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."

NATURE OF CHARGE: *Penicillin ointment.* Misbranding, Section 502 (1), the article was represented as a drug composed in part of crystalline penicillin potassium salt, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; and, Section 502 (a), the label statement "Contains: 1000 Units Per Gram of Penicillin Crystalline Potassium Salt" was false and misleading since each gram of the article contained less than 1,000 units of penicillin crystalline potassium salt. Further misbranding, Section 502 (a), the label statement "Expiration Date: February 1951" was misleading in that it represented and suggested that the article could be relied upon to retain its potency until February 1951, whereas the article could not be relied upon to retain its potency until February 1951 since it could not be relied upon to retain its potency for more than one year after the month in which it was manufactured.

Penicillin-G sodium crystalline. Misbranding, Section 502 (1), the article was represented as a drug composed wholly of crystalline penicillin-G sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law. It was further charged that the defendant, in violation of Section 301 (i), caused to be falsely represented and, without proper authority, to be used on the label of the *Penicillin-G sodium crystalline* certain marks and identification devices authorized and required by the regulations, in that the defendant labeled one shipment of the drug "200,000 Units * * * Lot No. 3467 C Exp. Date Dec. 1950" and labeled the other shipment "100,000 Units * * * Lot No. 3127 C Exp. Date Nov. 1950," which were marks and identifications authorized and required by the regulations to appear in the labeling of crystalline penicillin-G sodium which was from a batch which had been certified pursuant to the regulations, whereas the product so labeled and marked by the defendant was from an uncertified batch.

Multovals Multi-Vitamins Gelucaps. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each gelucap of the article purported and was represented to contain 3 milligrams of vitamin B_1, whereas each gelucap contained less than 3 milligrams of vitamin B_1. Misbranding, Section 502 (a), the label statement "Each gelucap contains * * * Vitamin B_1 . . . 3 mg." was false and misleading.

Amberons Vitamin B Complex Gelucaps. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each gelucap of the article purported and was represented to contain 666 U. S. P. units of vitamin B_1 equivalent to 2 milligrams of vitamin B_1, whereas each gelucap contained less than that amount of vitamin B_1. Misbranding, Section 502 (a), the label statement "Each Gelucap Contains: Vitamin B_1 . . . 666 U. S. P. Units (2 MG.)" was false and misleading.

Posterior pituitary ampuls. Adulteration, Section 501 (b), the article purported to be "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since its potency was less than the potency required by that compendium. Misbranding, Section 502 (a), the label statements "5 U. S. P. Units * * * Each ½ cc contains: Posterior Pituitary Solution 5 U. S. P. Units" and "U. S. P. * * * 5 Units" were false and misleading. The statements represented and suggested that each ½ cc. of the article possessed a physiologic activity equivalent to 5 U. S. P.

posterior pituitary units, whereas each ½ cc. of the article possessed a physiologic activity equivalent to less than 5 U. S. P. posterior pituitary units.

DISPOSITION: June 13, 1949. A plea of guilty having been entered, the court imposed a fine of $3,300.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2936. Misbranding of benadryl capsules, sulfathiazole lozenges, and dexedrine sulfate tablets. U. S. v. Curtis R. Watkins (Krest Drug Store). Plea of nolo contendere. Defendant placed on probation for 1 year. (F. D. C. No. 26715. Sample Nos. 27035–K, 27047–K, 27048–K.)

INFORMATION FILED: July 28, 1949, Western District of Arkansas, against Curtis R. Watkins, trading as the Krest Drug Store, Fort Smith, Ark.

INTERSTATE SHIPMENT: On or about March 3 and July 28, 1948, from Kansas City, Mo., and Philadelphia, Pa., of quantities of *benadryl capsules* and *dexedrine sulfate tablets*. The *sulfathiazole lozenges* were manufactured on or about June 3, 1946, at Indianapolis, Ind., and thereafter were shipped in interstate commerce into the State of Arkansas.

LABEL, WHEN SHIPPED: "Kapseals Benadryl * * * 50 Mg. [or "Lozenges Sulfathiazole * * * 5 grs. (0.325 Gm.)" or "5 mg. Each Dexedrine Sulfate Tablets"] Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about August 31, September 27, and October 4, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged drugs were labeled "Krest Drug Store * * * Fort Smith, Ark. * * * Benadryl 50 mg.," "Sulfathizal Tablets Take as Directed," and "Dexedrine Tab."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the *sulfathiazole lozenges* and *dexedrine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use since the directions in the labeling of the repackaged *sulfathiazole lozenges* "Take as Directed" were not adequate directions for use and since the other repackaged drugs bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 30, 1949. A plea of nolo contendere having been entered, the court placed the defendant on probation for 1 year.

*See also Nos. 2931–2934.