3. **Failure to ensure that reprocessed batches of product will conform with all established standards, specifications, and characteristics [21 CFR 211.115(a)] in that there were no written procedures and validation data that support the reprocessing and reworking of Albumin for both proteinaceous material (PM) and potential glass fragments.**

System Requirements

In response to the FDA's recent inspections in Clayton, Bayer has revised its procedures to state that it will only reprocess or rework product using validated procedures which have been approved in the product license. Bayer will send appropriate supplements or notifications to CBER if Bayer identifies further need to reprocess or rework product. The following procedures were revised as part of the improvements to the reprocessing and reworking procedures:

Site	Procedure #/Title	Revision	Effective Date

Actions Taken As a Result of Recent Inspections

Bayer Clayton Standard Operating Procedure XX.P.10, "Bayer Rework/Reprocessing Policy," approved September 25, 2000, establishes responsbility for reprocessing and reworking product. In particular, Regulatory Affairs is responsible for defining eligibility for reprocessing and reworking; Manufacturing is responsible for reprocessing and reworking product in accordance with approved procedures; and Quality Assurance is responsible for accepting and releasing product that has been reworked or reprocessed.

Standard Operating Procedure XX.P.10 also sets the conditions under which Bayer may release reprocessed or reworked product. Quality Assurance may only release such product under the following conditions: 1) Bayer must have validated the reprocessing or reworking procedure as a remedy for the specific defect for which the lot was reprocessed or reworked, and that validation must have been approved by FDA as a supplement to the product license, and 2) the FDA must have approved release of the reprocessed or reworked lot based on review of documentation submitted as a one-time exemption from the license. This revision, therefore, requires that written procedures and validation data support the reprocessing and reworking of product produced at Clayton, including Albumin.

In the future, Bayer will submit a license supplement for review and approval prior to releasing lots that have been reprocessed or reworked under a procedure that FDA has not approved as a remedy for the specific defect for which the lot was reprocessed or reworked.