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Howard C. Birndorf  
Chairman and Chief Executive Officer

July 31, 2007

VIA 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:

Nanogen requests that the Food and Drug Administration (FDA) extend by sixty days the comment period for the second version of Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (Docket No. 2006D-0347).

The draft guidance document was issued on July 26, 2007, and the comment period has been scheduled for thirty days.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.

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 Therefore, Nanogen requests that FDA extend the comment period for this draft guidance document by an additional sixty days.

Sincerely,

  
Howard C. Birndorf 2006D-0347

EXT 3

HCB/cg