

"Want proof of Testone's Effectiveness?" and an order blank headed "Don't Delay! \* \* \* Rush Your Testone Order Today."

The complaint alleged further that the defendants, in employing the above method of operation for their business, were violating Section 301 (k) by causing the capsules of wheat germ oil to be relabeled while held for sale after shipment in interstate commerce, which act resulted in the capsules being misbranded under Section 502 (a), in that the label on the bottles containing the capsules and the labeling accompanying the capsules contained statements which represented and suggested that the capsules contained hormonal activity equivalent to therapeutically significant amounts of testosterone and estrone; that the capsules were an adequate and effective treatment for male hormone deficiency, loss of sex urge, sleeplessness, irritability, lack of vigor, nervousness, loss of muscle power, loss of pep, tiredness, and premature old age; and that the capsules were effective to restore men to a life of vigor, vitality and sex enjoyment. These statements were false and misleading in that the capsules did not contain hormonal activity equivalent to therapeutically significant amounts of testosterone and estrone; the capsules were not an adequate and effective treatment for the conditions stated; and they were not effective to restore men to a life of vigor, vitality, and sex enjoyment.

The complaint alleged further that the defendants were violating Section 301 (a) by causing the introduction and the delivery for introduction, into interstate commerce, of the capsules, which were misbranded as described above.

**DISPOSITION:** On May 13, 1953, the court entered a temporary restraining order enjoining the defendants from the acts complained of. On June 18, 1953, the defendants having consented to the entry of a decree, the court entered a decree permanently enjoining the defendants (1) from shipping in interstate commerce *Testone wheat germ oil capsules* or any similar drug bearing a label or accompanied by labeling containing false and misleading statements of the nature described in the complaint, and (2) from causing any act to be done with respect to any such drug while held for sale after shipment in interstate commerce, which would result in such drug bearing a label or accompanied by labeling containing statements of the nature described in the complaint.

**4258. Misbranding of vitamin B<sub>1</sub> tablets. U. S. v. 275 Cards \* \* \*. (F. D. C. No. 35638. Sample No. 47534-L.)**

**LIBEL FILED:** September 17, 1953,, Southern District of Texas.

**ALLEGED SHIPMENT:** On or about May 20, 1953, from Newark, N. J.

**PRODUCT:** *Vitamin B<sub>1</sub> tablets.* 275 cards, to each of which was attached a cellophane envelope containing 4 tablets at Houston, Tex., in possession of the consignee, the McDonald Prescription Laboratories, Inc.

**RESULTS OF INVESTIGATION:** The tablets were shipped in interstate commerce unlabeled and, upon their receipt by the consignee, were repackaged by attaching a printed card to each four tablets in a cellophane envelope.

**LABEL, IN PART:** (Card) "Four Tablets Orange Vitamin B-1 100 mg. \* \* \* for Adults Only \* \* \* McDonald Laboratories, Inc., Houston, Texas."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the labeling of the article, namely, the card attached to the envelope of tablets, were false and misleading. The statements represented that the article was

an effective treatment for physical strain, overwork, mental fatigue, nervous tension, excessive alcoholism, loss of sleep, lack of energy and pep, laziness, hangovers, and mental strain, and that the article would cause one to feel good again and look better and nicer. The article was not an adequate and effective treatment for such conditions, and it would not effect such purposes. The article was misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** October 27, 1953. McDonald Laboratories, Inc., 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 for relabeling under the supervision of the Department of Health, Education, and Welfare.

**4259. Misbranding of Ko-rekT dental device. U. S. v. Demetrie C. Siampaus (Siampaus Mfg. Co.).** Plea of not guilty. Tried to the jury. Verdict of not guilty on count 1 and verdict of guilty on count 2. Sentence of 90 days in jail suspended. Costs assessed and defendant placed on probation for 1 year. (F. D. C. No. 33788. Sample Nos. 33667-L, 46538-L.)

**INFORMATION FILED:** August 11, 1953, District of Nebraska, against Demetrie C. Siampaus, trading as the Siampaus Mfg. Co., Omaha, Nebr.

**ALLEGED SHIPMENT:** On or about January 1 and March 13, 1952, from the State of Nebraska into the States of Illinois and Louisiana.

**PRODUCT:** Examination showed that the *Ko-rekT dental device* consisted essentially of 2 counter-rotating rubber discs mounted on metal shafts turned by a handcrank for the purpose of cleaning the teeth and massaging the gums.

**NATURE OF CHARGE:** Count 1. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, consisting of a cardboard carton insert headed "Throw Away Your Tooth Brush," were false and misleading. The statements represented and suggested that the device was adequate and effective for the prevention and treatment of bad breath, tartar formation, infected gums and their complications, tooth decay, and pyorrhea, and that the use of the device would assure a healthy mouth. The device was not adequate and effective for the prevention and treatment of the conditions mentioned, and the use of the device would not assure a healthy mouth.

Count 2. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, consisting of a cardboard carton insert headed "Throw Away Your Tooth Brush," circulars headed "Turn On That Smile with Ko-rekT," and "The Dialogue Below Reveals the Weakest and Therefore the Most Dangerous Part of Our Body," and a leaflet headed "Throw Away Your Tooth Brush," were false and misleading. The statements represented and suggested that the device was adequate and effective for the prevention and treatment of bad breath, tartar formation, infected gums and their complications, tooth and gum trouble, tooth decay, toothache, pyorrhea, infected teeth, loss of teeth, loose teeth, and recession of the gums; that use of the device would assure healthy gums, healthy mouth, good health, and increased longevity; and that the device would rebuild the teeth and jaw bone and preserve youthful appearance. The device was not adequate and effective for the prevention and treatment of the conditions mentioned, and it would not fulfill the promises of benefit stated and implied.