



November 7, 2011

On Thursday, November 3, 2011, the Food and Drug Administration (FDA) held a meeting with Cetero Research regarding the Cetero – Houston bioanalytical matter. I am pleased to announce that the FDA has accepted Cetero’s proposal to verify the integrity of data it collected from March 1, 2008, to August 31, 2009. **This action reduces the FDA’s original timeline of the period in question by more than two years.** The decision represents what we expect to be the FDA’s final position concerning the Cetero – Houston matter.

As stated through prior updates, Cetero continues to work closely with the Agency to resolve questions about the validity of data generated in our Houston bioanalytical facility narrowing the range of studies requiring rework. Through detailed analysis, deliberation and collaboration, we have taken action that we believe is in the best interest of our clients and, ultimately, the patients who rely on your safe and effective medicines. The resulting actions are summarized below.

- A revised, shortened timeline was agreed upon for which repeat studies or reanalysis would be required. The original timeline spanned from April 1, 2005, to June 15, 2010. Rework will now be required for relevant studies conducted from **April 1, 2005, to February 28, 2008**, following the FDA’s acceptance of the accuracy of Cetero’s electronic recordkeeping system, audit trail and redundancy procedures implemented in February 2008. Cetero is deemed compliant by FDA to conduct this rework on any sponsor’s behalf.
- As previously announced on October 26, 2011, the FDA indicated that data generated at Cetero – Houston from September 1, 2009, through June 15, 2010, is acceptable for regulatory submission and/or review. No further rework or audit is required for the FDA to accept data generated for these studies.
- The Agency confirmed that it will accept paper audits of electronic records conducted by independent auditors retained by sponsors, or by Cetero, for studies conducted from March 1, 2008, through August 31, 2009. No rework, other than the audit documentation, is required unless irregularities are detected in these audits, which is not anticipated. Sponsors will be allowed to submit third-party audits using auditors hired by Cetero.

The FDA agreed to confirm the timeline provided above through a formal acknowledgement on its website at <http://www.fda.gov/Drugs/DrugSafety/ucm265559.htm>, and through emails sent to sponsors requesting agency news from fda@service.govdelivery.com. Importantly, the Agency also reiterated that **any Cetero site** is suitable to perform rework as required.

From incident discovery through our internal investigation to the FDA evaluation, Cetero has taken this matter very seriously and is satisfied with the final outcome. State-of-the-art systems have been established to the satisfaction of FDA and Cetero that verify the integrity of study data.

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