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BY FEDERAL EXPRESS

Division of Dockets Management
HFA-305
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: 2006D-0347

To Whom It May Concern:

The Coalition for 21st Century Medicine requests that the Food and Drug Administration (FDA) extend by sixty days the comment period for the second version of Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (Docket No. 2006D-0347). The Coalition for 21st Century Medicine represents some of the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists, and patient advocacy groups – all linked by a common mission to develop advanced diagnostics that improve the quality of healthcare for patients. We strive to improve the quality of healthcare by encouraging the research, development, and commercialization of innovative new diagnostic technologies.

The draft guidance document was issued on July 26, 2007, and the comment period has been scheduled for thirty days. We appreciate that FDA has re-issued this document in draft, not final, form and that the Agency has allowed an additional comment period. However, the thirty-day comment period announced in the Federal Register is not sufficient; an additional sixty-day extension is necessary.

The Coalition for 21st Century Medicine recognizes that FDA significantly revised the text of the draft guidance in response to comments to the first version

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of the document. However, as a result, the document has changed in significant ways, including how an IVDMA is defined. These revisions raise a number of new scientific and regulatory questions. Stakeholders need more than thirty days to evaluate this substantially revised document.

In light of the complex issues in the draft guidance document, stakeholders require an additional sixty days beyond the current thirty-day comment period. This is especially true given the timing of the thirty-day comment period. Many stakeholders will be on vacation in August. Interested groups are not able to receive input from members or outside experts. Additional time is needed to prepare substantive comments that will assist the Agency. We also note that a thirty-day comment period is atypically brief; FDA routinely allows more time. We appreciate FDA's desire to finalize the guidance document. We believe, however, that given the complexity and importance of these issues, such a truncated review period is inappropriate.

FDA's regulation of IVDMIAs raises significant regulatory and health care implications. A thirty-day comment period is too short for such an important change in the application of FDA's regulatory requirements to an area that has not previously been regulated. This is especially true in light of difficulties that will arise due to scheduling issues during the current comment period. Therefore, the Coalition for 21st Century Medicine requests that FDA extend the comment period for this draft guidance document by an additional sixty days.

Sincerely,



Joseph Eyer
Administrator
Coalition for 21st Century Medicine