FDA Update

Clinical Laboratory Improvement Advisory Committee Meeting
September 5, 2007

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Center for Devices and Radiological Health
US Food and Drug Administration

Agenda

- Organizational Changes
- FDA Guidance Update
- User Fee Update
- Pre-Market Update
- Post-Market Update

Organizational Changes

- New Center Deputy Director
  - Mark Raza
- New Office Deputy Director
  - Alberto Gutierrez
- New/Old Division Director for Chemistry and Toxicology
  - Jean Cooper
- Return of Liz Mansfield as Senior Policy Advisor

FDA Guidance Update

- IVDMIA
  - → First Draft Published Sept. 2006
  - → 180 Day Comment Period
  - → Public meeting to discuss issues
  - → Second Draft Published July 2006

- ASR
  - → First Draft Published Sept. 2006
  - → 180 Day Comment Period

FDA Guidance Update

- Assayed and Unassayed Quality Control Material
- Pharmacogenetic Tests and Genetic Tests for Heritable Markers
- Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices
- In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path

FDA Guidance Update

Class II Special Controls

- Gene Expression Profiling Test System for Breast Cancer Prognosis
- Antimicrobial Susceptibility Test (AST) Systems
- Herpes Simplex Virus Types 1 and 2 Serological Assays

FDA Guidance Update

- CLIA Waiver Guidance – Working its way through the system.

User Fee Update

- MDUFMA II
  - →Specific OIVD Goals
    - o Guidance Commitments
    - o Performance Goals for CLIA Waiver Petitions
    - o Pilot Study for Co-review of PMA/510(k) and CLIA Waiver
    - o Re-classification of Class II and Class I devices
    - o Clear Path for Review of Molecular Diagnostic Tests

Pre-Market Update

- Veridex - Metastatic Breast Cancer
- Binax NOW - Malaria
- 7 Day Continuous Glucose Sensor

Post-Market Update

- Post-Market Transformation
- Lab Net
  - → Few Signals but significant identified
  - → OIVD actively calling the laboratories that have joined