

name of which is recognized in the National Formulary, an official compendium, and its strength differed from the official standard. The standard provides that isopropyl alcohol rubbing compound contains not less than 68 percent and not more than 72 percent of isopropyl alcohol by volume, whereas the article contained from 36.5 percent to 100 percent of isopropyl alcohol by volume.

Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear an accurate statement of the proportion of alcohol contained therein.

DISPOSITION: April 14, 1953. Default decree of condemnation and destruction.

4075. Adulteration and misbranding of clinical thermometers. U. S. v. 408 Thermometers * * *. (F. D. C. No. 34392. Sample No. 40625-L.)

LIBEL FILED: December 11, 1952, Western District of Washington.

ALLEGED SHIPMENT: On or about October 10, 1952, by the Dependable Thermometer Co., from New York, N. Y.

PRODUCT: 408 *clinical thermometers* at Seattle, Wash. Examination of 24 thermometers showed that 4 failed to meet the test for accuracy, that 2 failed to meet the test for retreating index, and that 1 was a hard shaker.

LABEL, IN PART: "Dependable Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which failed to meet the tests laid down in Commercial Standard CS1-52, issued by the United States Department of Commerce, for accuracy, retreating index, and hard shaker: (Brown envelope in which each thermometer is packaged) "Certificate and Guarantee of Accuracy and Reliability * * * Oral This Registering Clinical Thermometer was tested and examined on the above date and was found to meet all of the requirements and tests specified in Commercial Standard CS1-52, developed by the trade under the procedure of the Commodity Standards Division and issued by the United States Department of Commerce."

DISPOSITION: May 18, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4076. Misbranding of Duodex capsules. U. S. v. 36 Dozen Bottles, etc. (F. D. C. No. 33291. Sample No. 38740-L.)

LIBEL FILED: June 9, 1952, District of Columbia; libel amended June 4, 1953.

ALLEGED SHIPMENT: On or about June 2, 1952, by Harris Laboratories, Inc., from Glen Cove, N. Y.

PRODUCT: *Duodex capsules*. 36 dozen bottles, each containing 100 capsules, and 60 dozen bottles, each containing 50 capsules, at Washington, D. C., together with a number of leaflets entitled "Duodex The New Effective Treatment For Peptic and Duodenal Ulcer Sufferers," "At Last A Cure For Ulcers," and "The New Ulcer Story," a number of window streamers entitled "Come In For Free Booklet," and a number of display placards entitled "Stomach Ulcer Pains."

*See also Nos. 4069, 4072, 4073, 4075

LABEL, IN PART: (Bottle) "Duodex * * * each capsule contains approximately 0.3 grams of desiccated and partially defatted duodenal substance processed to retain the ingredients believed to relieve ulcer pains and symptoms of ulcerative colitis."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were misleading since they represented and suggested that the article was an adequate and appropriate treatment for relief of stomach ulcer pains and symptoms of ulcerative colitis, indigestion, gastritis and similar conditions, duodenal ulcer pains, and for peptic and duodenal ulcer sufferers, whereas such was not the case.

Further misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article would not be effective for the purposes stated and implied: (Leaflet entitled "Duodex The New Effective Treatment for Peptic and Duodenal Ulcer Sufferers") "Duodex, the new effective treatment for peptic and duodenal ulcer sufferers * * * Duodex acts as replacement therapy restoring to the mucosal surface that essential substance present in normal duodenum, that aids in healing the ulcer crater and restores a normal intestinal lining * * * It has been suggested that * * * Duodex provides * * * substances needed by nature to aid her in rebuilding the normal mucosal lining and smooth over the raw, eroded ulcer surface. Duodex * * * may repair the ulcerated area * * * Duodex is a valuable adjunct to aid in relieving this prevalent disease of modern strife and turmoil * * * Duodex * * * is today's ulcer therapy of choice * * * I have * * * used * * * Duodex Capsules * * * I have suffered from ulcers for 8 years and at last I can eat and sleep and I feel like a new man * * * Your capsules have worked * * *." and "Your Duodex Capsules have done so much for me that I feel as though I have never had any stomach ailment"; (leaflet entitled "At Last A Cure For Ulcers") "At Last A Cure For Ulcers? * * * Duodenum It may well be magic medicine for a painful disorder. You've got a stomach ulcer * * * Old Man Ulcer takes his added toll of fast-tempoed emotionally-upset 20th century citizens * * * I'm talking about myself. For seven years I was an expert on stomach ulcer misery * * * Now it's all over. My ulcer's just an unhappy memory. I have no pain. I have no discomfort * * * the real answer to peptic ulcer and ulcerative colitis * * * hog's duodenum * * * knocked out ulcer symptoms within 24 to 48 hours, kayoed the ulcer itself in a matter of weeks * * * Duodenum had been remarkably successful in more than 300 clinical cases, with no failures * * * restored a woman colitis victim on the verge of death to health within a month * * * my ulcer hemorrhaged * * * it was almost an inch deep, dangerously near a main artery * * * I began taking Duodenum, along with a liberal diet and amino acids * * * Two weeks later the ulcer crater had more than half healed * * * Was Duodenum mainly responsible? I feel it was. Never before have I been so free of pain, felt better physically and sharper mentally * * * 'Good-by, my aching ulcer' * * * I have * * * used * * * Duodex Capsules * * * I have suffered from ulcers for 8 years and at last I can eat and sleep and I feel like a new man * * * Your capsules have worked * * *." and "Your Duodex Capsules have done so much for me that I feel as though I have never had any stomach ailment."

Further misbranding (amended libel), Section 502 (a), the statements upon the counter display card "Tested in Leading Medical Centers for more than a year with remarkable results * * * Over 300 clinical cases with no failures—An Amazing Achievement" were false and misleading since such statements

represented and suggested that the article had been so tested, whereas such was not the case.

DISPOSITION: On October 28, 1952, Harris Laboratories, Inc., claimant, filed an answer denying that the product was misbranded. Interrogatories then were served upon the claimant by the Government, after which answers to certain interrogatories were filed by the claimant, together with objections to the remainder of the interrogatories. A motion for removal of the libel proceedings for trial in the Southern District of New York was filed also by the claimant. On April 4, 1953, the court denied the claimant's motion for removal, and on April 13, 1953, the court held a hearing on the interrogatories and ruled that the claimant should fully and completely answer certain interrogatories, but that it need not answer the remainder of the interrogatories.

On June 4, 1953, upon motion of the Government, the libel was amended to include the additional misbranding charge described above. Thereafter, the Government filed a motion for summary judgment, and on August 24, 1953, after hearing the argument on the motion and considering the labeling and the answers to the interrogatories, the court concluded that there existed no genuine issue as to any material fact. Accordingly, the court granted the Government's motion and entered a decree of condemnation and destruction.

4077. Alleged misbranding of Ridd medicated powder. U. S. v. 52 Cases * * * .
Motions for removal denied. Tried to the court; verdict for the Government. Decree of condemnation. Judgment reversed upon appeal.
Action subsequently dismissed. (F. D. C. No. 33105. Sample No. 22304-L)

LIBEL FILED: May 6, 1952, Northern District of Texas.

ALLEGED SHIPMENT: On or about February 18, 1952, by Ridd Laboratories, Inc., from Edmonds, Wash.

PRODUCT: 52 cases, each containing 144 1-ounce bottles, of *Ridd medicated powder* at Dallas, Tex. Analysis showed that the product was boric acid with a small amount of iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and display carton of the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for skin troubles, pimples, acne, barber's itch and skin itch, skin rash, ringworm, fungus, industrial skin irritations, boils, and varicose ulcers, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: Ridd Laboratories, Inc., claimant, filed an answer denying that the product was misbranded, and on May 27, 1952, it filed a motion for removal of the libel proceedings to the Western District of Washington. The court denied the motion on June 3, 1952, after which the claimant moved for removal to a district of reasonable proximity to the claimant's principal place of business.

This motion was denied on June 9, 1952, and the case came on for trial before the court without a jury on June 13, 1952. At the conclusion of the testimony, the court returned a verdict for the Government, and on June 16, 1952, entered a decree of condemnation and destruction. The claimant took an appeal to the United States Court of Appeals for the Fifth Circuit, and on April 2, 1953, the following opinion was handed down by that court: