

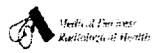
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Themes of FDAMA

**CDRH Meeting To Discuss
Section 406(b) of the
FDA Modernization Act of 1997**

August 18, 1998
Washington, D.C.

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- Collaboration
- More "user-friendly" FDA
- Serious commitment to time frames
- Reduced regulatory burden
- Focus on promotion of public health

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Overall Points to Consider

- "Consultation" = Meeting to discuss, decide, or plan (*Webster's Dictionary*)
 - ▶ connotes more than comments
 - ▶ good opportunity for ongoing dialogue
- Recognition of CDRH's Improvements
- Focus of 406(b): Development of Plan " *bringing the Secretary into compliance with each of the obligations under this Act*"
- Need for strong FDA

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Industry's General Recommendations

- Link function to risks to be prevented (*What is the public health benefit of this function?*)
- Determine cost-benefit of function
- Determine if alternate mechanism exists
- Stop functions with no or little pay-off
- "Stick to the knitting"
- Align resources appropriately
- Give initiatives time to work

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Industry's Specific Recommendations

Maximizing Information about Review Process

- Publish flow chart of internal processes for all submissions
- Make available more templates, prototypes, examples
- Work with industry to promote better understanding

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Maximizing Information about New Products

- New product promotion not a function for FDA
- FDA's role: to refer inquiries
 - ▶ professional societies
 - ▶ physicians
 - ▶ companies
- Consider internet hyperlinks

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Implementing Inspection and Postmarket Monitoring Provisions of the Act

Inspections:

- Support current stratification based on past history, risk of product, etc.
 - FDA should consider ISO certifications in prioritizing and should ultimately harmonize

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Implementing Inspection and Postmarket Monitoring Provisions of the Act

Inspections:

- Support current systemic approach
 - preinspection preparation
- Support education / joint training
 - better mfg. understanding of criteria
 - more focused inspectors

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Postmarket Monitoring

- Support Sentinel System
 - A potentially valuable tool for synergistic learning among all 3 parties
 - Recommend Industry-FDA-User Facility Working Group (Design/Funding)
 - Resource Shift
 - Clear Vision needed
- Support greater use of summary reporting

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Postmarket Surveillance: How to Make it Work

- Limit program to achievable purpose
- Reduce number of subject products (Rescission notice?)
- Better communication between OSE and ODE re: device

Point: Use postmarket tools to reduce premarket requirements

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Postmarket Issues

Tracking

- Base products to be tracked on validated risk model
- Provide opportunity to comment prior to tracking order

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Ensuring Access to Scientific and Technical Expertise

- Appropriate human resource management
- Greater use of consultants
- Deal with conflicts of interest thru disclosure
- Company tutorials
- Vendor days / Reviewer site visits
- Greater communication with professional societies and other organizations
- Graduate student internships

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Ensuring Access to Scientific and Technical Expertise - cont.

- Optimal use of scientific advisory panels (well trained, balanced, clearly defined)
- Use of FDAMA tools
 - ▶ Sec. 408 (Education and Training)
 - ▶ Sec. 409 (Centers for Education and Research on Therapeutics)
 - ▶ Sec. 414 (Interagency Collaboration)
 - ▶ Sec. 415 (Contracts for Expert Review)
- Recognition of limitations of staff
- Industry-FDA Working Group

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Establishing Mechanisms (by 7/1/99) for Meeting Submission Time Frames

- New FDAMA & Reengineering Tools
 - 510(k) paradigm
 - modular PMA
 - exemptions
 - risk-based classification
 - premarket vs. postmarket
 - general vs. specific
 - third party review
 - (add more devices to list; make process clear)

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Establishing Mechanisms (by 7/1/99) for Meeting Submission Time Frames

- Improved submissions through better communication of FDA's expectations
 - ▶ guidance documents
 - ▶ prototypes & examples on web site
- Standards emphasis
 - ▶ Expanded role of industry & FDA
 - ▶ More standards-based guidance documents
- Elimination of unnecessary functions
- Calculation of FDA Review Time
- Industry-FDA Working Group

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Establishment Registration, Device Listing Database

- Internal FDA management issue
- Determination of cost-benefit
- Consider whether *real* purpose can be achieved thru other means (e.g., notification of all orthopedic manufactures thru FDA's web site if generic problem is identified)

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Conclusion

- Use & evolve FDAMA/Reengineering tools
- Work synergistically with industry/others
- Focus activities on high pay-offs for public health

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