

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the product was represented to be "Gum Karaya," a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the standard set forth in such compendium since it contained more than 3 percent of bark and foreign and organic material and in a solution of the material (1 to 100), Millon's Reagent produced a yellow precipitate instead of a white precipitate as specified in the standard.

Misbranding, Section 502 (a), the label statement "Gum Karaya N. F." was false and misleading as applied to a product which failed to comply with the specifications in the National Formulary for gum karaya.

**DISPOSITION:** September 25, 1952. The shipper, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

On July 23, 1953, an amended decree was entered which provided for the relabeling of the product to indicate that it was not National Formulary gum karaya and to indicate the manner in which it differed from the National Formulary product.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**4033. Misbranding of Kordolin tablets. U. S. v. 1,960 Bottles, etc. (F. D. C. No. 33242. Sample No. 23486-L.)**

**LIBEL FILED:** May 7, 1952, District of New Jersey.

**ALLEGED SHIPMENT:** On or about April 3, 7, and 8, 1952, by the Kordol Corp., of America, from New York, N. Y.

**PRODUCT:** 1,960 100-tablet bottles and 864 50-tablet bottles of *Kordolin tablets* at Jersey City, N. J.

**LABEL, IN PART:** (Bottle) "Kordolin Tablets \* \* \* Active Ingredients per tablet \* Acket Acetphenetidin 2 gr. Calcium Succinate Caffeine Vitamin B<sub>1</sub> 1 m. \* Acket is Kordol Corporation of America's Brand Name of Salicylamide."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the labeling of the article, namely, the bottle label and the retail package carton, contained prominently displayed statements arranged to represent and suggest that the article was an adequate and effective treatment for arthritis, rheumatism, sciatica, bursitis, and neuritis, which statements were misleading since the article was not an adequate and effective treatment for such conditions; and the statement on the bottle labels and retail package cartons, namely, "Active Ingredients \* \* \* Calcium Succinate Caffeine Vitamin B<sub>1</sub>," was misleading since calcium succinate, caffeine, and vitamin B<sub>1</sub> were not active ingredients of the article for the purpose for which it was offered.

Further misbranding, Section 502 (c), the information required by Section 502 (e) (2) to appear on the label, namely, the common or usual name of each active ingredient, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, and devices in the labeling) and in such terms as to render it likely to be read and understood

\*See also Nos. 4021, 4026, 4027, 4029-4032.

by the ordinary individual under customary conditions of purchase and use since the coined term "Acket" had been used for the ingredient salicylamide, as explained in a footnote, and the ingredients, calcium succinate, caffeine, and vitamin B<sub>1</sub>, which were not active for the purposes for which the article was offered, appeared in such fashion as not to distinguish them from the active ingredients.

**DISPOSITION:** The Kordol Corp. of America appeared as claimant and filed an answer denying the allegations of the libel. On September 8, 1952, a set of written interrogatories was served upon the claimant by the Government. Thereafter, a motion was filed by the Government for an order striking the claimant's pleadings and for the entry of a default decree of condemnation upon the ground that the claimant failed to respond to the interrogatories within the time provided by the Federal Rules of Civil Procedure.

On April 10, 1953, the court granted the Government's motion, and in accordance therewith, it entered a decree providing for the condemnation and destruction of the product.

**4034. Misbranding of Kon-trol-R. U. S. v. 30 Dozen Bottles, etc. (F. D. C. No. 34449. Sample No. 56927-L.)**

**LIBEL FILED:** December 24, 1952, Southern District of Ohio.

**ALLEGED SHIPMENT:** On or about May 28, 1952, by the Kon-trol-R Co. of America, from Indianapolis, Ind.

**PRODUCT:** 24 dozen ½-pint bottles and 6 dozen 1-pint bottles of *Kon-trol-R* at Cincinnati, Ohio, together with a number of circulars entitled "Kon-trol-R For Your Figure." Examination showed that the product was mint-flavored cider vinegar.

**LABEL, IN PART:** "\* \* \* Kon-trol-R For Your Figure \* \* \* A Special Blend of Pure Apple Juice Processed for Optimum Acidity, Mint Flavored."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the statements on the label of the article and in the above-mentioned circulars, namely, "Kon-trol-R For Your Figure A Pleasant Aid to The Easiest System for Weight Control \* \* \* A Simple Weight Controlling System," were false and misleading. The statements represented and suggested that the article was effective to bring about a loss of body weight, whereas it was not effective for such purpose.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** February 4, 1953. Default decree of condemnation and destruction.

**4035. Misbranding of Aspergum. U. S. v. 48 Cartons \* \* \*. (F. D. C. No. 33562. Sample No. 37284-L.)**

**LIBEL FILED:** August 29, 1952, Southern District of New York.

**ALLEGED SHIPMENT:** On or about July 15, 1952, by White Laboratories, Inc., from Kenilworth, N. J.

**PRODUCT:** 48 cartons, each containing 1 dozen boxes, of *Aspergum* at New York, N. Y.