

**LABEL IN PART:** *Cattle mineral.* (Bag) "50 lbs. net Young's \* \* \* Cattle Mineral Fortified with Vitamins A and D"; (tag) "Guaranteed Analysis Calcium 22.00% Phosphorus 17.00% Iodine 0.02% Salt None Drugs None Ingredients Precipitated Bone Phosphate, Monocalcium Phosphate, Magnesium Carbonate, Potassium Iodine, Iron Oxide, Iron Sulfate, Copper Sulfate, Cobalt Sulfate, Zinc Sulfate, Manganese Sulfate, Vitamin A Feeding Oil, D—Activated Plant Sterol (source of Vitamin D<sub>2</sub>) Natural Flavors Added."

*Hog mineral.* (Bag) "50 Lbs. net Young's \* \* \* Hog Mineral Fortified with Vitamins A and D"; (tag) "Guaranteed Analysis Calcium 23.00% Phosphorus 16.00% Iodine 0.02% Salt None Drugs None Ingredients Dicalcium Phosphate, Monocalcium Phosphate, Magnesium Carbonate, Potassium Iodine, Iron Sulfate, Iron Oxide, Manganese Sulfate, Monohydrate, Zinc Sulfate, Vitamin A Feeding Oil, D—Activated Plant Sterol (source of Vitamin D<sub>2</sub>)."

*Stock tonic.* (Bag) "50 lbs. net Young's \* \* \* Old Prescription Stock Tonic and Mineral Supplement"; (tag) "Guaranteed Analysis not less than Calcium 17.00% Phosphorus 13.00% Iodine 0.10% Salt None Vitamin D<sub>2</sub> 75,000 U. S. P. units per pound Ingredients Foengreek, Licorice Root, Poke Root, Fennel Seed, Nux Vomica (minimum strychnine content .017%), Precipitated Bone Phosphate, Monocalcium Phosphate, Iron Oxide, Magnesium Carbonate, Potassium Iodide, Copper Sulfate, Cobalt Sulfate, Zinc Sulfate, Manganese Sulfate, Molasses, Distillers Dried Solubles, D—Activated Plant Sterol (source of Vitamin D<sub>2</sub>)."

**ACCOMPANYING LABELING:** Pamphlets designated "Breeding Record Book" and leaflets designated "Are Your Cattle Being Held Back?" "Would you like to make hog production more profitable," and "You Asked For It."

**LIBELED:** 9-9-55, N. Dist. Ohio.

**CHARGE:** 502 (a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the *cattle mineral* was adequate and effective for treating and preventing bowel trouble, udder trouble, breeding and freshening problems, breeding disorders, rundown conditions, fall slump, calving problems, digestive disorders, and irregular heat periods, and that it would eliminate disease in general; that the *hog mineral* was an adequate and effective treatment for lameness, stiffness, and swollen joints, that it would make hogs stronger, healthier, and gain weight faster, and that it would produce more and stronger hogs at birth; and that the *stock tonic* was an adequate and effective treatment for stimulating the appetite, aiding digestion, increasing milk production, reducing breeding troubles, purifying the blood, providing better health and vigor, and providing healthier offspring.

**DISPOSITION:** 10-24-55. Default—destruction.

#### DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM\*

**4959. Physiological saline solution.** (F. D. C. No. 37091. S. No. 68-719 L.)

**QUANTITY:** 214 vials at Brooklyn, N. Y.

**SHIPPED:** 7-21-54, from Baltimore, Md., by Bio-Ramo Drug Co., Inc.

**LABEL IN PART:** (Vial) "100 cc. Single Dose Vial Physiological Saline Solution U. S. P. Sodium Chloride 0.9% W/V \* \* \* Caution Contains no preservative."

\*See also No. 4923.

**RESULTS OF INVESTIGATION:** Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

**LIBELED:** 9-16-54, E. Dist. N. Y.

**CHARGE:** 502 (g)—the article purported to be a drug, namely, "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" packaged in multiple-dose containers.

**DISPOSITION:** Bio-Ramo Drug Co., Inc., claimant, filed an answer on 11-17-54, denying that the article was misbranded. Thereafter, the Government served interrogatories upon the claimant which were answered. On 8-31-55, with the consent of the claimant, judgment of condemnation was entered and the product was ordered destroyed.

**4960. Water for injection.** (F. D. C. No. 37080. S. No. 77-171 L.)

**QUANTITY:** 700 vials at Philadelphia, Pa.

**SHIPPED:** 7-15-54, from Baltimore, Md., by Bio-Ramo Drug Co., Inc.

**LABEL IN PART:** (Vial) "100 cc. Single Dose Vial Water For Injection U. S. P. \* \* \* Manufactured by Bio-Ramo Drug Co., Inc. Baltimore 1, Md. Caution Contains no preservative."

**RESULTS OF INVESTIGATION:** Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

**LIBELED:** 10-1-54, E. Dist. Pa.

**CHARGE:** 502 (g)—the article purported to be a drug, namely, "Water for Injection," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Water for Injection" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Water for Injection" packaged in multiple-dose containers.