

FDA Update

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Organizational Change - Center

- Jeff Shuren, MD, JD
- Nation wide search in progress for
 - New Deputy for Science
 - New Deputy for Policy



Agency Initiatives

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



Agency Initiatives

- Transparency
 - Twitter
 - Public Meetings
 - YouTube
 - Public Score Cards



Center Initiatives

- Ambitious Strategic Plan
- Program review – 510(k)
 - Internal Review
 - IOM Review



Center Initiatives – Public Meetings

- Incorporation of New Science Into Regulatory Decision making Program review – 510(k) – Feb 9
- Strengthening the Center for Devices and Radiological Health's 510(k) Review Process – Feb 18
- Blood Glucose Meters – March 16-17



Guidances

- Antimicrobial Susceptibility Tests
- Detection or Detection and Differentiation of HPV
- H1N1 EUA



Guidances – Special Controls

- Respiratory Panel
 - Influenza A Virus Subtypes
 - Human Metapneumovirus (hMPV)
 - Respiratory Viral Panel Multiplex

- Cardiac Allograft Gene Expression Profiling Tests



Notable New Approvals/Clearances

- Clearances
 - OVA1



Emergency Use Authorizations

- 14 EUAs
 - CDC, DoD, Manufacturers, and CLIA laboratories
 - 1 Moderate Complexity
 - Waiver on the horizon?



Notable Meetings

- Advisory Panel Meeting on Digital Pathology
- FDA-IDSAs Respiratory Tract Infections Workshop



Postmarket Actions – Class I Recalls

- Hettich Centrifuges with 2050 and 2076 Plastic Rotors – 11/21/09
- Pointe Scientific, Inc., Liquid Glucose Hexokinase Reagent – 10/19/09
- Biosite Incorporated, Triage Cardiac Panel 4/27/09



Postmarket Actions – Public Health Notification

- Potentially Fatal Errors with GDH-PQQ*
Glucose Monitoring Technology – 8/13/09



Postmarket Actions – Warning Letters

- Millipore Corp. Marketing unauthorized or unapproved H1N1 diagnostic products

CLIA Waivers

- 401 categorizations
 - 163 by regulation
glucose meters, urine dipsticks, FOB, urine pregnancy
 - 151 by OTC
drugs of abuse, cholesterol, HDL, triglyceride
 - 87 by request
Previously waived by studies but now relabeled or change in name/ distributor
 - 2 devices (31 categorizations) waived and 1 denied waiver

CLIA Waivers

□ Performance

FDA Decision	FDA Days	MFG Days	Total
APPR – Approved	233	0	233
APPR – Approved	204	64	268
Denied	320	38	744