

WilmerHale Seminar: Examining New FDA Reporting Requirements

2008-09-25

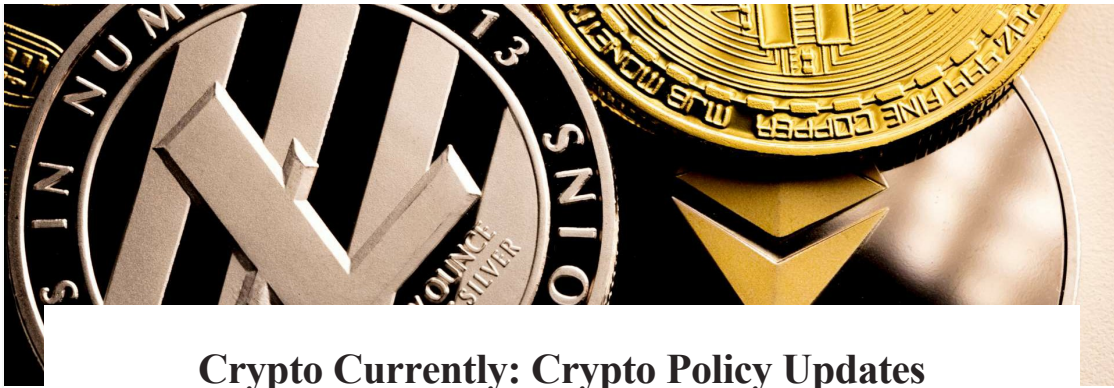
Please join us for a breakfast briefing to discuss new legal requirements imposed by the Food and Drug Administration Amendments Act of 2007 (FDAAA) for reporting clinical trial results to a public databank. These new requirements will go into effect on September 27, 2008, and entail significant penalties for non-compliance. Our discussion will be led by WilmerHale partner Scott Lassman and Robert A. Morgan, MS, JD, Senior Vice President, Regulatory Affairs & Quality/Clinical Development at Ziopharm Oncology, Inc.

We will review the requirements of the new law, the government's efforts to implement it, and also share company perspectives, including compliance approaches and challenges and potential uses for competitor intelligence gathering. The new law affects all companies sponsoring or conducting clinical research, from large pharmaceutical companies to small biotechs.

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