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FDA: Drug Companies Faked Thousands of Drug Documents

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 NaturalSociety
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According to the Food and Drug Administration, a major drug research contractor has been found faking documents and manipulating samples. The firm, Cetero Research, has tested medicines for major drug companies that are now being forced to reevaluate their products in response to warnings issued by U.S. regulators.

Reuters reports:

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The Food and Drug Administration said on Tuesday two 2010 inspections, an internal company investigation and a third-party audit uncovered "significant instances of misconduct and violations" at a Cetero facility in Houston.

The Cary, North Carolina-based firm does early-phase clinical research and bioanalytics for a number of drugmakers. The pharmaceutical companies can then use those studies as supporting evidence in drug approval applications to the FDA.

"The pattern of misconduct was serious enough to raise concerns about the integrity of the data Cetero generated during the five-year time frame," the FDA said, warning drugmakers they might have to repeat or confirm any studies Cetero did in support of their applications between April 2005 and June 2010.

It remains unclear which drugmakers have used Cetero's services to apply for regulatory approvals and the FDA is asking companies to identify such instances. The regulators said the measure is precautionary and the safety and efficacy of drugs already on the market are unlikely to be affected.

The FDA inspected Cetero in May and December last year and found falsified records about studies.

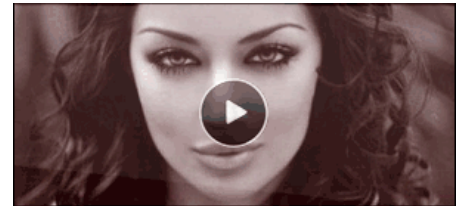


Specifically, in at least 1,900 instances between April 2005 and June 2009, laboratory

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technicians identified as conducting certain studies were not actually present at Cetero facilities at that time, the FDA said in its May report.

The FDA also said at the time that Cetero might have "fixed" studies to get the desired result, or did not include failed results in their report.

"Cetero's May 2010 and December 2010 responses are inadequate because the scope of their internal investigation was far too narrow to identify and adequately address the root cause of these systemic failures," the regulators said.

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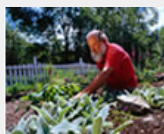


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