2602. Misbranding of Gomco ring pessaries. U. S. v. 17 Devices * * * (and 1 other seizure action). (F. D. C. Nos. 25753, 25764. Sample Nos. 27462–K, 27464–K, 37644–K.)

LIBELS FILED: On or about September 13 and 30, 1948, Eastern District of Missouri and District of Oregon.

ALLEGED SHIPMENT: On or about March 30, May 24, and July 30, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: *Gomco ring pessaries.* 17 devices at St. Louis, Mo., and 20 devices at Klamath Falls, Oreg., together with a number of circulars entitled "Gomco Intrauterine Ring." Examination showed that the device was a metallic ring, approximately one inch in diameter, which was fashioned from a coiled spring.

NATURE OF CHARGE: Misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration recommended and suggested in the circulars, namely, "It may be left in the uterus indefinitely. Cases have been reported in which the ring has been left in position for six years, without removal and with no ill effect. Pathological Tests Give No Indications of Malignancy. We would suggest however that the physician withdraw and place the Gomco Intra-Uterine Ring yearly * * * Technic: (As Suggested by Haire) 'The Ring Pessary should be inserted during menstrual period in order that one may be certain that patient is not already pregnant. The patient is placed in the lithotomy position, a vaginal speculum is inserted by means of special introducer. There is usually no pain following its introduction and no pain at the periods. Even in cases where menstruation has been painful, previously, the presence of the ring seems to diminish it. Technic of Gomco Intra-Uterine Ring. Gomco Intra-Uterine Ring in Uterus (Diagrams showing method of inserting Ring and its position in the Uterus)."

Further misbranding, Section 502 (a), the statements in the circulars "The Gomco Intra-Uterine Ring is used where a * * * safe procedure for contraception is indicated" was false and misleading since the device could not be safely used under any conditions; and, Section 502 (b) (1), the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: October 14 and November 5, 1948. Default decrees of condemnation and destruction.

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

2603. Misbranding of ring pessaries. U. S. v. 4 Medium ring pessaries, etc. (F. D. C. No. 25742. Sample Nos. 25869–K, 25870–K.)

LIBEL FILED: September 10, 1948, District of Minnesota.

ALLEGED SHIPMENT: On or about March 1, 1946, and January 29 and May 3, 1948, by the Gomco Surgical Manufacturing Corp., from Buffalo, N. Y.

PRODUCT: 4 medium and 3 small *ring pessaries* at Minneapolis, Minn. Examination showed that the device was a metallic ring, approximately one inch in diameter which was fashioned from a coiled spring.

*See also Nos. 2601, 2646.