

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 11975

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLED	REASON	TYPE	CLASS	OTC or Rx
D-348-4	Ampicillin Trihydrate 250 mg/5 ml	1	International Labs Inc. Mayaguez, P.R.	Label mix up - shipping containers & inner containers were labeled QID Ampicillin 125 mg/5 ml instead of QID Ampicillin 250 mg/5 ml.	Vol.	II	Rx
D-349-4	Ned-lytane Cream 1% (Neomycin-Hydrocortisone)	1	Dermik Labs, Inc. Syosset, N.Y.	Label error - The product is Neo-lytane Cream labeled Hydrotone Cream. The label only is mislabeled. The unit carton tube is properly labeled, as is the insert information printed on the inside of the unit carton.	Vol.	II	Rx
D-350-4	Digoxin Tablets 0.25 mg.	1	Blue Line Chemical Co. St. Louis, Mo.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-351-4	Digoxin Tablets	All	Kasco Efcu Labs, Inc. Hicksville, N.Y. recaller: E. Fougere & Co. Inc. Hicksville, N.Y.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-352-4	Lidocaine HCl. Injection 2% 100 mg in 5 ml (20.0 mg. per ml) in automated disposable syringe System units	1	Bristol Labs., Div. Bristol-Myers Co. Syracuse, N.Y.	Label error - two or more sealed unit dose packages contain an inner label insert for "Sodium Bicarbonate Injection USP 7.5%"	Vol.	I	Rx
D-353-4	Digoxin 0.25 mg. tablets	1	ReWall Drug Co. St. Louis, Mo.	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-356-4	Digoxin Tablets 0.25 mg.	1	Parke Davis & Co. Detroit, Michigan	Product failed USP Dissolution test and FR 1-22-74	FDA Init.	II	Rx
D-357-4	Cortisone Acetate Tablets 25 mg, 100's, 500s & 1000s. Also in bulk cartons 15,000s and 25,000	1	Pantry Div., Ormont Drug & Chemical Co. Englewood, N.J.	Cortisone Acetate tablets mixed w/an OTC anti-asthmatic drug.	Vol.	I	Rx