**b) Investigations into container integrity defects for finished product glassware lots CY243-1 and CY245-1 were limited to Prolastin lot 601W027 and failed to address other finished product lots which may have used the implicated lots of glassware.**

Bayer agrees that it is important to inspect all lots that may be impacted by a particular lot failure. Although in its investigation Bayer inspected all lots associated with the failure of the glass used for Prolastin lot 601W027, it did not include that data in the file for its Nonconforming Material Report. Bayer was able to provide this data to the inspector during the FDA inspection. As a result of the inspection, Bayer has now clarified its recordkeeping procedures to ensure that all relevant data is included in Nonconforming Material Reports and Discrepancy Event Reports and has trained its personnel accordingly.

At the time the defect in the glassware used for Prolastin lot 601W027 was discovered, Standard Practice AB-000-SP-026, "Discrepancy Management," and Clayton Standard Operating Procedure CQAP 637, "Requirements for Performing Investigation of Failures and/or Discrepancies," required Bayer to inspect all finished product lots using glass from the vial lots used for the lot in question. In particular, Clayton Standard Operating Procedure CQAP 637 required investigations to identify and evaluate impact on additional lots of the same product type, other products or product lines, and/or systems impacted by the discrepant event. A review of the data from the packaging inspection record showed that glass from lots CY 243-1 and CY 245-1 was used for 21 finished product lots. With the exception of Prolastin lot 601W027, the remaining 20 lots passed the inspection criteria for cracks contained in Clayton Batch Production Record X.V.L. 70, "Plasma Packaging Line Inspection Data Recording." Standard Practice AB-000-SP-026 and Clayton Standard Operating Procedure CQAP 637 also required Bayer to record the results of its review in the investigation file. However, these procedures did not clearly require Bayer to include in the file all of the underlying data examined during the review. To ensure that the underlying data is kept in the file, Bayer revised Clayton Standard Operating Procedure CQAP 637 on June 18, 2001 to require that all data evaluated during the course of an inspection be included in the report file. In addition, Discrepancy Event Investigators have been trained in the importance of including all documentation associated with an investigation in the discrepancy event file. Verification of the effectiveness of this corrective action will be included in the internal audit plan for the Discrepancy Event Reporting System.