

10026 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

COMPANY NAME STATE	MAILED TO INSPECTION DATE FDA, VA, PHS	DESCRIPTION OF VIOLATION
Kentuckiana Pharmaceuticals Inc. Louisville, KY	September 1973 October 1973	No written operating or inspection procedures. Insecticide, Sodium Fluoride, is packaged in the center of a large room used to store chemicals used in formulations. Metal scoops in ready-for-use racks had residue material from previous batches. Stainless steel tanks had residue of previously manufactured liquid material. Two of the tanks had odoriferous mold growth in the liquid. Master Formula for the proposed production batch of Lanolated Mineral Oil not available. Control of labels and labeling not established.
Solar Laboratories Brooklyn, NY	December 1973	Written procedures not available for production, quality control, laboratory, calibration, maintenance and sanitation. The low velocity exhaust system in hood area permits residue to fall on the work area in the hood. The hood exhaust system and balances in the hood area contained residue of previous operation.
Mallinckrodt Chemical Works St. Louis, MO	November 1973 December 1973	Cobwebs and dust was noted in the synthesis plant on a large number of drums of raw material. A fly was noted in the area where Meclizine Hydrochloride Powder was being transferred, after centrifuging, into plastic bags.
Pfizer Pharmaceuticals Barcloneta, PR	December 1973	The three different shifts in the plant use differing Systems of lot identification for the same product. As a result the integrity of the lot numbering system could not be satisfactorily explained by the company.