



FDA Update

Alberto Gutierrez, Ph.D.

Organizational Change

– Uwe Scherf

- Deputy Director Microbiology

– Reena Philip

- Deputy Director Immunology Hematology

– Carol Benson

- Deputy Director Chemistry Toxicology

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About the Center for Devices and Radiological Health

CDRH Strategic Planning

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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



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CDRH Reports

[CDRH Annual Reports](#)
[CDRH Ombudsman Annual Reports](#)
[CDRH Preliminary Internal Evaluations](#)
[▶ CDRH Plan of Action for 510\(k\) and Science](#)
[Medical Device Technology Forecasts](#)
[Office of Communication, Education and Radiation Programs Annual Reports](#)
[Office of Device Evaluation Annual Reports](#)
[Office of In Vitro Diagnostic Device Evaluation and Safety Annual Reports](#)
[Office of Science and Engineering Laboratories Annual Reports](#)

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 \(PDF - 243KB\)](#)
- [CDRH Preliminary Internal Evaluations -- Volume I: 510\(k\) Working Group Preliminary Report and Recommendations \(PDF - 1892KB\)](#)



Guidances

ACTION	MILESTONE	DATE OF COMPLETION
Evaluation of Automatic Class III Designation (De Novo) Guidance	Draft Guidance	September 30, 2011
510(k) Paradigm Guidance	Draft Guidance	September 30, 2011
510(k) Modifications Guidance	Draft Guidance	June 15, 2011
Clinical Trial Guidance	Draft Guidance	July 31, 2011
Pre-Submission Interactions Guidance	Draft Guidance	November 30, 2011



Internal and Administrative

ACTION	MILESTONE	DATE OF COMPLETION
Establish a Center Science Council	Post Council Charter to FDA Website	March 31, 2011
	Post initial results of 510(k) audit to FDA Website	June 15, 2011
Enhance Training	Develop and implement training on core competencies	August 31, 2011
Leverage External Experts	Post SOP to FDA Website	September 15, 2011



Programmatic and Regulatory

ACTION	MILESTONE	DATE OF COMPLETION
Implement an "Assurance Case" Pilot Program	Start pilot program	March 31, 2011
Establish "Notice to Industry Letters" as a Standard Practice	Post SOP to FDA Website	June 15, 2011
Improve the IDE Process	Complete program assessment	June 30, 2011
Improve Medical Device Labeling	Public Meeting	April 7 - 8, 2011
	Issue proposed regulation	December 31, 2011



Issues to be Referred to the IOM

ACTION	MILESTONE	DATE OF COMPLETION
Rescission Authority	IOM REPORT	SUMMER 2011
Postmarket Surveillance Authorities		
Establish a Class IIb		
Predicate Clarification		
Clarify and Consolidate Regulatory Terms		
Device Review		
Off-Label Use		

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 begun
- ACLA is taking part in the negotiations



Thanks

alberto.gutierrez@fda.hhs.gov