FDA Update

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Organizational Change

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CDRH 2011 Strategic Priorities

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FY 2011 Priorities

- Fully Implement a Total Product Life Cycle Approach
- Enhance Communication and Transparency
- Strengthen Our Workforce and Workplace
- Proactively Facilitate Innovation and Address Unmet Public Health Needs
Fully Implement a Total Product Life Cycle Approach

- Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions
  - Strengthen Premarket Review
  - Align Scientific Resources throughout CDRH
  - Optimize Data Collection and Analysis
  - Address Challenges Associated with Globalization
- Enhance Compliance Capability
Strengthen Premarket Review

• Implement selected recommendations of the 510(k) Working Group

• Address Class III device types currently allowed to enter the market through the 510(k) process

• Reassess the interactive review process
Align Scientific Resources throughout CDRH

- Optimally use CDRH’s scientific resources to support the Center’s programmatic functions
- Implement selected recommendations of the Task Force on the Utilization of Science in Regulatory Decision Making
Optimize Data Collection and Analysis

• Increase near real-time adverse event reporting from healthcare providers

• Increase the use of structured product information to improve the quality of data in regulatory submissions
Address Challenges Associated with Globalization

- Further harmonization efforts and exchange medical device information with foreign regulatory authorities

- Make use of Quality Systems Inspections conducted by other countries
Enhance Compliance Capability

- Complete and make public our “Case for Quality”
- Enhance the efficiency and clarity of the recall process
- Streamline the warning letter process
Enhance Communication and Transparency

• Implement a Strategic Approach to Stakeholder Communication and Improve Communication with CDRH Staff

• Increase Transparency and Facilitate External Communications
Strengthen Our Workforce and Workplace

• Develop a Life Cycle Approach to CDRH Employee Education

• Promote Transparent Employee Performance Review and Meaningful Recognition

• Improve Workload Management

• Develop Meaningful Metrics
Proactively Facilitate Innovation and Address Unmet Public Health Needs

• Foster the Development of Innovative Medical Devices

• Develop a Personalized Medicine Program
Foster the Development of Innovative Medical Devices

- Development of innovative medical devices and medical devices to address unmet public health needs
- Use of published literature to support pediatric device claims
- Medical Device Innovation Initiative
Develop a Personalized Medicine Program

• Review of submissions addressing genomic tests
Plan of Action For Implementation of 510(k) and Science Recommendations
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.

Related Documents

- 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps (PDF - 188KB)
- Plan of Action for Implementation of 510(k) and Science Recommendations (PDF - 131KB)
- Letter From the Center Director (PDF - 43KB)
- Questions About the Plan of Action? Submit Here
- Press Release: FDA to Improve Most Common Review Path for Medical Devices

Related Links

- CDRH Preliminary Internal Evaluations -- Foreword: A Message from the Center Director (PDF - 243KB)
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<td>Draft Guidance</td>
<td>July 31, 2011</td>
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<td>Pre-Submission Interactions Guidance</td>
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<td>November 30, 2011</td>
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<td>Establish a Center Science Council</td>
<td>Post Council Charter to FDA Website</td>
<td>March 31, 2011</td>
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<td>Post initial results of 510(k) audit to FDA Website</td>
<td>June 15, 2011</td>
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<td>Enhance Training</td>
<td>Develop and implement training on core competencies</td>
<td>August 31, 2011</td>
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<td>Leverage External Experts</td>
<td>Post SOP to FDA Website</td>
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**Programmatic and Regulatory**

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<td>Implement an &quot;Assurance Case&quot; Pilot Program</td>
<td>Start pilot program</td>
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<td>Establish &quot;Notice to Industry Letters&quot; as a Standard Practice</td>
<td>Post SOP to FDA Website</td>
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<td>Improve the IDE Process</td>
<td>Complete program assessment</td>
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<td>Improve Medical Device Labeling</td>
<td>Public Meeting</td>
<td>April 7 - 8, 2011</td>
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<td>Issue proposed regulation</td>
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## Issues to be Referred to the IOM

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<td>Establish a Class IIb</td>
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<td>Predicate Clarification</td>
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Office 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
- Public Panel Meeting March 8th and 9th
Office Initiatives

LDTs

• Public Meeting – July 19th and 20th on strengthening Oversight.

• Docket open until September 15th

• FDA plans to publish a guidance on the overall regulatory framework, a guidance on collecting information on what tests are offered, and a guidance describing the synergies between CLIA regulations and QSr.
Guidances

• Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)

• Detection of Antibodies to *Borrelia burgdorferi*

• Detection of *Clostridium difficile*
Guidances

• Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays

• Detection of Helicobacter pylori
Notable Clearances/Approvals

• Her2 for Gastric Cancer
• Norovirus Assay
• Everolimus Immunoassay
Significant Recalls

• Abbott Glucose Strips
• bioMérieux, Inc., VITEK 2 Gram Negative Susceptibility Cards Containing Piperacillin/Tazobactam (TZP)
Medical Device User Fee Program

• Negotiations have began
• ACLA is taking part in the negotiations
Thanks

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