

December 6, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

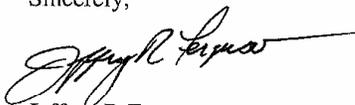
Re: **Docket No. 2006D-0347**

Eli Lilly and Company is pleased to have the opportunity to comment on the subject draft document. We fully support the FDA's efforts to clarify the regulations and develop policies to address various issues regarding In Vitro Diagnostic Multivariate Index Assays.

Attached are Eli Lilly comments on *FDA Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays*.

Please feel free to contact me at (317) 433-5615 for clarification of any comments.

Sincerely,



Jeffrey R Ferguson  
Manager, Global Regulatory Affairs,  
Chemistry Manufacturing and Control

**Lilly Comments to  
FDA Draft Guidance for Industry, Clinical Laboratories, and FDA Staff; In Vitro  
Diagnostic Multivariate Index Assays  
Docket No. 2006D-0347**

Eli Lilly and Company appreciates the opportunity to comment on the *FDA Draft Guidance; In Vitro Diagnostic Multivariate Index Assays*.

As a pharmaceutical company that values the benefits of tailored therapeutics, we could see how in vitro diagnostic multivariate index assays (IVDMIA) could play an important role in this area. We applaud the Agency for its effort to clarify the regulatory requirements with respect to IVDMIA.

The premarket and postmarket requirements outlined in this draft guidance appear to be reasonable with the least burdensome approach to manufacturers. We support FDA's efforts to clarify the regulations and develop policies to address various issues regarding IVDMIA. We look forward to continuing to work with FDA in this area.