

# COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11977

| RECALL NUMBER | PRODUCT                                                  | LOT(S) | MFR. & RECALLER                                                                                                       | REASON                                                                                                                                            | TYPE      | CLASS | OTC or Rx |
|---------------|----------------------------------------------------------|--------|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------|-----------|
| D-386-4       | Nesacaine - CE 3% Inf.                                   | 1      | Pennwalt Corp. Pharmaceutical Div. Rochester, N.Y.                                                                    | Label carton mix up - Nesacaine CE 3% in cartons labeled Nesacaine CE 2%.                                                                         | Vol.      | II    | Rx        |
| D-387-4       | Solu-Medrol Injectable 40 mg.                            | 2      | Upjohn Co. Kalamazoo, Mich.                                                                                           | Vials of Solu-Medrol 40 mg. Vol. were packaged in cartons labeled as Solu-Cortef 100 mg. per 2 ml. The Vials of Solu-Medrol are properly labeled. | Vol.      | II    | Rx        |
| D-388-4       | Neut. Sodium BI-carbonate 4% Additive Solution           | 1      | Abbott Labs. N. Chicago, Ill.                                                                                         | An in-process control failure that does not provide assurance of the products' sterility.                                                         | Vol.      | II    | Rx        |
| D-390-4       | Digoxin 0.25 mg. Tablets                                 | 2      | Heather Drug Co., Inc. Cherry Hills, N.J.                                                                             | Product failed USP Dis-solution tests and require-ments set forth in the FR 1-22-74                                                               | FDA Init. | II    | Rx        |
| D-393-4       | Digoxin 0.25 mg. Tablets                                 | 1      | Davies Rose Hoyt Pharmaceutical Div. of The Kendall Co. Needham, Mass.                                                | Product failed USP Dis-solution tests and require-ments set forth in the FR 1-22-74                                                               | FDA Init. | II    | Rx        |
| D-394-4       | Panalgesic Aerosol in 6 oz. can.                         | 1      | Wm. P. Poythress & Co. Inc. Richmond, Va.                                                                             | Reports of leaking containers and 4 reports of exploding cans                                                                                     | Vol.      | II    | OTC       |
| D-395-4       | Bronkophrine HCL Injection 10 ml vials                   | All    | Winthrop Labs. Rensselaer, N.Y. dist. & recaller: Breen Labs Inc. Subsidiary of Sterling Drug Inc. New York, New York | Precipitation                                                                                                                                     | Vol.      | II    | Rx        |
| D-396-4       | Diethylstilbestrol Tablets, Enteric Coated 1 mg. & 5 mg. | 3      | ICN Pharmaceutical Inc. Cincinnati, Ohio                                                                              | Product fails USP Dis-integration tests                                                                                                           | Vol.      | II    | Rx        |
| D-397-4       | Sodium Salicylate Tablets USP 600 mg.                    | 12     | ICN Pharmaceutical Inc. Cincinnati, Ohio                                                                              | Product fails USP Dis-integration test.                                                                                                           | Vol.      | II    | OTC       |