

**Cerulean Attends FDA Enforcement Conference in  
Washington, D.C. – Summary Report Available**Cerulean Associates LLC  
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FOR IMMEDIATE RELEASE

February 26, 2008 – Williamsburg, Va. – Cerulean’s Managing Director, John Avellanet, attended the joint FDA/FDLI conference on FDA enforcement trends this past week in Washington, D.C.

“Given that I guarantee all my clients help with their next FDA audit, it only makes sense to attend these types of conferences and then give my clients a report of the latest FDA expectations,” said Mr. Avellanet.

Mr. Avellanet attended presentations and panel discussions by FDA compliance directors and Department of Justice officials on recent FDA enforcement trends, what FDA inspectors are currently looking for both before and during pharmaceutical, medical device, food and biotechnology company inspections, and recommendations on structuring compliance programs.

Key takeaways from the conference included:

- FDA enforcement increases have been planned and budgeted for through 2009
- Executive liability, especially for corporate officers and board members, is increasing
- Postmarket surveillance is translating into a stronger FDA interest in whistleblower allegations and healthcare provider complaints.

“I’ve compiled a summary report and analysis,” added Mr. Avellanet, “and made it available through our website.”

The full report is available online at the Cerulean website: <http://www.ceruleanllc.com/reports>. Mr. Avellanet’s 17-page report summarizes the specific details and goals of each recommendation from FDA officials, speakers and panel discussions.

**Cerulean Associates LLC** is a small, private consulting company that helps executives achieve cost-effective regulatory compliance, quality by design, intellectual property security, and faster time to market. On the web at [www.ceruleanllc.com](http://www.ceruleanllc.com).

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