



August 15, 2011

Below is a summary update of Cetero Research's meeting with the U.S. Food and Drug Administration (FDA) on August 12, 2011.

We were pleased that the FDA agreed to meet with us to discuss the serious allegations described in their July 26 posting on the Agency's web site. Our meeting on Friday was the first opportunity to meet with the FDA face-to-face to discuss resolution of the issues at our bioanalytical facility located in Houston, TX. It was conducted in a spirit of cooperation and collaboration.

At the meeting, Cetero presented a practical proposal for systematically verifying the integrity of the studies analyzed during the period in question (April 2005 – June 2010). The approach, if accepted by the Agency, is designed to both ensure the safety of the American public as well as provide a more rapid resolution to this important matter. The FDA attendees agreed to evaluate our proposal and told us they will review it in detail over the next few weeks.

Notably as a first step, the FDA said they will re-inspect the Cetero-Houston facility as soon as possible. Cetero's management told the Agency that we believe the facility is ready for this inspection, as we have implemented a comprehensive corrective and preventive action (CAPA) plan to address the deficiencies cited during two previous inspections in May and December 2010.

Further, FDA said that, pending their re-inspection and certification, Cetero-Houston will be an acceptable option for re-testing that our clients are required to initiate at this point. Moreover, the FDA was also clear that Cetero's other sites are adequate and appropriate to perform any required re-analysis or re-dosing of previous studies.

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