FDA Update

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Summary

- OIVD 2012 Priorities and Updates
  - Class I/II IVD Exemptions
- Public Meeting on Highly Multiplexed
- Key Guidances
- Regulation of Lab Developed Tests

About FDA

FDA Organization

About the Center for Devices and Radiological Health

CDRH Reports

- CDRH Annual Reports
- CDRH Ombudsman Annual Reports
- CDRH Preliminary Internal Evaluations
- CDRH Plan of Action for 510(k) and Science
- Medical Device Pre-Market Programs: An Overview of FDA Actions
- Medical Device Reporting (MDR) Rate in 510(k) Cleared Devices Using

CDRH Plan of Action for 510(k) and Science

Implementation of Recommendations from the 510(k) and Science Reports

The links below provide information on steps CDRH is taking to foster medical device innovation and assure the safety and effectiveness of medical technologies used in the United States.

The Summary and Overview of Comments and Next Steps below describes which recommendations from the August 2010 reports on the 510(k) program and CDRH's use of science in its decision-making we will implement.

The Summary is accompanied by a Plan of Action, which outlines 25 specific actions and accompanying timelines for completion or for reaching a milestone in 2011. These actions will make the 510(k) program a blueprint for smarter medical device oversight; one that drives innovation and brings important technologies to patients.

Overview of FDA Actions

- Medical Device Pre-Market Programs: An Overview of FDA Actions
- Accomplishments: CDRH Plan of Action for 510(k) and Science

Actions to Improve Pre-Market Programs

- Culture change toward greater transparency, interaction, collaboration, and the appropriate balancing of benefits and risks
- Assure predictable and consistent recommendations, decision making, and application of the least burdensome principle
- Implement efficient processes and use of resources

Culture Change

- Better engagement with industry
- Greater use of external experts
- Balance benefits and risks and apply a more patient-centric approach
- Smart Regulation

Engagement with Industry

- Improve Interactive Review
- Improve Pre-Submission Meetings

External Experts

- Leverage External Scientific Expertise
- Experiential Learning Program

Benefits and Risks

- Guidance on Making Benefit-Risk Determinations
- Guidance on Early Feasibility Studies
- Guidance on IDE Decisions

Smart Regulation

- Innovation Pathway

Predictable and Consistent Recommendations

- Management Oversight
- Enhancing Training
- Improving Internal Processes
- Transparency Through Guidances
- New Communication Tools.

Improving Internal Processes

- Establish a Center Science Council
- Standard Operating Procedures (SOP)
  - When Additional Information can be Requested
  - Change in Reviewer
  - Corrective and Preventive Actions (CAPA)

Transparency Through Guidances

- The 510(k) Process
- 510(k) Modifications
- Clinical Trials

Developing New Communication Tools

- Notice to Industry Letters

Implement Efficient Processes

- *De Novo* Process
- External Appeals
- Use Post-Market Data
- Improve the Third Party Review Program
- Down-Classification
- Implement Triaging

Organizational Change – OIVD

- Working reducing manager/reviewer ratio currently 1/27 - ideal 1/10
- Adding post-market for radiology, mammography, and Radiological Health

Organizational Change

- Tamara Feldblyum
  - Associate Director Virology
- Yun-Fu Hu
  - Associate Director Immunology
- Ruth Chesler
  - Associate Director Chemistry

Public Meetings

- Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity, June 23, 2011
- Advancing Regulatory Science for Highly Multiplexed Microbiology/MCM Devices, October 13, 2011

Goals of Meeting

- Allowed FDA to put a proposal on the table
- Engage experts with different perspectives to opine on the proposal
- Gather information for development of draft FDA Guidance Document and identify any gaps

Guidances

- Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices - Draft
- Detection or Detection and Differentiation of Influenza Viruses - Final
- Mobile Medical Applications - Draft

Guidances

- Herpes Simplex Virus Types 1 and 2 Serological Assays – Special Controls
- Yersinia spp. - Draft
- HPV - Final
- Artificial Pancreas

LDTs

- Uncertainty around guidances
- Legislative proposal on the table
- Loop hole getting larger and having an increasing impact on public health, regulatory oversight and IVD industry

OncoHealth Takes on HPV Testing Market with Protein-Based Assay

"The company is currently conducting clinical studies for its test, which it plans to offer initially as an ELISA assay, and has analyzed about 3,000 patient samples."

"…ELISA format would allow OncoHealth's test to be used as a screen as well as a diagnostic."

"The company anticipates making the test commercially available in early 2012 as a laboratory-developed test offered through partners with CLIA labs. OncoHealth does not have a CLIA facility."

Thanks