

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

2951. Misbranding of Meta Androgen, Meta Lucyton, and Ascorbodium. U. S. v. 45 Bottles, etc. (F. D. C. No. 27813. Sample Nos. 55185-K, 55186-K, 55189-K.)

LIBEL FILED: September 6, 1949, Western District of Oklahoma.

ALLEGED SHIPMENT: By Dan Coombs, from Kansas City, Mo. The products were shipped on or about June 15, 1948, and February 5 and March 13, 1949; and certain printed matter was shipped in February 1948, and at various times thereafter.

PRODUCT: 45 150-tablet bottles of *Meta Androgen*, 20 150-tablet bottles of *Meta Lucyton*, and 15 100-tablet bottles of *Ascorbodium* at Oklahoma City, Okla., together with a loose-leaf book entitled "The New Master of Disease," and a page entitled "Meta Androstenedione and Meta Lucyton or Meta Androgen" which had been shipped for insertion in the book. Examination showed that the *Meta Androgen* contained methyltestosterone; that the *Meta Lucyton* contained anhydrohydroxyprogesterone; and that the *Ascorbodium* contained 103 milligrams of ascorbic acid per tablet.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the loose-leaf book and on the uninserted page were false and misleading since the articles were not effective for the purposes stated and implied. The statements represented and suggested:

That the *Meta Androgen* was effective to correct homosexual tendencies; to counteract the male climacteric and functional hypogonadism in middle-aged males; to restore physical and mental vigor and emotional equilibrium; to ameliorate psychic disturbances such as irritability and melancholia; to control insomnia associated with the male climacteric; to increase dynamic and static muscular performances, muscular strength, and resistance of the nervous system against fatigue; to correct the basic causes of most female functional disturbances; to favorably affect the vaginal mucous membrane and its allied secretory glands; to neutralize excess circulating estrogen, thereby removing a disturbing factor in the handling of female disorders; to treat hypogonadism or hypo-eccrisis (defective genitalia secretion) in the female; to treat cardiac cirrhosis; to increase muscular development and sense of well-being with a positive nitrogen balance in pituitary deficiencies; and to build up the uteri to within normal limits;

That the *Meta Lucyton* was effective to aid the development of abnormally small or hypoplastic breasts, whether as the solitary complaint or as part of the general picture of hypogonadism; to treat juvenile vaginitis; to suppress lactation; to prevent nausea and vomiting of pregnancy; and to remove fuzz from the upper lip or other masculine characteristics in a female in cases where the meta androstenedione may have a tendency to increase such characteristics;

That the *Ascorbodium* was effective to treat peripheral vascular disease, coronary thrombosis, inflammation of the blood vessels, Buerger's disease, blocked blood vessels, hay fever, asthma, skin eruptions associated with sensitivity to food, and similar conditions by stimulating histamine synthesis.

Further misbranding, Section 502 (j), the *Meta Androgen* 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) "Place

under tongue for absorption" and (uninserted page) "Directions for the male: 1 pellet under the tongue 4 times daily for a week or 10 days. 1 pellet under the tongue 3 times daily for a week or 10 days. 1 pellet under the tongue 2 times daily for a week or 10 days. 1 pellet under the tongue 1 time daily for a week or 10 days. * * * Directions for the female: Follow the same dosage as for the male until the first evidence of biological urge, or an itching sensation around the clitoris, then drop down to the next step, until 2 weeks after the beginning of the next menses period. Rest two days. On the third day give 1 pellet daily of Meta Lucyton until the beginning of the next menses, when you again give Meta Androstenedione in the same amount as given just before the 2 day rest."

DISPOSITION: October 26, 1949. Default decree of condemnation and destruction.

2952. Misbranding of Orange Blossom Suppositories. U. S. v. 35 Packages
* * *. (F. D. C. No. 27999. Sample No. 57010-K.)

LABEL FILED: September 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about August 24, 1949, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 35 packages each containing 6 *Orange Blossom Suppositories* at New York, N. Y. Examination showed that the suppositories consisted essentially of ammonium alum, approximately 50 percent, borax and siliceous material in a fatty base.

NATURE OF CHARGE: 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, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

DISPOSITION: January 16, 1950. Default decree of condemnation. The court ordered that a number of the suppositories be released to the Food and Drug Administration and that the remainder be destroyed.

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

2953. Misbranding of nembutal capsules, seconal sodium capsules, and Tuinal capsules. U. S. v. Benet's Pharmacies, Inc., and Harry Benet. Pleas of guilty. Fine, \$2,000. (F. D. C. No. 26706. Sample Nos. 18367-K, 18379-K, 18592-K, 18594-K, 18596-K, 19670-K, 19675-K, 19679-K, 19680-K, 19687-K, 19690-K to 19692-K, incl., 19696-K, 43834-K, 51222-K, 51312-K to 51315-K, incl.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Benet's Pharmacies, Inc., Cincinnati, Ohio, and Harry Benet, president and treasurer of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of May 6, 1948, and September 9, 1948, from the States of Illinois and Indiana into the State of Ohio, of quantities of *nembutal capsules*, *seconal sodium capsules* and *Tuinal capsules*.