

## DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2601. Misbranding of Lawrence's Iron and Liver Capsules, Lawrence's Mineral Tablets, Lawrence's Laxative No. 1 Tablets, Lawrence's Meth-Phos Pills, Lawrence's Nervo Tablets, Vitamin C Tablets, Lawrence's Vitamin E Capsules, and Lawrence's Heavy Base Ointment. U. S. v. Lawrence V. Devine (Lawrence Drug Co.). Plea of guilty. Fine, \$170. (F. D. C. No. 24282. Sample Nos. 20304-K, 20306-K to 20309-K, incl., 20311-K to 20313-K, incl.)

INFORMATION FILED: January 21, 1949, Western District of Missouri, against Lawrence V. Devine, trading as the Lawrence Drug Co., at Kansas City, Mo.

ALLEGED SHIPMENT: On or about August 28, 1947, from the State of Missouri into the State of Oklahoma.

LABEL, IN PART: "Capsules Iron & Liver \* \* \* Each capsule contains: Ferrous Sulfate U. S. P.  $3\frac{3}{8}$  gr. Liver concentrate equiv. to 7 gr. Vitamin B-1 . . . 331 U. S. P. Units Vitamin B-2 . . . 500 Gamma Niacinamide . . . 5.0 mg. Calcium Pantothenate . . . 1 mg."; "Lawrence's High Potency Mineral Tablets \* \* \* Containing: Di-Calcium Phosphate, Iron, Copper Peptonate, Manganese Carbonate, Zinc Oxide, Magnesium Oxide, and Potassium Iodide"; "Lawrence's famous Laxative No. 1 100 Brown Tablets \* \* \* Bile Salts compound . . . 1 gr. Papain . . . 2 grs. Phenolthalein . . .  $\frac{1}{2}$  gr. Ext. Nux Vomica . . .  $\frac{1}{16}$  gr. Ext. Cascara Sagrada . . .  $\frac{1}{2}$  gr. Oleoresin Capsicum . . .  $\frac{1}{40}$  gr."; "Lawrence's Meth-Phos Pills \* \* \* Each tablet contains: Hexamethylenamine . . . 5 grs. Sodium Acid Phosphate . . . 5 grs."; "Lawrence's Nervo Tablets \* \* \* Each tablet contains: Sodium Bromide . . . 5 grs. Potassium Bromide . . . 5 grs. Amonium Bromide . . . 5 grs."; Vitamin 'C' (Ascorbic Acid) Tablets 100 Mg. Each tablet Contains: 100 Mg. of Vitamin C U.S.P. equivalent to 2,000 U.S.P. units of Vitamin C (Ascorbic Acid)."; "Capsules Vitamin E Natural Mixed Tocopherols"; and "Lawrence's Improved Heavy Base Ointment." Analysis of the ointment showed that it contained chiefly zinc oxide.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing on the labels of the articles (other than the *Lawrence's Nervo Tablets*) and in an accompanying booklet entitled "Lawrence's 1947 Medical Catalogue and Little Doctor Book" represented and suggested that the articles were preferred by medical doctors;

That the *Lawrence's Iron and Liver Capsules* would be efficacious in the cure, mitigation, and treatment of anemia, would help to build up the blood, and would increase one's strength and vitality;

That the *Lawrence's Mineral Tablets* were a potent and rich source of minerals and would be efficacious in the cure, mitigation, and treatment of bronchial asthma and in healing the mucous lining of the bronchioles;

That the *Lawrence's Laxative No. 1 Tablets* would stimulate the liver and thin the bile and act as a gall bladder stimulant; that they would wake-up the liver; that they would be efficacious in the treatment of a sluggish, non-functioning liver and a sluggish gall bladder; that they would be efficacious in the cure, mitigation, and treatment of spots before the eyes, dizziness, indigestion, bleaching, colitis, pain over the gall bladder, inability to eat heavy or

fatty foods, gas, and bitter sour stomach; that the use of the article plus careful attention to the colon would save one from having an operation; and that its use in conjunction with colonic irrigations would heal a sluggish liver and a bad gall bladder and would give relief to one with a sluggish liver and a bad gall bladder;

That the *Lawrence's Meth-Phos Pills* would act as a stimulant and a diuretic to the kidneys; that they would be efficacious in the cure, mitigation, and treatment of bladder urinary irritation, frequent and burning urination, difficulty in passing urine, occasional backache, puffiness under the eyes, swelling of the ankles, low backache, frequent urination at night, scanty passage of urine, lazy kidneys, and kidney troubles; that they would correct sluggish kidney action; that they were used frequently by urologists in the treatment of sluggishness of the kidneys and infection in the urinary tract; and that they would be efficacious in the treatment of sluggishness of the kidneys and infection in the urinary tract.

That the *Vitamin C Tablets* would be efficacious in the cure, mitigation, and treatment of infections, colds, flu, pimples, hives, eczema, hay fever, asthma, and boils, and would be efficacious as an anti-allergic;

That the *Lawrence's Vitamin E Capsules* would be efficacious to restore loss of vigor and vitality and would be efficacious in the treatment and prevention of nerve weakness, paralysis, gray hair, and sterility;

That the *Lawrence's Heavy Base Ointment* would be efficacious in the cure, mitigation, and treatment of leg ulcers, varicose veins, and poor circulation.

The above statements were false and misleading since the products were not preferred by doctors; the *Lawrence's Mineral Tablets* were not a potent and rich source of minerals; and the products would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (2), the labeling of the *Lawrence's Laxative No. 1 Tablets* failed to bear a warning that they should not be used in the presence of abdominal pain, nausea, vomiting, and other symptoms of appendicitis.

*Lawrence's Nervo Tablets*. Misbranding, Section 502 (f) (2), the labeling of the drug failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, in that the drug contained bromides, the use of which may be dangerous to the health of persons with kidney disease, and frequent and continued use of a drug containing bromides may lead to mental derangement, skin eruptions, and other serious effects; and the labeling of the product failed to bear warnings of such dangers.

Further misbranding, Section 502 (j), the *Lawrence's Nervo Tablets* were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in their labeling, "Adult Dose: Take one tablet 2 or 3 times a day," since the labeling provided for the consumption of an excessive and dangerous amount of bromides.

Further misbranding, section 502 (e) (2), the *Lawrence's Heavy Base Ointment* was not designated solely by a name recognized in an official compendium, and its label failed to bear its common or usual name, "Zinc Oxide Ointment."

DISPOSITION: February 2, 1949. A plea of guilty having been entered, the court imposed a fine of \$170.