

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

3661. Misbranding of male and female hormones. U. S. v. 628 Linguets, etc.
(F. D. C. No. 31936. Sample Nos. 1039-L, 1040-L, 1062-L.)

LIBEL FILED: November 2, 1951, Southern District of Florida.

ALLEGED SHIPMENT: On or about June 25, 1951, and within the past 18 months from the date on which the libel was filed, from Cedar Rapids, Iowa.

PRODUCT: 628 5-milligram and 1,835 10-milligram *oral androgen male sex hormone linguets* and 887 *Vitro No. 318 oral estrogen female sex hormone linguets* at Jacksonville, Fla., in possession of the Vitro Co., together with a number of leaflets entitled "Oral Androgen Male Sex Hormones."

LABEL, IN PART: (Bottle) "Oral Androgen Male Sex Hormone Linguets for absorption through the oral mucous membranes 5 mg. [or "10 mg."]. Each linguet contains 5 mg. [or "10 mg."] of the pure methyl ester of testosterone, with more marked androgenic properties than testosterone when taken by mouth. Use as Directed by Your Physician. Distributed by the Vitro Company" and "Linguets Vitro No. 318 Oral Estrogen Female Sex Hormone Linguets for absorption through the oral mucous membranes. Each linguet contains naturally occurring estrogens, with estrons as the chief active principle, biologically standardized to the equivalent of 0.5 mg. estrogen=5000 I. U."

NATURE OF CHARGE: 5 and 10 milligram *oral androgen male sex hormone linguets*. Misbranding, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, in the leaflet entitled "Oral Androgen Male Sex Hormone," as follows: "5 mg. to 40 mg. 3 times or more weekly before meals and preferentially in divided doses. Dosage should be lowered as improvement occurs to minimum maintenance levels." Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions where their 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.

Vitro No. 318 oral estrogen female sex hormone linguets. Misbranding, 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 adequate warnings against use in those pathological conditions where the use of the article 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.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

3662. Misbranding of Detoxacolon (Hydr-Oxy-Colon) device. U. S. v. 1 Device * * *
(F. D. C. 31715. Sample No. 30862-L.)

LIBEL FILED: June 19, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: The product was ordered from, and invoiced by, the United X-Ray & Equipment Co., Los Angeles, Calif.; and various parts were shipped from Dallas, Tex., on or about June 23, 1950, and from Hollywood,