

# 11984 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

| RECALL NUMBER | PRODUCT                                                                                                                                          | LOT(S) | MFR. & RECALLER                                                                                                         | REASON                                                                                                   | TYPE      | CLASS | OTC or Rx |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-----------|-------|-----------|
| D-107-5       | Methamphetamine Mandelate USP 0.25 gm. Tablets                                                                                                   | 4      | Richlyn Labs.<br>Philadelphia, Pa. (MFR)<br>Robinson Laboratory, Inc.<br>San Francisco, Ca. (RECALLER)                  | Questionable disintegration                                                                              | Vol.      | II    | Rx        |
| D-110-5       | Allopurinol 100 mg. Zyluprim Brand Tablets                                                                                                       | all    | Burroughs Wellcome Co.<br>Greenville, N.C. (MFR.)<br>Research Triangle Park, N.C. (RECALLER)                            | Properly labeled zyluprim bottles were found packed in 12 bottle Imuran Carriers. **                     | Vol.      | II    | Rx        |
| D-124-5       | Prefrin-2 Ophthalmic Solution 1/2 oz.                                                                                                            | 7      | Allergan Pharmaceutical<br>Irvine, Ca.                                                                                  | A number of Ophthalmic (Rx) 15 cc bottles have been erroneously packaged in Prefrin-2 (OTC) unit cartons | Vol.      | I     | OTC       |
| D-127-5       | Potassium Phosphate Inj.                                                                                                                         | 1      | Travenol Labs., Inc.<br>Hays, Kan. (MFR)<br>Travenol Labs., Inc.<br>Deerfield, Ill. (RECALLER)                          | Vials of potassium phosphate in individual vial cartons labeled potassium chloride                       | Vol.      | II    | Rx        |
| D-131-5       | Neocaine - CE 28 30 ml. single dose vials - Inj.                                                                                                 | 3      | Taylor Pharmaceutical Co.<br>Dedatur, Ill. (MFR)<br>Pennsalt Corp.<br>Pharmaceutical Div.<br>Rochester, N.Y. (RECALLER) | Discoloration                                                                                            | Vol.      | II    | Rx        |
| D-132-5       | Digoxin Tablets 0.25 mg.                                                                                                                         | 1      | American Pharmaceutical Co.<br>Bronx, N.Y. (MFR)<br>The Reymen Drug Co.<br>Baltimore, Md. (RECALLER)                    | Product failed USP Dissolution tests and requirements set forth in the FR 1/22/74                        | FDA Init. | II    | Rx        |
| D-133-5       | Promethazine HCl 25 mg/ml in 10 ml multiple dose vials injection. Also packaged under private labels: "Anergen 25"; "Promex 25"; "Phenerject 25" | 3      | The Central Pharmaceutical Co.<br>Seymour, Ind.                                                                         | Crystallization                                                                                          | Vol.      | II    | Rx        |
| D-134-5       | Chlorpheniramine Oronasal 1000 Tablet bottles                                                                                                    | 1      | J. W. S. Delavan Co., Inc.<br>Philadelphia, Pa.                                                                         | Misbranded - contains undeclared antacid                                                                 | Vol.      | II    | OTC       |

\*\* The labels on the bottles of the two products are correct and the products themselves were not recalled. Corrective action involved a check of the cardboard carrier to assure that it is consistent with the bottle labels.