

10536 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Date	Conditions found	FDA action
Nov. 1967	Seven deviations from GMPs including the following four critical deviations: --No assay of raw materials. --No controls over labelling. --No manufacturing records other than master formula. --Lot numbers not assigned to batches. Also, firm did not clean bottles or caps used in packaging and did not have equipment to clean them.	Deviations discussed with representative of firm. Reinspection was scheduled for March 1968.
Mar. 1968	Inspection revealed no changes in firm's operations; owner made no effort to comply with previous inspector's oral recommendations. Eight deviations from GMPs were identified, including the following four critical deviations: --No assay of raw materials. --No working formulas. --No manufacturing records. --No label controls.	No listing of inspectional observations was issued. Post inspection letter issued 40 days after inspection. Letter did not cite any violation of the FD&C Act. No response was requested or received. Reinspection was scheduled for October 1968, but was not made until September 1969.
Sept. 1969	No improvements in manufacturing practices. Six deviations noted, two critical: --No assay of raw materials or finished products. --No manufacturing records. Also, failure to adequately clean packaging and labeling equipment.	A list of inspectional observations was issued. Post inspection letter was issued 22 days after the inspection. Response was requested but not received. Reinspection was scheduled for March 1970 but not made until June 1971.
June 1971	Firm was not registered as required by the act. Thirteen violations of GMPs were identified, five critical: --No master production and control records. --No batch production and control records. --No laboratory control. --No stability testing of finished product. --Lot distribution could not be readily determined.	A list of inspectional observations was provided. No post inspection letter was issued. Reinspection was to be scheduled, but no further action was taken as of December 31, 1971.