



Genomic Health, Inc.
301 Penobscot Drive
Redwood City · CA 94063
www.genomichealth.com

November 20, 2006

VIA Electronic Submission:

<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>

Dockets Management Branch
HFA-305
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20850

RE: 2006D-0347

Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays (IVDMIA)

Dear Sir or Ma'am:

On behalf of Genomic Health, Inc. ("Genomic Health"), we are writing to request that the Food and Drug Administration (FDA) extend the comment period for the above-captioned draft guidance by ninety (90) days during which time we would request that the Agency hold an open meeting with interested parties at which FDA can explain more fully its objectives and respond to stakeholder questions. We support strongly FDA's convening such an open forum—before the close of the comment period—to allow stakeholders an opportunity to understand better what FDA is doing and why. This approach will help assure that all stakeholders have the time and information needed to evaluate fully the implications of the draft guidance and to submit constructive comments to the Agency.

Genomic Health is a licensed clinical laboratory, located in Redwood City, California, that conducts genomic research to develop clinically validated molecular diagnostics that provide individualized information on the likelihood of disease recurrence and response to certain types of therapy. These diagnostic technologies generate information that physicians and patients use in making treatment decisions. Genomic Health provides its testing services only on request from physicians and provides information to the ordering physicians that is essential to their interpreting test results in each individual patient's case. Genomic Health has a Certificate of Accreditation as a "high complexity" laboratory under the Clinical Laboratory Improvement Amendments (CLIA) and is accredited by the College of American Pathologists (CAP).

The IVDMIA draft guidance was announced in the Federal Register on September 7, 2006 (71 Fed Reg. 52800 [Sept. 7, 2006]), and the comment period is scheduled to close on December 6, 2006. We understand from public comments made by FDA officials that the comment period will be extended by thirty (30) days until January 5, 2007; we have not seen official confirmation of this extension, however. The thirty day extension is simply is not enough time to elicit informed feedback on the substantial and new policies outlined in this very abbreviated document (5 pages).

The draft guidance sets out new FDA policy that would change the status of certain clinical laboratory services from being exempt from FDA regulation to being "unapproved medical devices" subject to full FDA regulation. This new category of in vitro diagnostic (IVD) assay is called "in vitro diagnostic multivariate index assays," (IVDMIA). The Agency is proposing to regulate both the assays it believes are IVDMIA—as medical devices requiring pre-market

2006D-0347

November 20, 2006

Page 2 of 2

review and clearance/approval—and the clinical laboratories that now provide these services under its Quality System Review regulations. Moreover, this new FDA regulation would be superimposed on compliance requirements under longstanding state and federal regulations for clinical laboratory services, including CLIA.

The IVDMIA draft guidance represents a major change in FDA policy and imposes substantial new burdens on affected laboratories, but it provides very little real “guidance” beyond its summary statements. Through our participation in meetings with the FDA and in various venues where Agency staff have discussed this draft guidance, we have identified numerous areas where we have questions and concerns as to how assays (and laboratories) are selected for FDA regulation and how any clinical laboratory (including single service providers like Genomic Health and academic medical center clinical laboratories) can comply with the policies described in the draft guidance. A public forum within an extended comment period is key to informing stakeholders fully of the Agency’s plans and to establishing an on-the-record set of questions and responses for purposes of enhancing the comments submitted. A thirty day extension that covers the Christmas and New Year holiday periods does not provide sufficient time for clinical laboratories and the clinicians and patients they serve to respond thoughtfully to this draft guidance.

With respect to the request for an open public meeting before the close of the IVDMIA comment period, we would note that FDA officials have stated their openness to holding such a meeting. Therefore, we respectfully request that FDA: (1) extend the comment period on the draft guidance for ninety (90) days beyond the original December 6, 2006 deadline and (2) convene a public meeting to discuss the draft guidance before the close of the comment period. Thank you for your consideration of this request.

Sincerely yours,

/s/

Randy Scott, Ph.D.

Chairman and CEO

Cc: Paul Radensky, MD, JD, McDermott, Will & Emery, LLP