



OIVD Update

Alberto Gutierrez, Ph.D.



Organizational Change - Center

- William Maisel, M.D., M.P.H.
 - Deputy Center Director for Science
- Michelle McMurry-Heath, M.D., Ph.D.
 - Associate Director for Science
- Susan Cummins, M.D., M.P.H.
 - Chief Pediatric Medical Officer

Organizational Change – OIVD+

- New manager since last meeting
 - “Peter” Zhihao Qiu, Assoc Director DCTD
- New Hires
 - DCTD 10
 - DMD 3
 - DIHD 7
 - Radiology 1



Agency Initiatives

- Protecting Public Health
 - Quick compliance actions
 - Pro-actively manage public health issues
 - Glucose Meters
 - Personalized Medicine
 - Emerging Infectious Diseases and Biodefense
 - Reducing Radiation Exposure



Center Initiatives

- CDRH Transparency

- Town Hall Meetings in Minneapolis, Boston, LA

- Objective-Provide a Greater sense of predictability and transparency

- Implement total product life cycle
- Enhance communication and transparency
- Strengthen workforce/workplace
- Facilitate innovation and address unmet public health needs



Center Initiatives

- Ambitious Strategic Plan
- Program review – 510(k)
 - Internal Review
 - Report published August 3rd
 - IOM Review



Center Initiatives – Public Meetings

- Incorporation of New Science Into Regulatory Decision making– Feb 9
- Strengthening the CDRH's 510(k) Review Process – Feb 18
- Webinar August 30th



Center Initiatives – DTC genetic testing

- Letters to manufactures advising them they were marketing IVDs.
- Congressional Hearing
- GAO report
- Manufacturers and FDA are working on bringing the manufacturers into compliance



Center Initiatives – LDTs

- Public Meeting – July 19th and 20th on strengthening Oversight.
- Docket open until September 15th
- FDA plans to quickly and clearly define a path to plug regulatory gaps and to create an even playing field while maintaining focus on innovation and patient access to new technology



Guidances

- In vitro Diagnostic (IVD) Device Studies-
Frequently asked Questions
- Recommendations for Premarket
Notifications for Lamotrigine and
Zonisamide Assays



Notable Clearances

- 510k Abbott FreeStyle Lite Glucose Test Strips and FreeStyle Glucose Test Strips using GDH-FAD to replace GDH-PQQ technology
- 510k *C. difficile* via nucleic acid assay
- 510k CDC rRT-PCR2009 H1N1.



Notable Clearances

- 510k Focus Diagnostics, Inc. Simplexa Influenza A H1N1 (2009) Test
- 510k Gen-Probe-Prodesse ProFast multiplex RT-PCR influenza with H1N1 detection
- 510k Abbott CT/NG (Chlamydia/Gonorrhea) test on M2000
- 510k Bio-Rad Bioplex 2200mmrvIgG multiplex assay for Mumps/Measles/Rubella/VZV infections



Notable PMAs

- PMA OraQuick HCV Rapid Antibody Test-whole blood claim
- 3 PMAs Roche Anti-HCV for the diagnosis of Hepatitis C, run on 3 different instruments.



Notable Panel Meetings

- ODAC voted 7 to 1 “yes” to the proposition that a well characterized in vitro diagnostic to identify patients with the T3151 mutation should be required and reviewed by the FDA prior to approval of omacetazine during the Oncology Drug Advisory Committee meeting.



Significant Recalls

- Agendia Mammaprint Class II Recall
- Beckman Coulter erroneous sodium test Class I Recall
- Beckman Coulter DXI troponin Class II Recall
- Cepheid MRSA Class I Recall
- Statspin Centrifuge Class I Recall
- Hettish Centrifuge Class I Recall



Warning Letters

- Beckman Coulter AccuTnl on the Access Immunoassay System
- MP Biomedicals Diagnostic Division
- Abbott FreeStyle glucose monitoring and Navigator CGM
- DexCom Seven PLUS CGM
- ARJ Medical, Inc. Urinalysis Reagent Strips
- Paragon Dx, LLC ASR Probe Mix
- Phoenix Bio-Tech Corp. TREP-SURE and TREP-CHECK Anti-treponema EIA screen
- Syntron Bioresearch Inc. drugs of abuse kits
- Branan Medical Corp., Inc. drug of abuse kits



Emergency Use Authorizations

- H1N1 emergency declaration terminated June 23



Letters to Sponsors

- Letters sent to all manufactures of cleared HbA1c tests inviting them to talk to OIVD
- Letters sent to all authorized entities of IVD devices for diagnosing 2009 H1N1 advising that no new requests can be submitted for EUA after June 23, 2010.



Public meetings

- Blood Glucose Workshop - March, 2010
- Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis (cosponsored by FDA, CDC, NIAID, and NIH) - June, 2010
- aCGH June, 2010
- Antimicrobial Resistance and Diagnostic Device and Drug Development Research for Bacterial Diseases (cosponsored by CDER/CDRH, HIAID/IDSA) – July, 2010



Lab Tip

- How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices
 - <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm>



Medical Alert – August 26

- CDC/FDA/CMS
- Use of Fingertick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens



Medical Device User Fee Program

Medical Device User Fee Amendments of 2007 (MDUFA)

- Expires September 2012

In the coming months, we will begin the negotiation process

with regulated industry

- Initiate the process by providing an opportunity for initial public input

Reauthorization required by September 2012 to continue the program

Public Meeting – September 14, 2010

- Location in the greater Washington, D.C. metropolitan area; 9am-5pm
 - Please monitor website for updates regarding meeting logistics
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm218250.htm>
- Purpose – to hear stakeholder views on MDUFA as FDA considers the next MDUFA program
 - What is your assessment of the overall performance of the medical device user fee program thus far?
 - What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?
- Reauthorization discussions focus on medical device review process, not regulatory policy