

ALLEGED VIOLATION: On or about January 17, 18, 21, and 25, 1950, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and sold without a prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules bore no label containing the name and place of business of the manufacturer, packer, or distributor, and no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative, the Federal Security Administrator, after investigation, has found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules bore no directions for use.

DISPOSITION: January 11, 1951. A plea of nolo contendere having been entered, the court imposed a fine of \$200.

3372. Misbranding of Lang's Mineral Iron and Aluminum Sulfate. U. S. v. 15 Pounds, etc. (F. D. C. No. 30343. Sample Nos. 86437-K to 86440-K, incl.)

LABEL FILED: December 19, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about October 7 and 25, 1950, and on other dates in 1950, by Margaret Lange, from Portland, Oreg.

PRODUCT: *Lang's Mineral Iron and Aluminum Sulfate.* 15 pounds in bulk; 25 envelopes, each containing $\frac{1}{3}$ ounce; 21 boxes, each containing 12 capsules; and 12 12-ounce bottles containing the product in solution, at Lang's Mineral Wonder, Los Angeles, Calif.

Also in the possession of the consignee were 8,000 empty envelopes, 200 labels for the capsules, 1,000 labels for the solution, and 1,000 copies of a folder entitled "Lang's Mineral Wonder."

RESULTS OF INVESTIGATION: The product was shipped, labeled as described below. The consignee repackaged the article into envelopes, each containing $\frac{1}{3}$ ounce; into boxes, each containing 12 capsules; and into bottles, each containing 12 ounces of a solution consisting of 1 pound of the article to 5 gallons of water. The consignee also caused the printing of the envelopes, the box and bottle labels, and a folder entitled "Lang's Mineral Wonder." This folder was given to prospective customers at the consignee's place of business and was mailed in response to inquiries.

LABEL, IN PART: (Bulk shipment) "Lang's Mineral Iron and Aluminum Sulfate"; (repackaged, in envelopes) "Lang's Mineral Wonder * * * Net Contents: $\frac{1}{3}$ oz."; (repackaged, in boxes) "Lang's Mineral Wonder * * * Lang's Female Capsules"; and (repackaged, in bottles) "Lang's Mineral Wonder * * * Net Contents: 12 oz."

NATURE OF CHARGE: Misbranding (bulk shipment), Section 502 (f) (1), the labeling failed to bear adequate directions for use since the labeling bore no directions for use. The article was misbranded in this respect when introduced into, and while in, interstate commerce.

Further misbranding (repackaged drug in envelopes, boxes, and bottles), Section 502 (a), certain statements in the accompanying folder entitled "Lang's Mineral Wonder" were false and misleading. These statements represented and suggested that the article would be effective as a treatment for

physical troubles; that it would help reach the cause of a wide variety of conditions; that it would end conditions that bring pain and distress; and that it would furnish the system with minerals essential for it. The article would not be effective in the treatment of the conditions and for the purposes stated and implied.

Further misbranding, Section 502 (a), certain statements on the label of the boxes of capsules were false and misleading since the statements represented and suggested that the article would be effective as a treatment for diseases of females, whereas it would not be effective as a treatment for diseases of females.

Further misbranding (envelopes, boxes, and bottles), Section 502 (a), the statements which appeared on the envelopes "Silica (SiO_2), Sodium & Potassium Oxide (Na_2O & K_2O), Phosphates (P_2O_5), Iron Oxide (Fe_2O_3), Aluminum Oxide (Al_2O_3), Sulphates (SO_3), Moisture @ 105°C , Water (Combined) (By Difference)" and the statements which appeared on the label of the bottles containing the solution—

	<i>Parts per million</i>	<i>Grains per gallon</i>
Silica (SiO_2)-----	5.0	.29
Iron Oxide (Fe_2O_3)-----	5120.0	299.00
Aluminum Oxide (Al_2O_3)-----	1332.0	77.79
Sulphuric Anhydride (SO_3)-----	9720.0	567.65
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Total Solids-----	16177.0	944.73

were misleading in that they failed to reveal the material fact that, when taken as directed, the article would supply no therapeutically useful substance; and the statements on the label of the boxes containing the capsules "Silica (SiO_2) 0.08% Sodium & Potassium Oxide (Na_2O & K_2O) trace, Phosphates (P_2O_5) trace, Iron Oxide (Fe_2O_3) 6.26%, Sulphates (SO_3) 39.92% Moisture @ 105°C 14.02%, Water (Combined) (By Difference) 19.50%" were misleading since they failed to reveal the material fact that the iron and aluminum sulfates were the only constituents of the article that, when taken as directed, would produce any significant physiologic effect. The product in the envelopes, boxes, and bottles was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 8, 1951. Florence Potter, also known as Florence Wilson, trading as Lang's Minerals, Los Angeles, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be relabeled, under the supervision of the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3373. Adulteration and misbranding of Succidol capsules. U. S. v. Calvital Co., Inc., and Alexander S. Race. Pleas of guilty. Fine of \$200 against corporation; fine of \$4 against individual remitted. (F. D. C. No. 29476. Sample No. 57251-K.)

INFORMATION FILED: January 12, 1951, Southern District of New York, against Calvital Co., Inc., Mount Vernon, N. Y., and Alexander S. Race, president of the corporation.