



July 11, 2003

Elizabeth Mansfield, Ph.D.  
Docket 03D-0120  
Dockets Management Branch (HFA-305),  
Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061,  
Rockville, MD 20852

Dear Dr. Mansfield:

Affymetrix respectfully submits the following comments on the Draft Guidance, "*Multiplex Tests for Heritable DNA Markers, Mutations and Expression Patterns.*" We support the FDA's efforts in finding a way to provide guidance in this very important area so that Americans can safely benefit from new science.

Our comments are divided into two sections: 1) general issues that we would like FDA to consider during the preparation of subsequent drafts and the final guidance; and 2) specific wording changes throughout the document. We have been working closely with a number of groups during the time since this document was released. As a result, some of our comments will refer to comments other organizations plan to submit.

Thank you for the opportunity to work with the Agency on developing this document. We look forward to reviewing the next draft.

Very best regards,

A handwritten signature in black ink, appearing to read "Thane Kreiner".

Thane Kreiner, Ph.D.  
Senior Vice President, Corporate Affairs

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