ASTERAND BIOSCIENCE
EXPERTS IN HUMAN TISSUE

September 21, 2016

Lori D. White, Ph.D., PMP
NTP Designated Federal Officer
NIEHS/NIH
P.O. Box 12233, MD K2-03
Research Triangle Park, NC 27709
whiteld@niehs.nih.gov

Dear Dr. White.

Asterand Bioscience associates themselves with the comments submitted by the Center for Responsible Science, specifically, section 1.A. Regulation: Advancing Innovation and use of Human-Relevant Test Methods through ICCVAM Member Agency Regulation Updates.

FDA's Investigational New Drug (IND) and Investigational Device Exemption (IDE) regulations give FDA the flexibility to accept non-animal test methods (NATMs), such as in vitro studies or prior experience with the drug or biological product in humans, when appropriate. However, despite this stated willingness to accept NATMs when they are at least as valid as other methods, FDA has not modified the text of its regulations to reflect this willingness. The current regulations facially require animal testing, which in turn discourages the use of non-animal tests, which may be more predictive of human response.

Modification of regulatory language is needed to encourage sponsor use of existing modern test methods and to signal further development to advance modernization of preclinical testing. Regulatory amendments would clear up any confusion, broaden testing options for sponsors, and spark innovation of more predictive methods.

John J. Canepa | **COO & CFO**

Peter Ferrigno | **CCO**

Cathie G. Miller, PhD | **Director of Product Marketing**