

# United States Department of Agriculture

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

22176-22200

[Approved by the Acting Secretary of Agriculture, Washington, D.C., September 11, 1934]

**22176. Adulteration and misbranding of Ergot Aseptic. U. S. v. 59 Packages of Ergot Aseptic. Default decree of condemnation, forfeiture, and destruction. (F. & D. no. 26338. I. S. no. 27200. S. no. 4666.)**

This case involved a shipment of Ergot Aseptic, a drug preparation which was labeled as containing, in each cubic centimeter, the therapeutically important principle of 1 gram of ergot. Samples tested were found to have a potency, per cubic centimeter, of not more than one-third gram of ergot.

On May 6, 1931, the United States attorney for the Eastern District of Louisiana, acting upon a report by the Secretary of Agriculture, filed in the district court a libel (amended March 30, 1932) praying seizure and condemnation of 59 packages of Ergot Aseptic at New Orleans, La., alleging that the article had been shipped in interstate commerce, on or about February 17 and March 3, 1931, by Parke-Davis & Co., from Detroit, Mich., and charging adulteration and misbranding in violation of the Food and Drugs Act.

It was alleged in the libel that the article was adulterated in that its strength fell below the professed standard under which it was sold, namely, "Ergot Aseptic \* \* \* One CC Equal to One Gm (15+½Grs) Ergot \* \* \* Tested Physiologically and Standardized."

Misbranding was alleged for the reason that the following statements on the labeling were false and misleading: (Carton) "Ergot Aseptic \* \* \* One CC Equal to one Gm (15½ Grs.) Ergot \* \* \* tested physiologically and standardized \* \* \* Ergot Aseptic may be administered hypodermically in any case in which Ergot is indicated. \* \* \* Accuracy of dose uniformity of chemical and physiological tests"; (individual ampoule carton and ampoule label) "Ergot Aseptic One CC Equal to One Gm (15+½ Grs Ergot"; (circular) "Solution of Ergot containing in each cubic centimeter the therapeutic activity of one gram (15+½ Grains) of Ergot of standard quality. It is standardized physiologically by noting the effect of definite graded doses on the vascularity of the comb and wattles of the rooster. On the basis of this typical reaction of the cocks comb Ergot Aseptic possesses the activity of fluid extract ergot, U. S. P. It represents the full activity of the ergot from which it is prepared \* \* \* Its therapeutic effect which is simply that of ergot is produced promptly \* \* \* It is a \* \* \* Potent form of Ergot. \* \* \* Its Activity is assured by Physiological assay \* \* \* It is possessed of exceptional potency"; (card insert) "Improved Formula \* \* \* retaining the Full Activity."

On March 15, 1934, the claim and answer of Parke Davis & Co., the sole intervener, having been withdrawn by permission of the court, judgment of condemnation and forfeiture was entered, and it was ordered by the court that the product be destroyed. On March 16, 1934, the decree was amended to permit release of the product to Parke Davis & Co., under a bond in the sum of \$500, conditioned that it be returned to Detroit, Mich., to be destroyed under the supervision of this Department.

M. L. WILSON, *Acting Secretary of Agriculture.*