

that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (a), in that the labeling contained statements which represented and suggested that the drug would be efficacious in the cure, mitigation, treatment and prevention of gingivitis and pyorrhea; would be efficacious to restore soft, spongy, bleeding gums to a healthy pink color, and would help keep gums firm and healthy; would cause swelling, bleeding, and tenderness in gums to subside; would aid materially in the healing process after tooth extractions; would be efficacious in the treatment of abscessed teeth, infected gums, and infected tonsils; would aid in the correction of the chief causes of rheumatism, heart trouble, kidney disorders, stomach trouble, and nervous disorders; and would prevent the absorption of germs and poisons developing in diseased teeth and in infected gums and tonsils; and that the said statements were false and misleading since the product would not be efficacious for the purposes represented, suggested, and implied.

The complaint alleged further that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (f) (1), in that the labeling failed to bear adequate directions for use in all conditions for which it was intended to be used and for which it was prescribed, recommended, or suggested in its advertising, disseminated or sponsored by or on behalf of the defendant, namely, bleeding gums, pyorrhea, loss of all teeth, soft, spongy, bleeding gums, and gingivitis.

The complaint alleged further that the defendant still continued to introduce into interstate commerce the drug which was misbranded as stated above, and alleged on information and belief that he would continue to do so unless restrained. The complaint prayed the entry of a decree perpetually enjoining the defendant from introducing the drug under the name *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1), and that he be ordered to show cause why he should not be restrained from such acts during the pendency of the proceedings.

DISPOSITION: On December 17, 1948, the defendant having consented to the entry of a decree, the court entered an order perpetually enjoining and restraining the defendant and all persons acting upon his behalf from directly or indirectly introducing into interstate commerce the above-described drug under the designation *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1). The decree contained the proviso that the defendant could introduce the drug, *Gingisol*, composed of a solution of potassium phenolate and a small proportion of fluorides, into interstate commerce under appropriate labeling so long as it was intended for use solely as a simple mouth wash for which no therapeutic claims were made.

3543. Misbranding of calcium polysulfide solution. U. S. v. Wilfred S. McKeon.
Plea of guilty. Fine of \$50, plus costs, on count 1; suspended sentence and probation for 2 years on count 2. (F. D. C. No. 24253. Sample Nos. 68292-H, 68293-H.)

INFORMATION FILED: April 19, 1948, Western District of Pennsylvania, against Wilfred S. McKeon.

INTERSTATE SHIPMENT: On or about February 26 and 27, 1947, from the State of Pennsylvania into the State of Kansas, of quantities of *calcium polysulfide solution*.

LABEL, IN PART: "Calcium Polysulphide Solution Active Ingredients: Calcium Polysulphide . . . 31% Calcium Thiosulphate . . . 1% Inert Ingredients . . . 68% Total Sulphur (At Least) . . . 24%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the drug failed to bear adequate directions for use since the labeling contained no directions for use.

DISPOSITION: July 1, 1948. A plea of guilty having been entered, the court imposed a \$50 fine, plus costs, on count 1 and suspended sentence and placed the defendant on probation for 2 years on count 2.

DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3544. Action to enjoin and restrain the interstate shipment of adulterated and misbranded rubber prophylactics. *U. S. v. Joseph Lader, Clara Lader, and Anna Lader (Crown Rubber Sundries Co.)*. Permanent injunction granted. (Inj. No. 97.)

COMPLAINT FILED: On or about June 12, 1945, Northern District of Ohio, against Joseph Lader, Clara Lader, and Anna Lader, partners, trading under the name of the Crown Rubber Sundries Co., Akron, Ohio.

NATURE OF CHARGE: The complaint alleged that the defendants since about the month of July 1944 had been and were at the time of filing the complaint engaged in purchasing, packing, distributing, and selling, and introducing and causing to be introduced into interstate commerce, from Akron, Ohio, devices known as *rubber prophylactics* or condoms; that these devices were adulterated under Section 501 (c) since they consisted of defective, imperfect, and old material, and contained holes and defects and other imperfections, so that their strength differed from, and their quality fell below, that which they purported and were represented to possess; that the said devices were misbranded under Section 502 (a) in that they were recommended and labeled as suitable for the prevention of venereal disease, and the labeling was false and misleading since the devices were not suitable for such purposes, because of the presence of holes.

The complaint alleged further that a large number of shipments of *rubber prophylactics* by the defendants had been examined; that seizures had been instituted against many of the firm's consignments; that the defendants had been given notice on three occasions of contemplated criminal action; that Joseph Lader refused to permit inspection of the defendants' plant in December 1944, following the investigation of a shipment which had been found to consist of old, rejected stock; that on January 8 and 23, 1945, inspectors again were refused permission to inspect the premises; and that in 1945 a considerable number of the firm's interstate shipments again were sampled, and the examination showed the product to be from 12.5% to 33% defective.

The complaint alleged further that on March 24, 1945, notice again was given to the Crown Rubber Sundries Co. and Joseph Lader that opportunity would be afforded them to present their views with respect to contemplated criminal proceedings charging violation of the law; that statements made by Joseph Lader at a hearing on March 26, 1945, established that no tests were made by the firm in order to discover imperfections before shipment in interstate commerce; and that during inspections Joseph Lader had been informed of the imperfections found in the devices and had been warned

and advised not to ship such devices in interstate commerce, but that such warnings and advice had been unheeded.

The complaint alleged further, on information and belief, that the defendants would continue to violate the law unless restrained from so doing, and prayed the issuance of a decree perpetually enjoining and restraining the defendants from the acts complained of; and that a temporary restraining order issue immediately, granting the relief prayed for.

DISPOSITION: On August 22, 1945, a temporary restraining order was issued as prayed in the complaint. On April 7, 1948, the defendants having admitted the allegations of the complaint and consented to the entry of a decree, judgment was entered that the defendants, their agents, servants and employees, and all persons acting for or on their behalf, be perpetually enjoined and restrained from introducing or delivering for introduction into interstate commerce, directly or indirectly, devices which the defendants, at the time or at any time thereafter, may have in their possession or under their control, which are adulterated or misbranded as charged in the complaint.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3545. Action to enjoin and restrain the altering of labeling and unlawful acts with respect to vitamin products while held for sale after shipment in interstate commerce. U. S. v. Vitamin Store of Missouri and Louis E. Krawitz and Miriam W. Krawitz. Injunction granted. (Inj. No. 160.)

COMPLAINT FILED: April 14, 1947, Eastern District of Missouri, against the Vitamin Store of Missouri, a partnership, St. Louis, Mo., and Louis E. Krawitz and Miriam W. Krawitz, partners.

NATURE OF CHARGE: The complaint alleged that the defendants had been and were at the time of filing the complaint engaged in the retail sale of vitamin products which had been shipped in interstate commerce and held for sale by the defendants after such shipment; and that it was the usual and common practice to display and cause to be associated with each of the vitamin products certain printed and graphic circulars, posters, and pamphlets which represented the product to be effective in the treatment or prevention of various ailments and diseases, and which constituted labeling of such products.

The complaint alleged further that the defendants had received in interstate commerce vitamin products which were labeled and designated, in part, "Multi-B-Plex Tablets," "Super B-Plex Plus Tablets," "Vitamin C Tablets," "Vitamin A Capsules," "Vita-Slim," "Arthron Vitamin D," "Super Potency Pan-A-Plex," "Super-Complex Special Formula No. 10," "Aller-Cedic * * * Capsules," "Nura-Plex Capsules," and "Ultra-Beta Capsules," and that while these products were held for sale after shipment in interstate commerce, the defendants caused the pamphlets, posters, and circulars referred to above to be displayed and associated with the products, which resulted in the products becoming misbranded under Section 502 (a); that certain statements in the pamphlets and posters represented and suggested that the *Super B-Plex Plus tablets* were effective in the treatment or prevention of, or would aid persons suffering from, fatigue, nervousness, insomnia, neuritis, constipation, and loss of appetite; that certain statements in the circulars and posters represented and suggested that the *Multi-B-Plex tablets* were effective in the treat-

*See also Nos. 3541, 3542, 3544.

ment or prevention of, or would aid persons suffering from, fatigue, nervousness, insomnia, neuritis, constipation, and loss of appetite; that certain statements in the pamphlets represented and suggested that the *vitamin C tablets* were effective in the treatment or prevention of, or would aid persons suffering from, anemia, hemorrhages, swollen, bleeding gums, tooth cavities, loose teeth, poor wound healing, gastric ulcers, and asthma and hay fever of allergic origins; that certain statements in the pamphlets represented and suggested that the *Arthron vitamin D* was effective in the treatment of arthritis; that certain statements in the circulars and posters represented and suggested that the *vitamin A capsules* were effective in the treatment or prevention of, or would aid persons suffering from, itching, burning, and dryness of eyes, night blindness, decreased vision, dry and rough skin, sinus infection, tendency to colds and infections, colds, and sinusitis; that certain statements in the circulars and posters represented and suggested that the *Vita-Slim* was effective in reducing and preventing overweight; that certain statements in the pamphlets represented and suggested that the *Super Potency Pan-A-Plex* was effective in the restoration of hair color; that certain statements in the posters represented and suggested that the *Super-Complex Special Formula No. 10* was effective in the treatment or prevention of, or would aid persons suffering from, arthritic pains, neuritic pains, rheumatic pains, fatigue, listlessness and nervousness; that certain statements in the pamphlets represented and suggested that the *vitamin A capsules* were effective in the treatment or prevention of, or would aid persons suffering from, colds, infections, sinus, eye trouble, dry skin, and acne; that certain statements in the circulars and posters represented and suggested that the *Aller-Cedic * * * capsules* were effective in the treatment or prevention of, or would aid persons suffering from, hay fever, asthma, and food allergies; that certain statements in the pamphlets represented and suggested that the *Ultra-Beta capsules* were effective as a tonic builder for persons suffering from loss of pep, poor appetite, sleeplessness, constipation, nervousness, and depression, and were effective in the treatment or prevention of such ailments and conditions; that certain statements in the pamphlets represented and suggested that the *Super-Complex Special Formula No. 10* was effective in the treatment or prevention of, or would aid persons suffering from, arthritic pains, neuritic pains, rheumatic pains, constipation, fatigue, nervousness, insomnia, depression, and sciatica; and that certain statements in the pamphlets represented and suggested that the *Nura-Plex capsules* were effective in the treatment and prevention of, and would aid persons suffering from, nervousness, fatigue, constipation, neuritis, skin disorders, and nervous indigestion. The statements and representations contained in the pamphlets, circulars, and posters were false and misleading since the products were not effective in the treatment or prevention of, and would not aid persons suffering from, the conditions and ailments stated and implied.

The complaint alleged further that the defendants had been warned and notified of their acts of misbranding, but had disregarded the warnings and continued to make false and misleading representations concerning these vitamin products; and alleged also, on information and belief, that they would continue to do so.

The complaint prayed that a preliminary injunction be granted, restraining and enjoining the defendants from the acts complained of, and that the preliminary injunction be made permanent after due proceedings.

DISPOSITION: April 29, 1947. The defendants having consented to the entry of a decree, the court issued a temporary injunction which was to become effective on May 5, 1947.

The decree enjoined the defendants and all persons acting on their behalf from directly or indirectly altering the labeling of, or doing acts with respect to, drugs while they were held for sale after shipment in interstate commerce, which acts would result in such drugs being misbranded within the meaning of Section 502 (a); and from causing any written, printed, or graphic matter which is false or misleading in any particular to accompany any article of drug while such article was being held for sale after shipment in interstate commerce in violation of Section 301 (k); and, further, from doing any other act which would result in such article being misbranded within the meaning of Section 502 (a).

3546. Misbranding of Gold-Lax Tonic. U. S. v. Eijiro Ishii (Gold-Lax Tonic Laboratory). Plea of nolo contendere. Fine, \$100, plus costs. (F. D. C. No. 21444. Sample Nos. 59860-H, 84844-K.)

INFORMATION FILED: August 27, 1947, Northern District of Ohio, against Eijiro Ishii, trading as the Gold-Lax Tonic Laboratory, Painesville, Ohio.

ALLEGED SHIPMENT: On or about April 14, 1946, and April 23, 1947, from the State of Ohio into the State of Pennsylvania.

LABEL, IN PART: (Bottle) "Ishii's Gold-Lax Genuine The active ingredient is senna pods. The article is recommended as a laxative for occasional constipation. Contains Asparagus, Beets, Carrots, Celery, Orange, Fennel Seeds, and Senna Pods."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Genuine Gold Lax Tonic" and "Genuine Ishii's Gold Lax Tonic" were false and misleading. These statements represented and suggested that the drug was a tonic; that it would be efficacious to prevent premature old age and death; that it would prevent a deficiency of minerals and vitamins, would prevent deposits of poisons and acids in the weakest areas of the body, would aid digestion of foods and assimilation of minerals, would be of benefit to diabetic sufferers, would create energy, would aid the body to secrete insulin, would remove impurities, would build up resistance and restore energy, pep, and stamina, would enable the user to be pure within and without, and would correct stomach trouble and enable the user to assimilate all elements; that it would be efficacious in the prevention and treatment of anemia, arthritis, asthma, diabetes, dropsy, female periodic complaint, heart ailment, high blood pressure, low blood pressure, liver trouble, kidney trouble, gall bladder trouble, pimples, pernicious anemia, psoriasis, rheumatism, shingles, swollen legs, streptococcus infection, tuberculosis, varicose ulcers, and colds; that it would aid in removing poisons from the intestines and kidneys, would improve the appetite, would supply necessary minerals, vitamins, and many other health giving foods, would improve the user's health, would settle the nerves and regulate the kidneys, and would prevent a feeling of tiredness in the morning and enable the user to sleep soundly at night; that it would be efficacious in the treatment of mucous trouble and bowel trouble and would enable the user to gain weight; that it would be efficacious in the treatment of constipation, tense nerve condition,