



FDA Update

Alberto Gutierrez, Ph.D.



Organizational Change - Agency

- New Commissioner

Dr. Margaret A. Hamburg, M.D.

- New Principal Deputy Commissioner

Josh Sharfstein, M.D.



Organizational Change - Center

- Nation wide search for new director in progress
 - Dan Schultz, MD - resigned
 - Jeff Shuren, MD, JD - acting



Organizational Change -- OIVD

- Alberto Gutierrez, Director
- Don St.Pierre, Deputy Director for New Device Evaluation
- New Personalized Medicine Staff



Personalized Medicine Staff

- Liz Mansfield – Director
- Zivana Tezak- Associate Director for Science and Technology
- Marina Kondratovich– Associate Director for Clinical Studies
- Plan to hire a total of about 15 reviewers with expertise in this area



Guidances

- Anti-Nuclear Antibody (ANA) Test System
- Post-Approval Studies



Notable New Approvals/Clearances

- Approvals

- Cervista HPV 16/18
- Cervista HPV HR test

- Clearances

- AVantage A/H5N1 Flu Test - rapid test



Emergency Use Authorizations

- CDC's rRT-PCR Swine Flu Panel
- CDC's rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA) and Viral Culture
- Focus Diagnostics Influenza H1N1 (2009) rRT-PCR diagnostic test



Notable Panel Meetings

- Advisory panel meeting on HemoCue's White Blood Cell Analyzer waiver application



Postmarket Actions

- Quest Subsidiary, Nichols Institute Diagnostics, pleaded guilty to felony misbranding – \$302 million settlement