CELERA DIAGNOSTICS
A Joint Venture With Applied Biosystems

October 26, 2001

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

Reference Subject: **Comments on the draft Guidance for Industry: "Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls"**

To Whom It May Concern:

After reviewing the FDA's draft Guidance for Industry "Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls", published by the FDA on August 29, 2001 under Docket #01D-0286, our comments are as follows:

Section V - Product Modification

HIV drug resistance testing is a continuously evolving field. It is anticipated that new and more potent antiretroviral drugs will become rapidly available. New mutations conferring resistance to these drugs will also be identified. Furthermore, as technology evolves, new common laboratory equipment/instrumentation (e.g. Thermocyclers and DNA Sequencers) will become available. The product will have to be validated/updated to accommodate these changes. Implementing these changes in an expeditiously and timely manner will be of great medical benefit to patients on antiretroviral therapy and public health.

In this context we anticipate making changes to our drug interpretation, validating new mutations algorithm, and using new equipment. We anticipate these changes to be frequent. Subsequently, it is our proposal that they are covered under a new "Abbreviated 510(k)" using design control to validate the changes, rather than through submission of an entirely new, "Traditional 510(k)". This abbreviated 510(k) would include one or more of the following:

A. We propose that changes to drug resistance interpretation algorithms are made based on published literature (IC_{50} and IC_{90} values; drug binding data and clinical outcome studies) and data submitted to CDER by the pharmaceutical companies.

B. It is our recommendation that newly identified mutations be validated using only studies that define Limit of Detection (LOD), and determination of minimal mutant viral mixture proportions. Since the changes do not entail modifications to kit reagent formulations, we suggest that studies be done with a single lot.

C. We propose that new instruments (thermocyclers/ sequencers) should be validated by performing comparability studies. These studies should be designed to compare the output from a particular instrument with samples being processed identically through all other steps of the assay.

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01D-0286

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If you wish to discuss our comments with us, please feel free to contact me at (650) 554-2352.

Thank you for your consideration.

Sincerely yours,

Tony C. Lam
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LAM, SR. MANAGER
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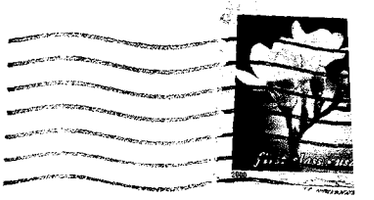

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