



FDA Update

Alberto Gutierrez, Ph.D.



Organizational Change

- Steve Gutman – Retired
- Don St.Pierre – Acting Office Director

Organizational Change -- continued

- Liz Mansfield on Detail to the agency
- Sousan Altaie- Assistant Regional Director (Middle East Office), OIP
- Maria Chan – Director of Division of Immunology and Hematology Devices
- Courtney Harper – Acting Director of Division of Chemistry and Toxicology Devices

Guidances

continued

- IVD MIA – under review
- Migration Studies
- Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA

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Guidances

continued

- CDER/CDRH joint Guidance Document draft published in 2007 on Antimicrobial Susceptibility Testing (AST) break points
 - Novel use of FDA's standard recognition



Guidances

- ASR Questions and Answers – September 15, 2007; clarifying letter issued June 6, 2008
- Manufacturers provided plans to come into compliance
- Met with laboratory representatives including representatives from Pan American Society for Clinical Virology (PASCV) to address impact on laboratories



Notable New Clearances

- rRT-PCR Flu Panel test – a CDC Test to Detect Human Influenza



Notable Panel Meetings

- Advisory panel meeting on Fujirebio Diagnostics Inc. HE4 Enzyme Immunoassay and Risk of Ovarian Malignancy Algorithm™ (ROMA™)
- ODAC panel meeting on K-RAS testing



Postmarket Actions

- Warning letter to LabCorp for OvaSure



Critical Path Programs

- Genomics – interactions with NCI including EDRN, SPORE, PACCT, BRN and with CDC (EGGAP)
- Artificial pancreas
- Nanotechnology



User Fee Mandates

- Review times tight
- Guidances published or under development
- AdvaMed and FDA survey on pre-IDEs
- AdvaMed proposal for mass exemption of products



Cancer Biomarker Consortium– AACR, FDA, NCI

- Biorepositories
- Bioinformatics
- Bioassay validation
- Data sharing



Waiver of CBC/Differential Cell Count

- No new development on the CBC/Differential Cell Count waiver issue
- Panel meeting to determine the waiveability of specific instrument will be convened when a manufacture files a specific waiver request



Regulation of Laboratory Developed Test

- Genentech Petition under review