



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

August 3, 2007

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Amy M. Miller, Ph.D.
Public Policy Director
Personalized Medicine Coalition
1225 New York Avenue, NW, Suite 450
Washington, DC 2005

Re: Docket No. 2006D-0347

Dear Dr. Miller,

The In Vitro Diagnostic Multivariate Index Assay (IVDMIA) guidance document has been the subject of attention, comment, and public discussion for almost a year. The current draft incorporates many of the suggestions made in public comments and has simplified the definition of IVDMIA and provided a variety of specific examples to assist sponsors in understanding that definition.

We believe that a 30 day period should be ample time to provide comments on this second draft and believe that there will be real benefit to providing direction in this important area. We therefore are denying your request. Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 27, 2007.

Thank you,

Jeffrey Shuren
Assistant Commissioner for Policy

cc: Steven Gutman, OIVD/CDRH
Laura Epstein, OCC/FDA
Jarilyn Dupont, OP/FDA
Catherine Lorraine, OP/FDA

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