2531. Adulteration of Creme-A-Tone. U. S. v. 52 Bottles, etc. (F. D. C. No. 24910. Sample Nos. 2252–K to 2254–K, incl.)

LIBEL FILED: June 30, 1948, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about March 15 and May 20, 1948, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 52 quart bottles and 63 pint bottles of *Creme-A-Tone* at Clarksburg, W. Va. Analysis of the product (both sizes) showed that it contained an average of 2.49 percent of aluminum oxide. Analysis of the product packaged in the pint size showed that the volume of tenth-normal acid required to neutralize one gram of the gel was not more than 8.84 cc.

LABEL, IN PART: "Creme-A-Tone Aluminum Hydroxide Gel."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Aluminum Hydroxide Gel," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in such compendium since the article, in each size, contained the equivalent of materially less than 3.6 percent aluminum oxide, whereas the compendium provides that aluminum hydroxide gel shall contain the equivalent of not less than 3.6 percent of aluminum oxide; and in the case of the article in the pint-size bottles, the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc., whereas the compendium provides that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc.

DISPOSITION: September 18, 1948. Default decree of condemnation and destruction.

2532. Adulteration and misbranding of adhesive bandages. U. S. v. 480 Packages * * *. (F. D. C. No. 25260. Sample No. 28566–K.)

LIBEL FILED: August 13, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 25, 1948, by the American White Cross Labs., Inc., from New York, N. Y.

PRODUCT: 480 packages each containing 36 *adhesive bandages* at Denver, Colo.

LABEL, IN PART: "White Cross Sterile Waterproof Adhesive Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the standard provides that adhesive absorbent gauze must be sterile and meet the requirements of the sterility tests for solids prescribed therein, whereas the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: September 28, 1948. Consent decree of condemnation and destruction.

2533. Adulteration and misbranding of prophylactics. U. S. v. 1,681 Gross * * *. (F. D. C. No. 24952. Sample No. 34250–K.)

LIBEL FILED: June 18, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about December 21, 1947, and January 12, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: 1,681 gross of *prophylactics* at San Francisco, Calif. Examination of samples showed that 4.8 percent were defective in that they contained holes.

LABEL, IN PART: "Duratex."

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 label statements "Prophylactics * * * for your protection * * * each piece thoroughly tested" were false and misleading as applied to an article containing holes.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2534. Alleged misbranding of Glyoxylide, Benzoquinone, and Malonide. U. S. v. Koch Laboratories, Inc., Dr. William F. Koch, and Louis Koch (2 indictments). Pleas of not guilty. Tried to a jury. No verdict rendered because of inability of jury to agree. Cases retried before second jury, but before verdict could be rendered, illness of one of twelve jurors required discharge of the jury. Case subsequently dismissed. (F. D. C. No. 6439. Sample Nos. 7694–E to 7696–E, incl., 23632–E, 23633–E, 63479–E, 72742–E, 72745–E, 73179–E, 73183–E, 79252–E, 79621–E.)

INDICTMENTS RETURNED: Between April 2 and 15, 1942, Eastern District of Michigan, against Koch Laboratories, Inc., Detroit, Mich., Dr. William F. Koch, president, and Louis Koch, secretary-treasurer.

ALLEGED SHIPMENT: On or about January 23 and February 2, 3, 4, 5, 6, and 19, 1942, from the State of Michigan into the States of California, Missouri, Kentucky, Indiana, and Oregon.

LABEL, IN PART: "Koch's Synthetic Antitoxins Glyoxylide Prepared from Aliphatic sulphonates We ascribe to it the formula OCCO Each ampoule contains approximately 2 cc. (dilution 10–12) for Allergy Cancer Infection Sold to Physicians Only"; "(Koch's Synthetic Antitoxins) * * * (1:4 Benzoquinone) Koch Each ampoule contains approximately 2 cc. aqueous solution (dilution 10–6) For the Infections and Their Sequelae Sold only to Physicians"; and "(Koch's Synthetic Antitoxins) Malonide O-c-c-c-O Each ampoule contains approximately 2 cc. aqueous solution (dilution 10–12) Anti-Alergic Sold Only to Physicians."

NATURE OF CHARGE: Misbranding, Section 502 (a), it was alleged that certain statements on the labels of the articles were false and misleading. The statements on the respective labels represented and suggested that the *Glyoxylide* was efficacious in the care, mitigation, treatment, and prevention of cancer, allergic conditions, and infection, and that it was efficacious as an antitoxin; that the *Benzoquinone* was efficacious in the cure, mitigation, treatment, and prevention of infections and sequelae of infections, and that it was efficacious as an antitoxin; and that the *Malonide* was efficacious in the cure, mitigation, treatment, and prevention of allergies, an dthat it was efficacious as an antitoxin. The indictment charged that the products would not be efficacious for those purposes.

DISPOSITION: Pleas of not guilty having been entered, the matter came on for trial before a jury on January 12, 1943. The trial continued to May 28, 1943, at which time the jury announced that it was unable to agree upon a verdict. Retrial of the matter was held, beginning February 20, 1946, and continuing to July 23, 1946. On this latter date ,the trial was ended when one of the members of the jury, then considering and deliberating upon a verdict, stated that because of illness he was unable to proceed. The Government's attorney moved the court to permit the 11 remaining jurors to continue their deliberations with a view to reaching a verdict, but because of the opposition of counsel for the defendant, the court discharged the jury. On August 17, 1948, the Government's attorney made a motion for the entry of an order of nolle prosequi, and, on the same date, the court entered an order to that effect.

2535. Misbranding of Glancaps. U. S. v. Darnell Drug Co., Wilbur F. Darnell, and George W. Darnell. Pleas of guilty. Fine of $250 against company and $10 against each individual. (F. D. C. No. 24265. Sample No. 83156–H.)

INFORMATION FILED: June 30, 1948, Southern District of Indiana, against the Darnell Drug Co., a partnership, Indianapolis, Ind., and Wilbur F. Darnell and George W. Darnell, partners in the partnership.

ALLEGED SHIPMENT: On or about July 15, 1947, from the State of Indiana into the State of Ohio.

LABEL, IN PART: "Glancaps * * * Active ingredients: Oil of Albasantal, minims 3. Oleoresin Cubeb, minims 2. Oil of Copaiba, minims 3. Rectified Oil of Terpen, minims 2. Extract of Zea Mays, grains 5. Each capsule contains 13.3 minims."

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*See also Nos. 2502–2505, 2511–2517, 2521, 2523, 2524, 2526–2529, 2532, 2533.