

The information charged also that another article known as *C. M. A. Formula #21 tablets* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 20, 1951. Pleas of not guilty having been entered, the case came on for trial before the court without a jury on July 16, 1951. At the conclusion of the trial on July 20, 1951, the court rendered a verdict of guilty on all counts and fined the corporation \$800, Robert E. Davis \$1,000, and Carrie Davis \$400. In addition, Robert E. Davis and Carrie Davis were each sentenced to 2 years in prison. The prison sentences were suspended, however, and each individual defendant was placed on probation for 3 years, conditioned that each would not violate Federal or State food and drug laws or the State Medical Practices Act.

3584. Adulteration and misbranding of dextro-amphetamine sulfate tablets.

U. S. v. 5 Bottles * * *. (F. D. C. No. 31381. Sample No. 3111-L.)

LIBEL FILED: July 31, 1951, District of Columbia.

ALLEGED SHIPMENT: On or about April 12, 1951, by the Kumfort Drug Products Co., from Cleveland, Ohio.

PRODUCT: 5 unlabeled bottles each containing 1,000 tablets represented as 5 milligram *dextro-amphetamine sulfate tablets*. Examination showed that each tablet contained approximately 4.25 milligrams of amphetamine sulfate.

RESULTS OF INVESTIGATION: The product was shipped in response to an oral order given by the consignee to a representative of the shipper for 5 milligram *dextro-amphetamine sulfate tablets*.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, 4.25 milligram amphetamine sulfate tablets, had been substituted for 5 milligram *dextro-amphetamine sulfate tablets*.

Misbranding, Section 502 (i) (2), the article was an imitation of another drug; Section 502 (i) (3), it was offered for sale under the name of another drug; Sections 502 (b) (1) and (2), it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug, namely, amphetamine sulfate tablets; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and Section 502 (f) (2); the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children 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.

DISPOSITION: August 31, 1951. Default decree of condemnation and destruction.

3585. Misbranding of male hormone with vitamin B₁. U. S. v. 35 Packages, etc.

(F. D. C. No. 31383. Sample No. 1214-L.)

LIBEL FILED: On or about August 13, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about October 16 and December 8, 1950, and February 16 and March 8, 1951, by the Hudson Products Co., from Long Beach, Calif.

PRODUCT: 35 30-tablet packages and 19 60-tablet packages of *male hormone with vitamin B₁* at Atlanta, Ga.

LABEL, IN PART: (Package) "Male Hormone (methyl testosterone) combined with Vitamin B₁ * * * Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B₁ (Thiamin Hydrochloride)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label on the packages of the article contained statements which represented and suggested that when taken as directed, the article would be efficacious in the treatment of male hormone deficiency, which statements were false and misleading since the article when taken as directed, was not efficacious for such purpose; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the diseases or conditions of the body for which the article was intended; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form, as are necessary for the protection of users since the technical medical terminology in which the cautionary statement on the labeling was couched, namely,

CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardio-vascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

was inadequate to warn the ordinary lay user that use of the product may accelerate the malignant growth of the prostate gland or may cause sterility.

DISPOSITION: August 27, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3586. Adulteration of extract of Glycyrrhiza. U. S. v. MacAndrews & Forbes Co. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 30119. Sample No. 81757-K.)

INFORMATION FILED: April 26, 1951, District of New Jersey, against MacAndrews & Forbes Co., a corporation, Camden, N. J.

ALLEGED SHIPMENT: On or about October 13, 1950, from the State of New Jersey into the State of Tennessee.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the article had been prepared under insanitary conditions whereby it may have become contaminated with filth.

The information alleged also that the defendant had shipped in interstate commerce a quantity of licorice paste which was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 17552.

DISPOSITION: July 11, 1951. A plea of guilty having been entered, the court placed the defendant on probation for 2 years on the count charging adulteration of the *Glycyrrhiza*. (The defendant was fined \$250 on the count charging adulteration of licorice paste.)