

# COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11973

| RECALL NUMBER | PRODUCT                                                                                        | LOT(S) | MFR. & RECALLER                                                      | REASON                                                                                                                                                                                                                     | TYPE | CLASS | OTC or RX |
|---------------|------------------------------------------------------------------------------------------------|--------|----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------|-----------|
| D-313-4       | Lido-caine HCl.<br>Inj. USP 2% (100 mg in 5.0 ml) 2.0 mg per ml                                | 1      | Bristol Labs.<br>Div. of Bristol-Myers Co.<br>Syracuse, N.Y.         | Physical malfunctioning of units                                                                                                                                                                                           | Vol. | II    | Rx        |
| D-318-4       | Aminophylline 1 1/4 gr. with Phenobarbital 1/4 gr. E.C. tablets                                | 1      | Manhattan Drug Co.<br>Hillside, N.J.                                 | Failed USP XVIII Test for disintegration                                                                                                                                                                                   | Vol. | II    | Rx        |
| D-320-4       | Levo-Dromoran 2 mg Brand 4 of Levophanol Tartrate                                              | 4      | Roche Labs., Div. of Hoffman La Roche Inc.<br>Nutley, N.J.           | Label error - boxes of 10 Ampules Levo-Dromoran 2 mg. containing back panel ingredient, Dosage and storage information, which is actually meant for "Proctigamin Injection." Other panels, labels and inserts are correct. | Vol. | II    | Rx        |
| D-323-4       | Nitrofurantoin<br>Tablets 50 mg                                                                | 1      | Roche Labs. Inc.<br>Long Beach, Ca.                                  | Product exceeds the USP limit for dissolution                                                                                                                                                                              | Vol. | II    | Rx        |
| D-328-4       | Vaponefrin Meter-matic Aerosol Mist (Racemic epinephrine HCl) 15 cc Complete Units and refills | All    | USV Pharmaceutical Corp.<br>Tuckahoe, N.Y.                           | Delivers super potent dosage                                                                                                                                                                                               | Vol. | II    | OTC       |
| D-329-4       | Asthmafrin Aerosol Mist (Racemic epinephrine HCl) 15 & 30 cc complete Units & 15 cc refills    | All    | Mitchum Thayer Inc.<br>Tuckahoe, N.Y.                                | Delivers super potent dosage                                                                                                                                                                                               | Vol. | II    | OTC       |
| D-331-4       | Potassium Chloride 30 mg. 2 Injection                                                          | 2      | Invenox Pharmaceuticals<br>Div. of Mogul Corp.<br>Grand Island, N.Y. | Glass particles found in product                                                                                                                                                                                           | Vol. | II    | Rx        |
| D-332-4       | Potassium Chloride 60 mg. Injection                                                            | 2      | Invenox Pharmaceuticals<br>Grand Island, N.Y.                        | Glass particles found in product                                                                                                                                                                                           | Vol. | II    | Rx        |