4. Failure to maintain and/or follow written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to posses and to assure that such procedures, including any changes, are drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by quality control [21 CFR 211.100]. For example:

c) The Quality Assurance procedure entitled "The Discrepancy Event Reporting (DER) System" is inadequate in that the procedure provides no timeframes for the completion and closure of corrective actions.

Bayer recognizes the importance of promptly completing and closing corrective actions that result from a Discrepancy Event Report (DER) related to a product lot. As a result, Bayer will revise Clayton Standard Operating Procedure CQAP 637, "Requirements for Performing Investigations of Failures and/or Discrepancies," and Berkeley Standard Operating Procedure **[insert number and name]**. The revised procedures will require that all corrective actions associated with a DER that was issued for a product deviation must be closed within 30 days of issuance of the DER. All other corrective actions will be tracked and monitored in a quarterly review by the directors of Quality Control, Quality Assurance, Operations, and Engineering. These procedures will be revised and implemented, and training will be completed, by the third quarter of 2001.