

10020 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

FIRM NAME CITY AND STATE	RECEIVED DATE	MAILED TO FDA, WASH. D.C.	DESCRIPTION OF VIOLATION
White Cross Pharmaceutical Company Detroit, Mich.	February 1972	February 1972	The firm has no full time Quality Control Director. A pharmacist who owns a retail drugstore would be called in. This pharmacist was not in the plant at the time of the survey. The firm used Urea. Manufactured by Marck & Company, Lot 51432, in their formulation of the Vaginal Cream. This lot of material is 21 years old. The United States Pharmacopoeia XIV was then in effect. Tests in the melting range and lack of assay requirements differ from the requirements of the current United States Pharmacopoeia XVIII. The firm has no program of retesting material in stock. No Master-Formula or Batch-Production Record was available for the bid item, Sulfacetamide, Sulfahenamide, Sulfathiazole and Urea Vaginal Cream. The firm had an inadequate lot control numbering system. Finished material (Hydrocortisone Cream and Sulfathiazole Cream) had no lot numbers. A bag of "Sulfathiazole", lot ST53330, which is a component in the bid item, Vaginal Cream, was found in the same container with a bag of "Salicylic Acid".
Solar Pharmaceutical Corp.	February 1972	February 1972	There was a lack of efficient exhaust system in their tablet compression area. At time of visit, the firm was compressing Vitamin B 12, Lot 012909. The entire area was heavily laden with the pink powder. Hardly a wall, equipment or container did not have a heavy layer of pink powder on it. Halls, floors and overhead pipes in the quarantining location (where hold material is sampled) were dusty and dirty. The firm's policy is to assign only one lot number to incoming raw materials, no matter how many different lots of the same item they received at the same time. An example was: Solar's Ascorbic Acid, lot 5037 was composed of supplier's lots F2325, F2975, and F2937.