

## 11974 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

| RECALL<br>NUMBER | PRODUCT                                                                                       | LOT(S) | MFR. & RECALLER                                                        | REASON                                                                                                                              | TYPE      | CLASS | OTC<br>or<br>RX |
|------------------|-----------------------------------------------------------------------------------------------|--------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------|-------|-----------------|
| D-333-4          | Lidocaine HCl.<br>Injection USP<br>1% 30 ml                                                   | 4      | Invenex Pharmaceuticals<br>v Div. of Mogul Corp.<br>Grand Island, N.Y. | Glass particles found in<br>product                                                                                                 | Vol.      | II    | Rx              |
| D-334-4          | Lidocaine HCl.<br>Injection USP<br>2% 30 ml.                                                  | 2      | Same as above                                                          | Glass particles found<br>in product                                                                                                 | Vol.      | II    | Rx              |
| D-335-4          | Procaine HCl<br>Injection USP<br>2% 30 ml.                                                    | 1      | Same as above                                                          | Glass particles found<br>in product                                                                                                 | Vol.      | II    | Rx              |
| D-336-4          | Digoxin Tablets<br>USP .25 mg.                                                                | 1      | Premo Pharmaceuticals<br>South Hackensack, N.J.                        | Product failed USP<br>dissolution test and<br>FR 1-22-74                                                                            | FDA Init. | II    | Rx              |
| D-338-4          | Pitocin (oxytocin<br>Injection U.S.P.)<br>Synthetic 10 units<br>per ml steri-dose<br>Syringes | 1      | Parke Davis & Co.<br>Detroit, Mich.                                    | Some inserts for tetanus<br>Toxid were in error.<br>Placed in packages labeled<br>as and containing pitocin<br>disposable syringes. | Vol.      | II    | Rx              |
| D-339-4          | Digoxin Tablets                                                                               | 1      | Heather Drug Co.<br>Cherry Hill, N.J.                                  | Product failed USP Dis-<br>solution Test<br>FR 1-22-74                                                                              | FDA Init. | II    | Rx              |
| D-345-4          | Digoxin Tablets<br>USP 0.25 mg                                                                | 1      | Barr Labs.<br>Northvale, N.J.                                          | Product failed USP Dis-<br>solution test and FR<br>1-22-74                                                                          | FDA Init. | II    | Rx              |
| D-349-4          | Digoxin Tablets<br>USP 0.25 mg.                                                               | 2      | Stanlabs Inc.<br>Portland, Ore.                                        | Product failed USP Dis-<br>solution test and FR<br>1-22-74                                                                          | FDA Init. | II    | Rx              |
| D-346-4          | Digoxin Tablets<br>USP 0.25 mg.                                                               | 1      | Marshall Pharmacal Corp.<br>South Hackensack, N.J.                     | Product failed USP dis-<br>solution test and FR<br>1-22-74                                                                          | FDA INIT. | II    | Rx              |