



Cetero Research Responds to FDA Untitled Letter

Cary, NC (July 27, 2011) - Cetero Research, the leading provider of early phase research services, remains fully committed to maintaining the quality and integrity of the data collected in each of its facilities, including the Houston, TX, bioanalytical laboratory. It is this commitment that makes the broad action announced publicly by FDA on July 26, 2011, even more difficult to understand.

Cetero initiated its own internal investigation of its Houston bioanalytical laboratory over two years ago when it discovered the recording of inaccurate day/time data by a small number of research chemists in its Houston facility. Cetero proactively contacted the FDA to self-report its preliminary findings, as well as seek agency feedback on its comprehensive investigation plan. At that time, Cetero clients were also contacted to make them aware of the situation. The Untitled Letter does not accept the results of our rigorous scientific analysis and discredits the Company's 1,200 dedicated and experienced employees. The research conducted on behalf of our pharmaceutical sponsors can be, and has been, properly validated.

The FDA said in its public announcement: ***"It is unlikely that these concerns relating to data integrity affect the overall safety and efficacy of drugs already on the market and, at this time, there is no evidence of problems with the safety, quality, purity or potency of drugs already approved."*** Thus, the FDA has not questioned the safety or efficacy of drugs already approved, marketed, and based on data generated from Cetero's Houston bioanalytical laboratory.

We are pleased that we will now have the opportunity for the first time since our voluntary disclosure was filed in June 2009 to meet with FDA decision-makers to seek to resolve this matter in an appropriate manner. Cetero will continue to cooperate fully with FDA and with our clients and support them through this confusing process.

Background:

Cetero initiated an internal investigation over two years ago. It contacted the FDA to self-report its preliminary findings that six chemists in its Houston facility had misreported the date that samples were extracted prior to analysis. The chemists did this to seek additional compensation through weekend pay and pay for hours when they did not actually work. At the time the findings were initially reported to the FDA, Cetero also provided its proposed investigation plan seeking input to ensure a thorough and robust investigation. In an attempt

to remain fully transparent and forthcoming, the company disclosed all material facts to the Agency in 2009 and requested feedback from the FDA on the nature and scope of its investigation plan. Over the course of an 18-month investigation, FDA has not responded and remained silent to its content and all monthly status reports.

FDA inspected the Houston facility itself in May and December 2010. As expected, Form 483's, notices of observations, were issued as a result of the above findings which had been self-reported in June 2009. Responses were submitted to the Agency in a timely fashion, with no response until the public announcement to the press and on its safety website immediately upon receipt of an Untitled Letter on July 26, 2011, despite numerous follow up requests for resolution with the FDA.

What is most important is that the processes being used today at Cetero are state-of-the-art. They are in full compliance with FDA regulations and bioanalytical industry standards. We intend to continue to work closely with FDA and our clients, and request the same in return, as we work to successfully resolve the issues raised by the FDA.

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