

11982 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

FISCAL YEAR 1975 (TO DATE)

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC 3/ or Rx 4/
D-002-5	Megardine HCl Inj. 25 mg/ml	1	Krohl Pharmaceutical Co. Whitpany, N.J.	Cartons labeled Megardine HCl 100 mg/ml which contained ampules correctly labeled as Megardine HCl 25 mg/ml.	Vol. 1/	II	Rx
D-004-5	Digoxin Tablets 0.25 mg.	1	The Lannett Co., Inc. Philadelphia, Pa.	Product failed USP Dissolution test and requirements set forth in the FR Announcement 1/22/74	FDA 2/ Init.	II	Rx
D-008-5	Debratol 18" Sutures USP - Code 6-915	1	Debnabel Inc. Queens Village, N.Y.	Non-sterile	Vol.	II	Rx
P-010-5	Lidocaine HCl Inj. USP 1/2%, 30 ml.	1	Invenex Pharmaceuticals Div. of Mogul Corp. Grand Island, N.Y.	Glass particles found in product	Vol.	II	Rx
D-011-5	Gentamycin 10 mcg. No. 822E 100 Sensitivity Disks	1	Pfizer Diagnostic Div. Haywood, N.J. (MFR) Pfizer Diagnostic Div. New York, N.Y. (RECALLER)	Mislabeled - Gentamycin susceptibility Disks - contain some disks which are labeled as streptomycin	Vol.	II	Rx
X-012-5	Vitamin B-12 (Cyanobalamin USP) 50 mcgms Tablets	1	Banner Gelatin Products Corp. Chatsworth, Ca. (MFR) Indianapolis Pharmaceutical Co. Indianapolis, Ind. (RECALLER)	Mislabeled - two bottles containing Vitamin B, lot 37406 were mislabeled as Vitamin B-12 tablets 50 mcgm.	Vol.	II	OTC
X-013-5	Prompar Tablets 100 mg (Chlorpromazine HCl)	1	Bulk Tablets - Cord Labs. Detroit, Mich. Blister Packaging - Sautex/ Sparks, Inc. Harleysville, Pa. Parke Davis & Co. Detroit, Mich. (RECALLER & DIST.)	Label mix-up - 100 mg. tablets labeled as 50 mg. tablets	Vol.	II	Rx

1/ Voluntary

2/ FDA Initiated

3/ Over-the-Counter Drug

4/ Prescription Drug