

11986 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

RECALL NUMBER	PRODUCT	LOT(S)	MFR. & RECALLER	REASON	TYPE	CLASS	OTC or Rx
D-148-5	Kelevin Tetracine 250 mg. Capsules	1	ICN Pharmaceuticals Cincinnati, Ohio (MFR) Kessel Labs. Hialeah, Fla. (REPACKER) Kelvin Pharmaceutical, Inc. Miami, Fla. (RECALLER)	The capsules were repacked without re-certification	Vol.	II	Rx
D-150-5	Diphenhydramine HCl Capsules 25 mg. Antihistamine	1	J. W. S. Delavan Co. Philadelphia, Pa.	Product failed USP XVIII content uniformity requirements	Vol.	II	Rx
D-151-5	Digoxin Tablets 0.25 mg.	1	Lederle Labs. Div. American Cyanamid Co. Pearl River, N.Y.	unit dose blister pack labeled xxx Digoxin tablet 0.25 mg. xxx & actually contain 2 tablets totaling 0.50 mg. in some units	Vol.	II	Rx
D-156-5	Phenobarbital elixir 20 mg/5 ml.	2	Abbott Labs. N. Chicago, Ill.	Over fill of unit dose containers	Vol.	II	Rx
D-157-5	Phenobarbital elixir 15 mg/3.75 ml.	1	Abbott Labs. N. Chicago, Ill.	Over fill of unit dose containers	Vol.	II	Rx
D-164-5	Progesterone in glass vials	1	Medvick Labs., Inc. Melrose Park, Ill.	Clumping of suspension	Vol.	II	Rx
D-165-5	Sodium Salicylate tablets 100's & 1000's	3	Kirkman Labs., Inc. Portland, Ore.	Product failed to meet USP disintegration requirements for enteric coated tablets	Vol.	II	OTC
D-170-5	Digitoxin "Purodigin" 0.05 mg. tablets	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-171-5	Digitoxin "Purodigin" 0.1 mg. tablets	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-172-5	Digitoxin "Purodigin" 0.15 mg.	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx
D-173-5	Digitoxin "Purodigin" 0.2 mg.	all	Wyeth Labs. Philadelphia, Pa.	Error in dosage statement in package insert **	Vol.	I	Rx

** Letters were sent to all pharmacists and wholesalers with replacement inserts with replacement inserts on November 21, 1974. The letters called attention to the fact that the insert contained an incorrect digitalizing dose for infants. The notification was provided to all segments of the profession who would be in a position to initiate any corrective action. The product itself is not being recalled.