

preservative Intramuscular and Intravenous Morton Pharmaceuticals Inc. Ethical Distributors Memphis, Tenn."

RESULTS OF INVESTIGATION: Examination of the *calcium gluconate* showed that it was pyrogenic and that the other drugs involved were not sterile as represented but were contaminated with viable micro-organisms.

CHARGE: 501 (c)—the purity and quality of the *triple hormone suspension* and the *testosterone*, when shipped, fell below that which they purported and were represented to possess; 502 (a)—the labels of the *progesterone* and *testosterone*, when shipped, contained false and misleading statements that the articles were sterile; and 502 (j)—when shipped, the *calcium gluconate* was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Usual Dose: Adults, intravenous or intramuscular 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram."

PLEA: Nolo contendere.

DISPOSITION: 5-29-57. \$1,250 fine, plus costs.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

5302. Pega Palo vine and root. (F. D. C. No. 40131. S. No. 70-865 M.)

QUANTITY: 7 bags, ½ oz. each, and 1 bag, containing ¼ oz., of *Pega Palo vine*, and 1 ctn., containing 11 lbs. 9 oz., of *Pega Palo root*, at Iowa Falls, Iowa, in possession of Richard H. Snook, d/b/a Competition Chemicals.

SHIPPED: During January 1957, from the Dominican Republic and Haiti, by Richard H. Snook.

ACCOMPANYING LABELING: Leaflets entitled "Pega Palo Vines and Roots (Fortidom)" and reprints entitled "Pega Palo The Vine That Makes You Virile."

LIBELED: 4-8-57, N. Dist. Iowa.

CHARGE: 505 (a)—the article, when shipped, was a new drug which may not be shipped in interstate commerce since an application filed pursuant to 505 (b) was not effective with respect to such drug; and 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use for the purpose for which it was intended, namely, as an aphrodisiac.

DISPOSITION: 5-20-57. Default—destruction.

5303. Pega Palo vine. (F. D. C. No. 40123. S. No. 54-372 M.)

QUANTITY: 439 cellophane envelopes at Yakima, Wash.

SHIPPED: 2-14-57, from Chicago, Ill., by A-1 Import Co.

ACCOMPANYING LABELING: Reprints of an article from the January 1957 issue of "Confidential" magazine entitled "Pega Palo The Vine That Makes You Virile" and leaflets headed "Pego Palo Vine Directions For Use."

RESULTS OF INVESTIGATION: The reprints were shipped from Chicago, Ill., by A-1 Import Co., and the leaflets were printed locally.

Examination showed that the article was a dried, woody, vine-like material.

LIBELED: 4-10-57, E. Dist. Wash.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use as an aphrodisiac, which was the purpose for which the drug was intended; and 505 (a)—the article was a new drug which may not be introduced into interstate commerce since

an application filed pursuant to law was not effective with respect to the drug.
DISPOSITION: 7-26-57. Default—destruction.

DRUGS FOR VETERINARY USE

5304. Animal feeds containing diethylstilbestrol. (F. D. C. No. 39063. S. Nos. 40-624/5 M, 40-627/9 M, 40-631 M.)

QUANTITY: 127 50-lb. bags of *Cattle Concentrate*, 134 50-lb. bags of *Cattle Concentrate pellets*, and 99 50-lb. bags of *Purdue Supplement pellets* at Quimby, Iowa, in possession of Simonsen Mill-Rendering Plant.

SHIPPED: The articles contained diethylstilbestrol, which had been shipped on 1-10-56, from New York, N. Y.

LABEL IN PART: "Simonsen Cattle Concentrate * * * Stilbestrol Special Mix * * * Each 1 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol," "Simonsen Cattle Conc. Pellets * * * Stilbestrol Special Mix * * * Each 2 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol," and "Simonsen Modified Purdue Supplement * * * Pellets * * * Stilbestrol Special Mix * * * Each 1 pounds [or "1½ pounds"] contains 10 milligrams of Diethylstilbestrol."

RESULTS OF INVESTIGATION: The articles were manufactured by Simonsen Mill-Rendering Plant at Quimby, Iowa, using the diethylstilbestrol which had been shipped as described above.

LIBELED: 5-7-56, N. Dist. Iowa.

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

The articles, by reason of the presence therein of the active ingredient, diethylstilbestrol, which had been shipped in interstate commerce, were new drugs within the meaning of the law; and an application filed pursuant to law was not effective with respect to the drugs.

DISPOSITION: 6-28-56. Default—destruction.

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

5305. Tetracycline hydrochloride tablets and capsules. (F. D. C. No. 40171. S. Nos. 67-507/8 M.)

QUANTITY: 3 200-tablet btls. and 1 100-capsule btl. at Silver Spring, Md., in possession of Medical Supplies, Inc.

SHIPPED: From New York, N. Y.

LABEL IN PART: (Btl.) "Tetracycline Hydrochlor. [or "Hcl."] * * * 250 mg."

RESULTS OF INVESTIGATION: A sales representative of the manufacturer delivered in person to the consignee sample bottles of 8 tablets or capsules. The sales representative had received the articles from New York, N. Y., and the consignee had repacked into bottles and relabeled the tablets and capsules described above. Neither of the repacked lots had been certified.

LIBELED: 4-24-57, Dist. Md.

CHARGE: 502 (1)—the article, while held for sale, was a drug composed in part of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 5-22-57. Default—destruction.