

February 28, 2007

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

RE: 2006D-0347, FDA Draft Guidance on *In Vitro Diagnostic Multivariate Index Assays*,
Federal Register, September 7, 2006 (Volume 71, Number 173, Pages 52800-52801)

Dear Sir/Madam:

We thank the FDA for the opportunity to comment on this draft IVDMIA guidance document. At this time, Invitrogen Corporation is submitting comments on the Administration's draft guidance, *In Vitro Diagnostic Multivariate Index Assays*.

GENERAL COMMENTS:

With respect to the regulatory environment for innovative molecular diagnostics, clarification of the regulations will be critical to facilitate product development in this field, and to ensure timely patient access to these innovative products. Invitrogen is aware of the complexities associated with innovative molecular diagnostics, and the corresponding difficulty in developing a coherent and comprehensive regulatory approach to them. We believe the IVDMIA draft guidance is a starting point for developing a framework for regulating these types of products. However, we would like to see all the stakeholders involved with the development of this guidance to ensure that quality innovated products continue to be made available to patients in a timely manner. To this end, we would like to see the FDA hold a series of workshops to allow for a scientific exchange of information and mutual development of an IVDMIA guidance document.

Invitrogen believes that if implemented without further clarification and refinement, the draft guidance would have significant unintended consequences with respect to the development and delivery of many innovative, medically needed diagnostics. Life saving tests may be delayed or prevented altogether from reaching patients. Because FDA's diagnostics review processes do not easily accommodate products that are continually improved, assays covered by the draft guidance may begin to lag behind available science, in contrast to those assays being developed and regularly improved under the existing regulatory framework. We believe that the availability of the CLIA and ASR pathways have stimulated the development and availability of innovative diagnostic products, and that the elimination of these pathways would significantly curtail the number of innovative products that are developed and enter the marketplace in the years to come.

SPECIFIC COMMENTS:

Our specific comments on the IVDMIA guidance document are as follows:

1. We request that the FDA delay finalization and implementation of the draft guidance, and instead, hold a series of meetings with stakeholders to allow for an interactive exchange of scientific information, focused towards the mutual development of an IVDMIA guidance document that compliments the CLIA and ASR regulations.
2. We request the FDA to follow the more formal rulemaking process to ensure clear and detailed regulation of IVDMIA's, and provide industry with a comprehensive regulatory analysis that explains the basis for FDA regulation of innovative molecular diagnostics, including in-vitro diagnostic multivariate index assays (IVDMIAAs), and clarification as to why the existing regulatory framework is inadequate.
3. We request the FDA to clarify how the IVDMIA regulation will work in conjunction with the existing CLIA requirements and ASR guideline.
4. The definition of IVDMIA in the draft guidance appears to be very broad, and we request further clarification from the FDA to eliminate confusion regarding which diagnostics will be subject to pre- and post-market requirements. We would like the guideline to be applicable to a narrow range of devices, and based on a risk based approach: Higher risk regulated by FDA, lower risk to continue using the CLIA framework.
5. We request the FDA to clearly define a process for the development of "Orphan IVDMIA Products" to ensure availability to small patient populations which otherwise would not make financial sense to develop.
6. We request the FDA to allow a process within the developing regulatory framework for the continued improvement of tests that will facilitate timely delivery to clinical laboratories and ultimately the patient.

Please do not hesitate to contact us for further input or clarification of our comments. Invitrogen would be pleased to work with FDA and other stakeholders to advance public discussion and participate in workshops with the FDA to resolve issues raised by the draft guidance, and to develop a framework for regulating high risk IVDMIA's.

Sincerely,



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