

use in drugs in accordance with the regulations, and were other than ones from batches that had been certified in accordance with the regulations.

DISPOSITION: On December 8, 1948, pleas of guilty were entered on behalf of all defendants. On January 13, 1949, the court imposed a fine of \$600 against the corporation, and January 20, 1949, the court imposed fines of \$50 each against defendants Garber and Kaplan and \$20 against defendant Sherman.

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

2656. Action to enjoin and restrain the interstate shipment of isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, sodium ascorbate and dextrose injection, sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate, and sodium thiosulfate. U. S. v. Bristol Laboratories, Inc. Tried to the court. Case dismissed. (Inj. No. 198.)

COMPLAINT FILED: On or about September 25, 1948, Northern District of New York, against Bristol Laboratories, Inc., Syracuse, N. Y. The complaint alleged that the defendant had been and was then shipping in interstate commerce drugs which were adulterated and misbranded.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection* purported to be and were represented as drugs, the names of which are recognized in the United States Pharmacopoeia, and the *sodium iodide and sodium salicylate, sodium iodide and sodium salicylate with colchicine, sodium cacodylate, and sodium thiosulfate* purported to be and were represented as drugs, the names of which are recognized in the National Formulary; and the purity and quality of the drugs fell below the official standards therefor since they were not and had not been substantially free of undissolved material which could be detected readily without magnification when tested in accordance with the method prescribed by the standards; and the differences of the drugs in quality and purity from the standards were not plainly stated, or stated at all, on their labels.

Misbranding, Section 502 (a), the names of the drugs, *isotonic solution of sodium chloride, water for injection, epinephrine hydrochloride injection, aminophylline, and sodium ascorbate and dextrose injection*, and the statement "U. S. P." appearing in the labeling of a number of such drugs, were false and misleading since such names and statement represented and suggested that the drugs conformed to the specifications of the United States Pharmacopoeia, whereas they did not conform to such specifications.

PRAYER OF COMPLAINT: That a preliminary injunction issue, restraining the defendant from commission of the acts complained of; and that, after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: Pursuant to a motion filed on behalf of the defendant, the court on October 8, 1948, entered an order directing the Government to show cause why an order should not be made requiring it to answer the following interrogatories:

*See also No. 2654.