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"Talking with Stakeholders About FDA Modernization"

Open Public Meeting
Center for Devices and Radiological Health
Scripps Research Institute
LaJolla, California

Susan K. Zagame
Vice President for Technology & Regulatory Affairs
Health Industry Manufacturers Association
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General Recommendations

- Focus on core statutory obligations
- Devote resources to high risk devices and new technology-based devices
- Continue to reengineer and implement FDAMA
- Seek additional resources

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#1: Science & FDA Decision-Making

Overall Theme: Ensure appropriate quantum of science

- Company tutorials
- Vendor days
- Cosponsored educational workshops
  - ▸ CRADAs

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#1: Science & FDA Decision-Making

- CME for FDA physicians
- CME equivalent for other staff
- Optimal "collaboration" meetings
  - ▸ Need for continuity
- Outside experts
  - ▸ Need to revise conflict of interest policy

#1: Science & FDA Decision-Making

- Competent scientists
  - Need for deference
- Standards for high risk devices

#2 Exchange & Integration of Scientific Information

Overall Theme: Focus on principles of risk assessment (how to ask the right questions)

#2 Exchange & Integration of Scientific Information

- Optimal use of staff college and staff training
  - "Train the Trainer"
  - Disseminate learning (e.g., e-mail)
  - Diversify attendance
  - Use industry and other experts
- Attention to annual reports

#3 Public Education : Risks and Benefits Balance

Overall Theme: No magic bullet

- Marketplace/Consumer-Driven
- FDA Web Site
  - General guidelines for consumers
  - Links to government/industry sites

#4: Focus FDA Scarce Resources on Greatest Risks

- Device funds: appropriate levels and allocation
- Continuous FDAMA implementation and reengineering, e.g.,
  - Increase exemptions
  - Expand recognized standards
  - Streamline reclassification
  - Optimize use of "collaboration" meetings

#4: Focus FDA Scarce Resources on Greatest Risks

- Industry/Agency education
- Elimination of redundant functions
  - FDA should not become another NIH or NSF
  - Primary role of FDA is *not* to conduct scientific research

#4: Focus FDA Scarce Resources on Greatest Risks

- Continuation of Inspection Initiatives
  - Triage/Recognition of ISO inspections
  - Time-saving mechanisms (e.g., QSIT)
  - Change to biennial inspection requirements

#5: Ongoing Stakeholder Feedback on FDAMA

- Need for true *consultation* not just comments
- Little feedback on comments from industry

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#5: Ongoing Stakeholder Feedback on FDAMA

- Agency & Industry should focus on select issues
  - Most complex (i.e., "least burdensome")
  - Most resource-saving potential
  - Most mutually beneficial

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#5: Ongoing Stakeholder Feedback on FDAMA

- HIMA Questionnaire
  - Ongoing effort
  - Share results with agency

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Conclusions

- Good progress—Room for More
- Need for Meaningful Stakeholder Interaction
- Promise of FDAMA Must be Achieved