

Section 502 (a), in that certain statements in the leaflet entitled "New Horizons" accompanying the device were false and misleading. The statements represented and suggested that use of the device was effective in improving the sexual capacities of older men by enlarging and reinforcing the sexual organ. The device was not effective for such purpose, and it would not fulfill the promises of benefit made for it.

The libel alleged also that if the leaflet entitled "New Horizons" was not part of the labeling of the device, then the device was misbranded when introduced into and while in interstate commerce within the meaning of Section 502 (f) (1), in that its labeling failed to state the purposes and conditions for which the device was intended, namely, to improve the sexual capacities of older men by enlarging and reinforcing the sexual organ.

DISPOSITION: June 13, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

#### DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4031. Adulteration and misbranding of Vio-Ferronate tablets. U. S. v. Rowell Laboratories, Inc. Plea of nolo contendere. Fine, \$350. (F. D. C. No. 34351. Sample No. 48581-L.)

INFORMATION FILED: March 19, 1953, District of Minnesota, against Rowell Laboratories, Inc., Baudette, Minn.

ALLEGED SHIPMENT: On or about February 7, 1952, from the State of Minnesota into the State of North Dakota.

LABEL, IN PART: (Bottle) "Coated Tablets Vio-Ferronate Ferrous Gluconate with Liver and Vitamin B-12 \* \* \* Rowell Laboratories Division of Burbot Liver Products Co. Baudette, Minnesota."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each tablet of the article purported and was represented to contain 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C, whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C.

Misbranding, Section 502 (a), the label statements displayed upon the bottles were false and misleading in that the statements represented and suggested that each tablet of the article contained 3 milligrams of thiamine hydrochloride, 1 milligram of pyridoxine, and 30 milligrams of vitamin C (ascorbic acid), whereas each tablet contained less than 3 milligrams of thiamine hydrochloride, less than 1 milligram of pyridoxine, and less than 30 milligrams of vitamin C (ascorbic acid).

DISPOSITION: May 20, 1953. The defendant having entered a plea of nolo contendere, the court fined it \$350.

4032. Adulteration and misbranding of gum karaya. U. S. v. 75 Drums \* \* \*. (F. D. C. No. 33513. Sample No. 54058-L.)

LIBEL FILED: September 3, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 28, 1952, by Dodwell & Co., Ltd., from Newark, N. J.

PRODUCT: 75 300-pound drums of *gum karaya* at Franklin Park, Ill.