that it was misbranded for the reasons appearing above.

It also was alleged to be misbranded in violation of the Federal Caustic Poison Act, as reported in notices of judgment published under that act.

On September 30, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

335. Misbranding of Dr. Young's Rectal Dilators and Dr. Young's Piloment. U. S. v. 67 Sets of Dr. Young's Rectal Dilators and 83 Packages of Dr. Young's Piloment. Default decrees of condemnation and destruction. (F. D. C. Nos. 2490, 2491. Sample Nos. 33914-E, 33915-E.)

The rectal dilator would be dangerous to health when used with the frequency and duration prescribed, recommended, or suggested in the labeling. The labeling of both products bore false and misleading representations regarding their efficacy in the treatment of the conditions indicated below.

On August 7, 1940, the United States attorney for the Southern District of New York filed libels against 67 sets of Dr. Young's Rectal Dilators and 83 packages of Dr. Young's Piloment at New York, N. Y., alleging that the articles had been shipped in interstate commerce within the period from on or about May 10 to on or about June 10, 1940, by F. E. Young & Co. from Chicago, Ill.; and charging that they were misbranded.

Examination of the sets of rectal dilators showed that they consisted of four hard plastic cylinders, flanged at one end, slightly enlarged and pointed at the other end, and varying in diameter from $\frac{1}{2}$ inch to 1 inch and varying in length from 3 to 4 inches. Analysis of the Piloment showed that it consisted essentially of petrolatum (99.15 percent), with phenol (0.73 percent) and extracts of drugs including a mydriatic drug such as belladonna.

The rectal dilator was alleged to be misbranded in that representations in the labeling that it was a simple, harmless, convenient, nonhabit-forming, and ideal treatment to bring satisfactory results and permanently overcome constipation and piles by inducing natural and regular bowel movement by reaching and correcting the cause of constipation by strengthening and toning the muscles controlling defecation; that it would improve and strengthen the body, not weaken or injure it; that it would be efficacious in the treatment of piles and troubles caused by faulty elimination; that it would restore the sphincter muscles to a normal condition, relieve congestion of blood and establish a healthy, vigorous circulation; would relieve constipation of long standing; would bring health and comfort and promote more refreshing sleep, and would be efficacious to aid nature in conditions commonly associated with constipation such as coated tongue, foul breath, bad taste in the mouth, sallow skin, acne, erythema, urticaria, anemia, lassitude, mental hebetude, insomnia, more or less marked degree of anorexia, headache, "spurious" diarrhea, colicky pains caused by enterospasm, neuralgic pains, hemorrhoids, fissure pruritus, occasional prolapse, auto-intoxication, flatulence, indigestion, nervousness, irritability, and cold extremities; that recovery would be permanent and that one need have no fear of using it too long or too much, were false and misleading, since the article would not be efficacious for such purposes and might be used too long or too much.

The dilator was alleged to be misbranded further in that it would be dangerous to health when used with the frequency and duration prescribed, recommended, or suggested in the following labeling: (Carton) "Adults begin with No. 1 Dilator. First warm dilator in warm water; then lubricate outside of dilator with Dr. Young's Piloment (or if it is not available, with vaseline) and while in a squatting position—or while lying on the side with knees drawn up—gently insert in the rectum as far as the flange or rim. Hold in place a minute and the anal muscles will close and retain it. Sit or lie down and allow it to remain for half an hour or an hour to get the best results. Ten minutes will accomplish much. When ready to go to the next larger size, it is best first to use for a few minutes the same size you have been using, inserting and withdrawing it several times. This is very beneficial and should not be overlooked. Children. The Dilators should not be used by any child under 8 years except under the instructions of a physician. An 8 to 12 year old child may use progressively our Nos. 0, 1 and 1½ Dilators. * * * Directions for use are the same as in the above paragraph for adults. Any larger sizes than these for children of these ages should be used only under direction of a physician. Children from 12 to 18 years should follow the same directions as those given for children from 8 to 12 years except that they may use the Nos. 2 and 2½ Dilators after they have used the smaller sizes according to directions. Try to use the Dilators each day; * * * Keep your Dilators and make occasional use of them. * * * Important: Do not neglect to use your Dilators; * * * It is advisable to use occasionally as a precautionary measure. You need have no fear of using them too much."

Dr. Young's Piloment was alleged to be misbranded in that representations in the labeling that it would promote healing of piles, and that in conjunction with Dr. Young's Dilators it would be efficacious in the treatment of rectal irritation, and would be efficacious as an auxiliary treatment and relief of constipation and piles, was a soothing treatment for itching and bleeding piles, and would help in a more speedy recovery from piles, were false and misleading since it would not be efficacious for such purposes.

On December 6, 1940, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

Nos. 336 to 339 report the seizure and disposition of intra-cervical or intra-uterine types of metal or rubber-covered stem pessaries which were potentially dangerous.

336. Misbranding of pessaries. U. S. v. 2 Small and 6 Medium-Sized Pessaries (and 1 other seizure action against pessaries). Default decrees of condemnation and destruction. (F. D. C. Nos. 2542, 2646. Sample Nos. 8936-E, 27361-E, 27362-E, 27363-E.)

On August 15 and October 1, 1940, the United States attorneys for the Northern District of Ohio and the District of Minnesota filed libels (the former amended on or about September 25, 1940) against 2 small and 6 medium-sized pessaries at Toledo, Ohio; and 5 small, 7 medium-sized, and 9 large pessaries at Minne-