



MEMORANDUM

Via E-Mail

DATE: February 2, 2006

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: Stakeholder Briefing on EPA's Final Human Studies Rule

On **February 13, 2006**, the U.S. Environmental Protection Agency (EPA) will hold a stakeholder briefing for persons interested in EPA's final rule regarding protections for subjects in human research, which EPA released on January 26, 2006. The stakeholder briefing will begin at 10:00 a.m. and last until noon in Room 1126 of Crystal Mall II, 1801 Bell Street, Arlington, Virginia. EPA will make conference call lines available for this briefing, and more information will be available in a forthcoming *Federal Register* notice. The final rule, which has not yet been published in the *Federal Register*, is available on the Internet at http://www.epa.gov/oppfead1/guidance/human_studies_finalrule.pdf, and more information on the final rule is available at <http://www.epa.gov/oppfead1/guidance/human-test.htm>.

According to EPA, the final rule "significantly strengthens and expands the protections for participants in third-party research" by:

- Prohibiting new research involving intentional exposure of pregnant women or children, intended for submission to EPA under the pesticide laws;
- Extending the ethical protections in the Federal Policy for the Protection of Human Subjects of Research (the "Common Rule") to other human research involving intentional exposure of non-pregnant adults, intended for submission to EPA under the pesticide laws;
- Requiring submission to EPA of protocols and related information to ensure any future studies meet this highest ethical safeguard; and



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- Establishing an independent Human Studies Review Board to obtain expert peer review of both proposals for new research and completed third-party intentional dosing, research on which EPA may rely on under the pesticide laws.

In addition, the final rule:

- Categorically prohibits any EPA-sponsored research involving intentional exposure of pregnant women or children to any environmental substance; and
- Adopts the Department of Health and Human Services regulations to provide additional protections beyond those of the Common Rule to pregnant women and children in EPA observational research where there is only minimal risk and when research does not involve intentional exposure to any substance.

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We hope this information is helpful. As always, please call if you have any questions.