



**Genetics and Public Policy Center**  
Berman Bioethics Institute • Johns Hopkins University  
1717 Massachusetts Ave. N.W., Suite 530  
Washington, D.C. 20036  
202.663.5971  
Fax: 202.663.5992  
www.DNApolicy.org

November 2, 2006

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

Re: Docket No. 2006D-0347:Request for Comment Period Extension

Dear Sir/Madam:

The Genetics and Public Policy Center respectfully requests that FDA provide a 60-day extension of the comment period for its Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays. The new draft guidance raises complex and novel regulatory issues with far-reaching implications. Additionally, it affects entities that may previously have had limited interaction with the agency and for whom FDA regulatory issues may be unfamiliar. Extending the comment period would permit participation by a broader range of stakeholders, including clinical laboratories and patients, and would thereby assist FDA in developing a regulatory framework that is informed by the expertise, insights, and concerns of those who are likely to be affected by the agency's actions.

Sincerely,

A handwritten signature in cursive script that reads "Kathy Hudson".

Kathy Hudson  
Director