



October 18, 2011

On Thursday, October 13, Cetero Research held its third meeting in as many months with the FDA regarding the Cetero-Houston bioanalytical matter. We remain very encouraged by their willingness to work with us to reach a practical solution to this matter. The tone of the recent meeting remained collaborative and consistent with that of the September 22, 2011 meeting.

Cetero has been working closely with the Agency to positively resolve questions about the validity of data generated in our Houston bioanalytical facility with the identification of studies potentially requiring re-work. Through detailed analysis, deliberation, and collaboration, we are making solid progress that we believe is ultimately in the best interests of our clients and, importantly, those patients that rely upon the safe and effective medicines which you produce.

I am pleased to provide you with our latest update:

- The original timeline concerning data validity spanned April 1, 2005 to June 15, 2010. The FDA has now indicated that data generated in Cetero-Houston from September 1, 2009 through June 15, 2010 is immediately acceptable for regulatory submission and/or review. No further work or audit is required for the FDA to accept data generated for these studies.
- The FDA has publicly acknowledged this decision on its website (www.fda.gov/Drugs/DrugSafety/ucm265559.htm).
- The FDA will further evaluate the feasibility and structure of a paper-audit program covering the time period between March 1, 2008 and August 31, 2009. This strongly indicates that data generated during this time may be deemed rehabilitated, following Agency acceptance of Cetero's quality assurance procedures to ensure data validity. External consultants will be utilized for this activity.
- Cetero will consider reanalyzing or re-dosing all definitive studies submitted to the FDA as identified by clients as needing rework from April 1, 2005 – March 1, 2008.
- The FDA will further evaluate Cetero's request for a timeline extension of repeat work, following receipt of a timeline for identified studies needing re-work, reflecting the time period modification stated above. We will share with FDA the proposed timeframe required for the necessary re-work through re-dosing or re-analysis, along with the timeframe for those studies that will be re-evaluated through the proposed audit evaluation proposal. We are optimistic that the Agency will continue to work collaboratively with us to accommodate the needed time to achieve these objectives.

From incident discovery through our internal investigation to the FDA evaluation, Cetero has taken this matter very seriously and is satisfied with our current position and possible ultimate outcome. We are in the process of providing additional supportive data and will continue to update you as the matter comes to a close.

For more information, please contact:

April Johnson
Vice President, Business Relationship Management
Cetero Research
Direct Line: 919-468-4214
Email: april.johnson@cetero.com

Troy W. McCall, Ph.D.
Chief Executive Officer
Cetero Research
Direct Line: 919-674-0280
Email: troy.mccall@cetero.com