Amersham

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July 17, 2003

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

Dear Elizabeth Mansfield,

We are very pleased to see that the FDA has issued a draft guidance regarding docket number 03D-0120 on Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns; Availability for Medical Devices for Industry and FDA Reviewers.

We understand that after a review of the industry comments the agency intends to issue a new draft guidance for additional discussion.

Amersham plc has taken a collaborative approach to providing comments to the FDA. This has been accomplished by bringing together a team of technical and regulatory resources from Amersham Biosciences and Amersham Health. As a team, we have reviewed the draft guidance carefully and have some general comments and suggestions as well as some specific questions and recommendations. These are outlined in the attachment to this letter. We appreciate this opportunity and hope that the comments we have provided will be helpful to the agency and the industry as a whole.

Once again, thank you for this opportunity and we look forward to reviewing the electronic comments from all parties as well as the second draft from the agency.

Sincerely,

Trevor Hawkins
Executive Vice President of Development
Amersham Biosciences

William Clarke
Executive Vice President of Research and Development
Amersham Health

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