

11976 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

RECALL NUMBER	PRODUCT	LOT(S)	REF. # RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-358-4	Milk of Magnesia Tablets, Bottles of 100 & 250	2	L. Perrigo Co., Allegan, Michigan	Aspirin Tablets in bottles labeled as Milk of Magnesia Tablets	Vol.	II	OTC
D-359-4	OTC Decongestant Nasal Spray in 1/2 oz. plastic squeeze spray bottles	2	L. Perrigo Co., Allegan, Michigan	Excess Sodium Bisulfite	Vol.	II	OTC
D-365-4	Digoxin 0.25 mg. tablets 100's & 1000's	2	Towne Paulsen & Co. Montevia, Ca.	Product failed USP Dissolution test and requirements set forth in the FR dated 1-22-74	FDA Init.	II	Rx
D-366-4	Promethazine Hydrochloride USP 12.5 mg. Tablets	1	Danbury Pharmaceutical Danbury, Conn. dist: Spencer Mead Valley Stream, N.Y.	Promethazine HCl. 50 mg. lot 6516 mislabeled as 12.5 mg. Promethazine HCl.	Vol.	I	Rx
D-367-4	Digoxin Tablets USP 0.25 mg.	1	Barr Labs Northvale, N.J.	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-368-4	Digoxin Tablets 0.25 mg.	1	Heather Drug Co. Cherry Hill, N.J.	Product failed USP Dissolution test and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx
D-372-4	Pitocin (oxytocin inj.) Synthetic 10 units per ml in packages of ten 1 ml Steri-Dose Syringes	2	Parke Davis & Co. Detroit, Michigan	One or more unit dose syringes labeled as Fluogen	Vol.	I	Rx
D-374-4	Aminophylline 1 1/2 gr. E.C. Tablets 1000's	1	Manhattan Drug Co., Inc. Hillside, N.J.	Failed disintegration requirements	Vol.	II	Rx
D-383-4	Hemodialysis Concentrate	3	Mallinckrodt Chemical Works St. Louis, Mo.	Misprint in labeling re Chloride and sodium Content	Vol.	II	Rx
D-384-4	Digoxin Tablets 0.25 mg.	2	Phillips Roxane Labs. Inc. Columbus, Ohio	Product failed USP Dissolution tests and requirements set forth in the FR 1-22-74	FDA Init.	II	Rx