

the standard of strength as determined by the test laid down in the said pharmacopoeia, and its own standard of strength was not stated on the container.

Misbranding was alleged for the reason that the statements on the label, "Tincture * * * Digitalis * * * U. S. P. X. * * * It is of full U. S. P. strength", were false and misleading, since it had a potency of not more than two-thirds of that required by the United States Pharmacopoeia for digitalis tincture.

On June 29, 1933, no claimant having appeared for the property, judgment of condemnation was entered and it was ordered by the court that the product be destroyed by the United States marshal.

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

21235. Adulteration and misbranding of Ergot-Apiol. U. S. v. 213 Packages and 68 Packages of Ergot-Apiol. Default decree of condemnation and destruction. (F. & D. nos. 30345, 30346. Sample nos. 17334-A, 29832-A.)

These cases involved a drug preparation which was labeled to convey the impression that it contained the therapeutically important principles of ergot. Biological tests of the article showed that it contained no ergot alkaloids. Examination further showed that the article contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed on the box label and in a circular shipped with the article.

On April 21, 1933, the United States attorney for the Southern District of California, acting upon reports by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of 281 packages of Ergot-Apiol at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce in various shipments on or about September 2, October 15, and December 6, 1932, by the American Pharmaceutical Co., from New York, N.Y., and charging adulteration and misbranding in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article by this Department showed that it consisted essentially of material derived from plants, including a nonvolatile oil such as apiol, and a volatile oil such as savin oil. It contained no ergot alkaloids.

It was alleged in the libels that the article was adulterated in that its strength fell below the professed standard and quality under which it was sold, namely, on tin box and circular, "Ergot."

Misbranding was alleged for the reason that the statements on the tin box, "Ergot", and in the circular, "Ergot * * * is a skillfully prepared compound of * * * Ergot", were false and misleading. Misbranding was alleged for the further reason that the following statements regarding the curative and therapeutic effects of the article were false and fraudulent: (Tin box) "For amenorrhea, dysmenorrhea and menstrual disorders"; (circular) "For the Treatment of Menstrual Disorders; Relieves Pain * * * for amenorrhea, dysmenorrhea and menstrual disorders * * * for use in the treatment of Menstrual disorders * * * is of value, and in general is indicated, in the conditions described below * * * ; Amenorrhea—When menstrual flow is absent or scanty as a result of shock, exposure, or nervous strain, 1 capsule should be given 3 times a day for 3 days, then increased to 2 capsules 3 times a day until the flow has been established, when it is reduced to 1 capsule twice a day. Dysmenorrhea—in cases where the complaint is chronic, Ergot-Apiol should be taken a few days in advance of the period and continued until the flow has ceased. In most cases one capsule 4 times a day is sufficient, but when pain is unusually severe 2 capsules may be given 4 times a day. Menorrhagia—When the flow is excessive, resulting in weakness and lack of energy, one capsule may be administered 4 times a day. Menostasis—To re-establish the flow, 2 tablets may be administered 3 to 4 times a day, in conjunction with frequent sitz baths, if preferred. Menopause * * * an aid in easing the disturbances attending final cessation of the menstrual functions."

On July 3, 1933, no claimant having appeared for the property, judgments of condemnation were entered and it was ordered by the court that the product be destroyed by the United States marshal.

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