

DISPOSITION: May 25, 1954. Byrne Products, Inc., having filed a claim and answer and later having withdrawn such claim and answer, judgment of condemnation was entered and the court ordered that the product be destroyed.

4355. Adulteration and misbranding of rubber prophylactics. U. S. v. 32 Gross * * *. (F. D. C. No. 36229. Sample No. 60129-L.)

LABEL FILED: January 8, 1954, Northern District of Georgia.

ALLEGED SHIPMENT: On or about October 5, 1953, by the Chemical Latex Exchange, from Philadelphia, Pa.

PRODUCT: 32 gross of *rubber prophylactics* at Atlanta, Ga. Examination of 144 units of the product showed that 8 were dried out and could not be unrolled without damage and were therefore unsuitable for use.

LABEL, IN PART: "Zenith Lubri-Pak."

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 "Prophylactic" and "For the prevention of disease" were false and misleading as applied to the article, which was dried out and could not be unrolled without damage.

DISPOSITION: February 3, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4356. Misbranding of Gramer's Sulgly-Minol. U. S. v. 21 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 36215, 36216. Sample Nos. 14749-L, 14750-L.)

LABELS FILED: January 4, 1954, District of Colorado.

ALLEGED SHIPMENT: During the last 6 months of the year 1953, by Walter W. Gramer, from Minneapolis, Minn.

PRODUCT: 127 bottles of *Gramer's Sulgly-Minol* at Denver, Colo., together with a number of circulars headed "Arthritis Hundreds Claim Its Grip Broken" and "A Light Should Not Be Hidden Testimonials * * * we have received from people who have been relieved from the pains of Arthritis and Rheumatism by using 'Sul-Gly Minol.'"

LABEL, IN PART: (Bottle) "4 Fl. Ozs. Gramer's Sulgly-Minol * * * A solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6% * * * For the relief of muscular pains and soreness, add 1 tablespoon to 1 quart of warm water for foot bath, also apply direct to soles of feet. Add one-fourth bottle to tub of water for sulphur tub bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circulars accompanying the article were false and misleading. The statements represented and suggested that the article, diluted with water and used as a foot bath, applied to the soles of the feet, or used as a tub bath, was an adequate and effective treatment for arthritis, pain in the legs, hips, back, and arms, ailments of a rheumatic nature, and stiffness and soreness of legs and knees. The article, when used as directed, was not an ade-

*See also Nos. 4350, 4352-4355.

quate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: March 3, 1954. Default decrees of condemnation and destruction.

4357. Misbranding of Ozonator device. U. S. v. 2 Cartoned Devices, etc. (F. D. C. No. 35401. Sample No. 65445-L.)

LABEL FILED: September 15, 1953, District of South Dakota.

ALLEGED SHIPMENT: During the month of June 1953, by A. L. Gesche, from Spokane, Wash.

PRODUCT: 2 cartoned *Ozonator devices* at Lemmon, S. Dak., together with a number of leaflets entitled "Northwest Ozonator" and a booklet entitled "Ozone God's Gift to Humanity."

The device consisted of 8 tubes, together with the electrical equipment necessary to produce an electrical discharge through the tubes when the device was connected to an appropriate power source.

LABEL, IN PART: (Sticker attached to device) "A. C. 60 Cycle 115-20 V. Ozonator Guaranteed for 1 year against defects Northwest Ozonator Co. W. 1610 Gardner Ave. Spokane 11, Washington."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned leaflets and booklet accompanying the device were false and misleading. The statements represented and suggested that the device was an adequate and effective treatment for all kinds of ailments and for many so-called incurable diseases; that its use would increase the number of red blood corpuscles; that it was an effective treatment for asthma and all diseases of the respiratory organs; that it would dissolve and break up abnormal deposits such as arthritis and nephrolithiasis or cholelithiasis; that the device was an adequate and effective treatment for anemia, pernicious anemia, colitis, arthritis, sinusitis, head colds, cardiovascular renal disease, tuberculosis, and rheumatism; and that it would improve the general health and make one more active physically, psychologically, and sexually. The device was not an adequate and effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: April 21, 1954. Default decree of condemnation. The court ordered that the devices and accompanying labeling be delivered to the Food and Drug Administration.

4358. Misbranding of Miracle hearing aid. U. S. v. 237 Devices, etc. (F. D. C. No. 35413. Sample No. 55168-L.)

LABEL FILED: August 31, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about July 28, 1952, by Miracle Hearing Aid, Inc., from East Orange, N. J.

PRODUCT: 237 unassembled devices called the *Miracle hearing aid* at Sheboygan, Wis., together with a number of brochures and window placards designated as "Sensational, New Miracle Hearing Aid."

When assembled, the device consisted of a piece of wire, twisted into the shape of a miniature tuning fork, and rubber discs with perforated centers into which the wire was to be inserted.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned brochures and placards were false and misleading. The statements represented and suggested that the device was effective for ena-