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November 20 2006

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

RE: 2006D-0347

To Whom It May Concern:

I am writing on the behalf of Aureon Laboratories, Inc. to request that the Food and Drug Administration (FDA) extend by ninety (90) days the comment period for the Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (Docket No. 2006D-0347).

The draft guidance document was issued on September 7th, 2006, and the comment period was originally scheduled to close on December 6th, 2006. The FDA has avowed that the agency is extending the comment period by thirty (30) days. Aureon believes, however, that an additional sixty (60) day extension beyond that is obligatory. We would also like to request that the FDA hold a public hearing to discuss the issues raised in the draft guidance document prior to comment period termination. Holding the meeting before the close of the extended comment period would help Aureon and others in drafting comments. FDA has recently extended the comment period for its proposed rules on "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs" and has scheduled a public meeting before the conclusion of that extended comment period.

We understand that this is a complex issue, where the industry needs time to assess and analyze the draft guidance, so that we can respond in a cogent fashion. To this end, on behalf of Aureon, I request that the FDA extend the comment period for this draft guidance document by ninety (90) days and hold a public meeting prior to the end of the extended comment period.

Sincerely,



Vijay Aggarwal, PhD
President & CEO

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