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MERCK
Research Laboratories

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

Electronic comments to: http://www.fda.gov/dockets/ecomments

RE: [Docket No. 03D-0120] *Medical Devices: Draft Guidance for Industry and FDA Reviewers: Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns*

Merck & Co., Inc, is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's Research and Development (R & D) pipeline has produced many of the most important pharmaceutical products on the market, today.

Merck, as many pharmaceutical industry companies, expects that the future of products in our pipeline will be largely dependent upon the research in pharmacogenomics that we are conducting today. We have invested in this technology --both in human and capital resources -- with the expectation that this investment will develop into personalized medicine products, in the very near future. We fully anticipate that most of the research information we create and collect now will be relevant to the FDA's examination of the safety and efficacy of these products before they are marketed to the public. For this reason, Merck is very interested in the concepts discussed in this *Draft Guidance for Industry and FDA Reviewers: Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns*, (hereafter referred to as *The Draft Guidance*), as they will be relevant to future strategic regulatory decision-making pertaining to our products.

General Comment:
Merck commends FDA for considering the complexity of the issues, so early in the evolution of this technology. We are all eager to learn together and to share expertise as we gain it, and as the technology evolves. As always, Merck will be concerned about premature restraints on science which might interfere with progress in this field and about duplicative or unusual regulatory requirements that may not be well considered. With this is mind, we offer just a few comments on points that are made within *The Draft Guidance.*

Specific Comments
Comment 1. The MIAME specification provides us with a guideline as to the "Minimal Information Associated with a Microarray Experiment" for gene expression studies. MIAME was not intended to directly apply to other data types. Since this point in *The Draft Guidance* falls under the heading "*General considerations for planning and evaluating clinical studies*",

it should make clear the concept that the MIAME guidance applies only to gene expression data.

Comment 2. The information about the technology platform requested to support diagnostics applications is a reasonable list, but at this point in microarray evolution does little more than demonstrate a sincere effort by the applicant. That is probably appropriate at this stage of the field, but it should be acknowledged in *The Draft Guidance* that future developments will likely lead to a more specific guidance. In particular, a "kit" for validation of microarray platforms should be considered for the future.

Merck welcomes this opportunity to provide comments on *The Draft Guidance for Industry and FDA Reviewers: Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns.*

Sincerely,

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