

article by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

**DISPOSITION:** Pleas of not guilty having been entered, the case came on for trial before the court without a jury on June 22, 1949. On July 13, 1949, the court returned a verdict of guilty on all counts as to both defendants and imposed a fine of \$700 against the corporation and \$700 against the individual.

✓ **2933. Misbranding of Metandren Linguets. U. S. v. George H. McKinlay (Health Chemicals). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, \$300. (F. D. C. No. 25603. Sample Nos. 24585-K, 28038-K, 30045-K.)**

**INFORMATION FILED:** March 28, 1949, Southern District of California, against George H. McKinlay, trading as Health Chemicals, Los Angeles, Calif.

**ALLEGED SHIPMENT:** On or about October 30, 1947, and April 1 and 26, 1948, from the State of California into the States of North Dakota, Colorado, and Arizona.

**LABEL, IN PART:** "Metandren Linguets \* \* \* Compressed water especially designed for absorption from under the tongue or inside the cheek. Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements relating to the article in an accompanying circular entitled "Hormones and the Male Climacteric" were false and misleading. The statements represented and suggested that the article would be an adequate treatment for headache, excessive fatigue, nervousness, irritability, insomnia, decreased memory and power of concentration, a feeling of uncertainty and tremulousness, vasomotor disturbances, such as flashes, sweats, chills, and paresthesias, vague pain, particularly in the region of the bladder, a loss of force in the urinary stream, clinical signs of prostatic hyperplasia or nonspecific prostatitis, decrease in libido and potency, symptoms of climacteric syndrome, and involuntional melancholia; and that the article would prevent the "clock of life" from running down and would permit the user to resume with confidence normal business and social activities. The article would not be an adequate treatment for the conditions represented; it would not prevent the "clock of life" from running down; and it would not permit the user to resume with confidence normal business and social activities.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warning against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone); and the labeling failed to warn that the use of the article may result in sterility and that its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. Further misbranding, Section 502 (j), the article was dangerous to health, when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone), and the use of a drug containing 5 milligrams of male hormone in each linguet with the frequency prescribed, recommended, and suggested in the labeling, namely, "3 to 4 Linguets per day," would be dangerous to health since use of the article may

result in sterility; and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: July 13, 1949. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court returned a verdict of guilty and fined the defendant \$300.

**2934. Misbranding of Foille Emulsion. U. S. v. 3 Bottles \* \* \*. (F. D. C. No. 26973. Sample No. 23984-K.)**

LIBEL FILED: April 20, 1949, Western District of Louisiana.

ALLEGED SHIPMENT: On or about March 14, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 3 1-gallon bottles of *Foille Emulsion* at Ville Platte, La.

LABEL, IN PART: "Foille A Protective Dressing. Analgesic Antiseptic \* \* \* Active Ingredients: Benzocaine, Carbolic Acid (Less than 2%), Calcium Oleate, Calcium and Potassium Iodides, Oxyquinoline Base, Calcium Thiosulfate and sulphur in a Vegetable Oil Base."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form, as are necessary for the protection of users, since the article contained carbolic acid; and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply liberally to gauze compress or directly to wound area."

DISPOSITION: January 9, 1950. Default decree of condemnation and destruction.

**DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED**

**2935. Misbranding of penicillin ointment and penicillin-G sodium crystalline, and adulteration and misbranding of Multovals Multi-Vitamins Gelucaps, Amberons Vitamin B Complex Gelucaps, and posterior pituitary ampuls. U. S. v. VCA Laboratories (Vitamin Corp. of America). Plea of guilty. Fine, \$3,300. (F. D. C. No. 26687. Sample Nos. 9437-K to 9439-K, incl., 9875-K, 10521-K, 10682-K.)**

INFORMATION FILED: March 23, 1949, District of New Jersey, against the VCA Laboratories, a corporation, trading as the Vitamin Corp. of America, at Newark, N. J.

INTERSTATE SHIPMENT: On or about February 27, March 8 and 19, and July 1, 2, and 21, 1948, from the State of New Jersey into the State of New York.

LABEL, IN PART: "Harco \* \* \* Penicillin Ointment \* \* \* Harco Pharmaceutical Corp. Division of VCA Laboratories Newark, New Jersey," "Penicillin-G Sodium Crystalline \* \* \* Manufactured for Solvecillin, Inc. Division of VCA Laboratories Newark, New Jersey," "Gelucaps Multovals Multi-Vitamins \* \* \* Vitamin Corporation of America Division of VCA Laboratories Newark, New Jersey," "Gelucaps Amberons Vitamin B Complex \* \* \* Vitamin Corporation of America Distributors Newark, New Jersey," and "Ampuls \* \* \* Posterior Pituitary (Obstetrical) \* \* \* VCA Laboratories Newark, New Jersey."