

For cases in which the cause of deafness has been medically diagnosed as hearing nerve deafness due to carbohydrate metabolic disturbance as indicated by high pyruvic acid level in the blood (higher than 2 mg. per 100 cc. under basal conditions), this product may be of value when used in conjunction with other suitable treatment prescribed by your physician. A blood test is necessary to determine whether the level of pyruvic acid in the blood is high.

The decree further enjoined the defendants against introducing the article into interstate commerce unless it was accompanied by written, printed, or graphic matter which clearly stated and enumerated every disease, condition, symptom, and purpose for which the article was intended to be used and for which it was represented by any means to the public.

**4765. Ovarian extract, corpus luteum extract, Pit-Ovarin, and anterior pituitary extract. (F. D. C. No. 37586. S. Nos. 14-603/6 M.)**

**QUANTITY:** 66 vials of *ovarian extract*, 77 vials of *corpus luteum extract*, 91 vials of *Pit-Ovarin*, and 22 vials of *anterior pituitary extract* at St. Louis, Mo.

**SHIPPED:** Between 10-7-54 and 12-1-54, from Philadelphia, Pa., by National Drug Co.

**LABEL IN PART:** (Vial) "List #167 Multiple Dose Vial 15 cc. Ovarian Extract \* \* \* Each cc. contains the water and alcohol soluble extractives derived from 40 grains of fresh Ovarian Glands with Chlorobutanol 0.5% \* \* \* For intramuscular use in non-specific therapy," "List #80 Multiple Dose Vial 25 cc. Extract Corpus Luteum \* \* \* Each cc. contains the water soluble extractives derived from 18 grains of Chlorobutanol \* \* \* 0.5% Contains no known hormonal therapeutic activity. For Intramuscular Use In Ovarian Dysfunction," "List #283 Multiple Dose Vial 25 cc. Pit-Ovarin \* \* \* Each cc. contains water soluble solids from 20 gr., fresh Whole Ovary and from 5 gr., fresh Anterior Pituitary gland with Procaine Hydrochloride 1% and Chlorobutanol \* \* \* 0.5% For use in nonspecific therapy," and "List #118 Multiple Dose Vial 25 cc. Anterior Pituitary Extract \* \* \* Each cc. contains the water soluble ingredients obtained from 18½ grains of fresh anterior pituitary lobe tissue with Chlorobutanol 0.5%."

**LIBELED:** 1-7-55, E. Dist. Mo.

**CHARGE:** 502 (a)—the statement on the label of the *corpus luteum extract* when shipped, namely, "For \* \* \* Use In Ovarian Dysfunction," was false and misleading as applied to the article, which would be of no value in the treatment of ovarian dysfunction, and the label statements of such article "Contains no known hormonal therapeutic activity" and "For \* \* \* Use In Ovarian Dysfunction" were misleading when considered together since they were mutually contradictory; and 502 (f) (1)—the labeling of all of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

**DISPOSITION:** 2-3-55. Default—destruction.

**4766. Elemin vitamin and mineral tablets. (F. D. C. No. 37520. S. Nos. 5-566/7 M.)**

**QUANTITY:** 6 cases, 24 retail cartons each, and 10 cases, 12 retail cartons each, at Milwaukee, Wis.

**SHIPPED:** Between 11-24-53 and 4-6-54, from Berkeley, Calif.