2410. Adulteration of physiological solution of sodium chloride and distilled water and adulteration and misbranding of Dolamin, Cal-G-Sol, and sodium salicylate and iodide with colchicine. U. S. v. Harvey Laboratories, Inc., and Aaron Lichtin. Pleas of nolo contendere. Fine of $3 against each defendant. (F. D. C. No. 24225. Sample Nos. 40298–H, 54292–H, 66147–H, 73688–H, 87641–H, 87643–H, 87646–H, 87647–H.)

INDICTMENT RETURNED: March 5, 1948, Eastern District of Pennsylvania, against Harvey Laboratories, Inc., Philadelphia, Pa., and Aaron Lichtin, treasurer of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 2 and April 11, 1947, from the State of Pennsylvania into the States of Florida, New Jersey, Ohio, and New York.

NATURE OF CHARGE: *Dolamin.* Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be of a purity and quality suitable and appropriate for parenteral use, whereas it was not of such purity and quality since it contained undissolved material. Misbranding, Section 502 (a), the label statement "For local and perineural infiltration" was false and misleading in that it represented and suggested that the article would be suitable and appropriate for parenteral use, whereas it would not be suitable and appropriate for such use since it contained undissolved material.

Physiological solution of sodium chloride. Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Solution of Sodium Chloride," a drug the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the official standard. The standard provides that unless specified for use other than parenteral use, the drug must conform to the requirements for injections prescribed in the Pharmacopoeia. The article was not specified for use other than parenteral use and it failed to meet the requirements for injections, since it was not substantially free of undissolved material; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label. Further adulteration, Section 501 (d) (2), phenol had been substituted in part for "Physiological Solution of Sodium Chloride," in that the specifications for physiological solution of sodium chloride, which are set forth in the United States Pharmacopoeia, do not provide for the inclusion of phenol, and the article contained phenol.

Distilled water. Adulteration, Section 501 (b), the article purported to be "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, but its quality and purity fell below the official standard since it contained undissolved material which could be detected readily when tested in accordance with the prescribed method; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on the label.

Sodium salicylate and iodide with colchicine. Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Salicylate and Iodide with Colchicine," a drug the name of which is recognized in the National Formulary, but its quality and purity fell below the official standard since it contained undissolved material that was readily discernible by the unaided eye when viewed in accordance with the prescribed method; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label. Misbranding, Section 502 (a), the label statement "For Intravenous Use" was false and misleading, in that the article was not suitable and appropriate for intravenous use since it contained undissolved material.

Cal-G-Sol. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be of a purity and quality suitable and appropriate for intravenous and intramuscular use, whereas it was not of such purity and quality since it contained undissolved material. Misbranding, Section 502 (a), the label statement "For Intravenous or Intramuscular use" was false and misleading.

DISPOSITION: June 22, 1948. Pleas of guilty having been entered, the court imposed a fine of $300 against each defendant.