IR-4 Advisory #2003-01

Title: **Responding to FDB QA Findings**

Issue/ Question: How should you respond to a field data book (FDB) QA finding that requires correction to the raw data or a lengthy, detailed explanation of how you did something?

Background: First and foremost, remember: QA audits and your responses to findings cannot be viewed by EPA without a subpoena. Therefore, if your response to a particular finding requires additional or corrected raw data, or provides extensive additional data or explanations that are important for a reviewer to understand how you conducted the trial, this raw data and/or information must go into the FDB. If you simply enter the additional or corrected raw data or lengthy response directly on pages of the audit, someone (usually the Study Director) must recapture this information in the appropriate part of the FDB.

Resolution: If you face this situation when responding to an audit finding, you should comment on the QA audit form that you entered the response (data or explanation) in the FDB in one of several ways:

1) WHEN THE ORIGINAL FDB IS STILL IN YOUR POSSESSION:
   - By making corrections or additions directly on the original FDB page(s) where the additional data or explanation applies;
   - By adding an entry in FDB Part 3 (Notes and Communication – always a good "catch-all" place), either as an additional entry or as a separate page;
   - By capturing additional data/explanation on a separate piece of paper as a "Memo to the FDB," and inserting it into the FDB where it applies.

2) WHEN THE ORIGINAL FDB IS NO LONGER IN YOUR POSSESSION:
   - By making corrections or additions on a copy of the FDB page(s) from your certified copy of the FDB;
   - By providing a separate page (with corrections, additions, explanations) for insertion in either Part 3, or to the section of the FDB where it applies, or as a "Memo to the FDB."

In both 1) and 2) above, the corrected or additional page(s) become part of the original raw data. Additional pages must be identified with the trial#, and be initialed and dated. For 2) above, attach the corrected/additional page(s) to the QA audit (for the SD to include in the raw data), and insert a copy in your certified copy of the FDB.

(This advisory is an expansion of Item 4 in the San Antonio Results Document, dated 9/27/02.)

If you have any questions, please contact your Regional/ARS Field Coordinator or the appropriate QA auditor/Study Director for further guidance.