

Insilicos

Life
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December 1, 2006

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Division of Dockets Management (HFA-305)
ATTN: Ms. Courtney Harper
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number 2006D-0347

Dear Ms. Harper,

The purpose of this letter is to support the FDA's publication of the In Vitro Diagnostic Multivariate Index Assay (IVDMIA) guidance document. Physicians depend on accurate information to make treatment decisions that impact the lives of their patients. To enable needed improvements in both speed and accuracy of diagnoses, risks to these patients must be appropriately mitigated and balanced with the benefits of these innovative products. Insilicos applauds FDA's recognition that the questions that arise in regulation of IVDMIAs extend beyond those applied to yesterday's diagnostic tools.

Insilicos is a life science software company applying pattern-recognition techniques to proteomics to develop new and better diagnostic tools. Insilicos has been in contact with FDA's Office of In Vitro Diagnostics (OIVD) since last year prior to beginning the clinical trial to validate Insilicos' cardiovascular diagnostic product. OIVD staff have been clear and open in their communications, consistent with FDA's goals for supporting innovation with a least burdensome approach and transparency about requirements.

Insilicos would welcome an opportunity to discuss IVDMIA requirements in more detail, either to assist FDA in addressing comments on the guidance document or in future initiatives the Agency may undertake. Please do not hesitate to contact me if there are any questions about this letter, either by phone at (206) 979-4832 or by email at erikn@insilicos.com.

Sincerely,



Erik Nilsson
President

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