CDRH Update

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Director

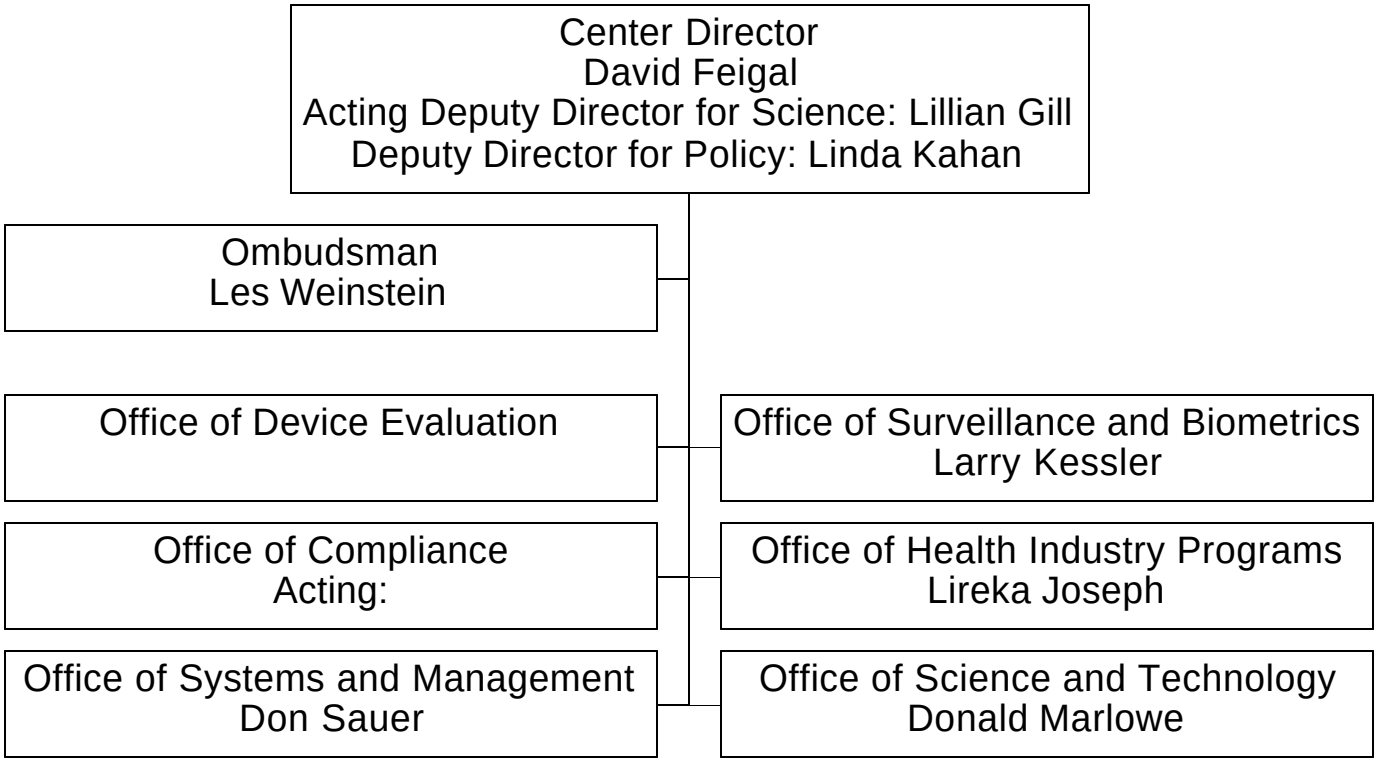
Center for Devices and Radiological Health

FDLI, Washington, DC, June 5, 2000

Overview

- Staffing Update
- International Device Regulation
  - Global Harmonization Task Force
  - International Standards
  - Mutual Recognition Agreements
  - Inspectional Resources
- Least Burdensome

Center for Devices and Radiological Health



Ombudsman

Les Weinstein

- BA Political Science, JD, MPA
- HHS: Medicaid programs, HMOs
- CDRH: Regulations, International areas
- FDA (agency level): Deputy Dir., FOI Staff; Denials & Appeals Officer
- Adjunct Professor, member of DC Bar

Ombudsman

- Investigates complaints and resolves disputes
- Reports directly to the Center Director
- Outreach
- Quality Assurance relating to common problem areas

International Device Regulation

FORCES:

Global Harmonization Task Force

Mutual Recognition Agreements

Standards Conformance

Global Harmonization Task Force

Next Meets: September 18-22, 2000 Ottawa, Canada

Four study groups:

- Regulatory Requirements / Premarket Review
- Device Vigilance / Post-Market Surveillance
- Quality System Requirements and Guidance
- Auditing

www.ghtf.org

Global Harmonization Task Force

Progress continues…

- 12 documents approved, from four study groups
- Formal operating principles being developed
- MOU between GHTF and ISO/TC210 Committee on quality management
  - Approved by ISO/TC210, awaiting approval by GHTF

International Standards

Role in US Device Regulation

- Quality Standards
- Cross-product performance standards
- Product specific standards

Can replace portions of 510(k) applications

- E.g., A mechanical wheel chair 510(k) application can consist of declaration of conformance to 12 standards.

Using Standards to Support SE Decisions in 510(k)s

- FDAMA intended to
  - Encourage using FDA-recognized standards
  - Provide a formal option but not limit past practices
- Declarations are legally binding & enforceable
- Cross-cutting standards used most often
- Least burdensome approach

Using Standards to Support SE Decisions in 510(k)s

Three alternatives:

- FDA recognized standard with a declaration
  - Mfr. has data now
- FDA-recognized standard without declaration
  - Mfr. does not have supporting data at time of submission but will before marketing
- Non-recognized standard
  - Less assurance that standard will be acceptable
  - FDA may need to request additional information

International Standards Organizations

	ANSI	BSI	DIN	Centralized European			CDRH
				CEN	C	ETSI	
Budget (Millions $)	15	293	100	10	4	21	140
Staff	79	4000	1000	115	36	107	1200 Including field
Committees	262	2888	4600	1844	387	64	
Standards	14202	19129	24000	5131	2863	709	500 Recognized

Mutual Recognition Agreements

- MRAs do not harmonize requirements, standards or even tests.

- The goal of MRAs is to allow conformity assessment bodies (CABs) in various regions to do testing and certification that will be recognized in other regions as well as in their own.

- It is expected to lead to the reduction of requirements for multiple accreditations and certifications and the reduction of related costs.

MRA: Scope

Inspections/Audits

- All devices regulated by both parties

Product reviews/evaluations

- For EU CABs, 97 devices covered by FDAMA Third Party Program [510(k)]
- For US CABs, all devices regulated by both parties

Vigilance Reports

- All devices regulated by both parties

MRA: Where are we?

- Both sides evaluated and nominated potential CABs
- We are starting to receive information on EU CABs to evaluate, especially for conflict of interest and qualifications
- Before sending US CAB information to the EC we are awaiting assurance that information will be held confidential

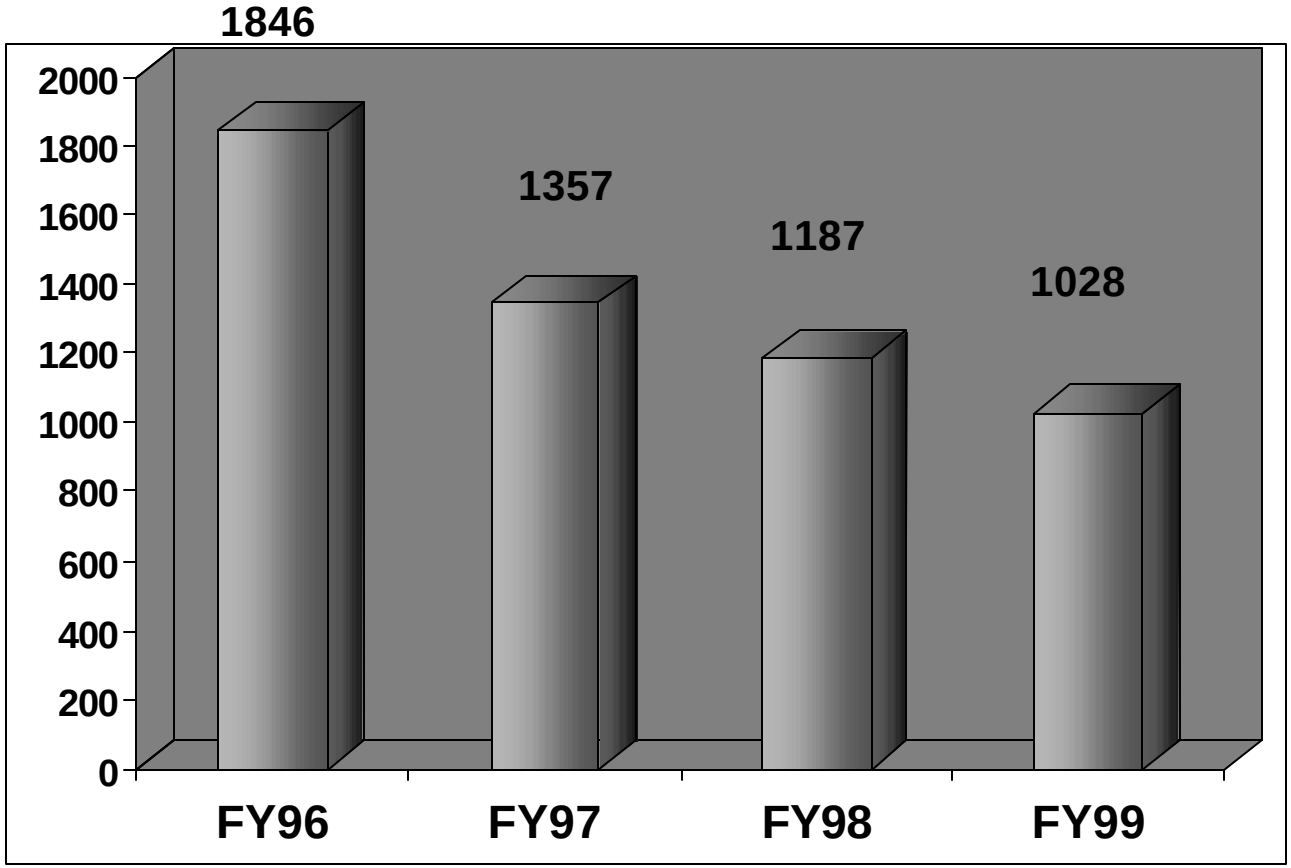
MRA: Where are we?

Training EU CABs

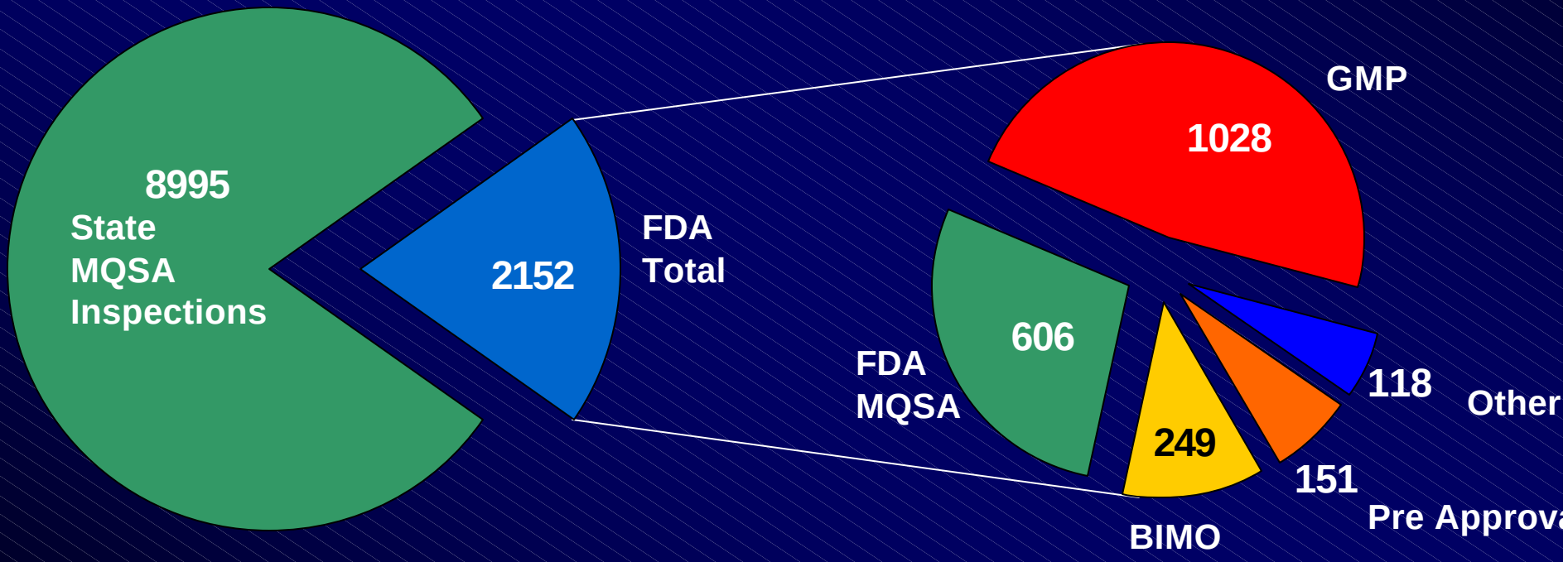
- Classroom training on 510(k) reviews, Quality System Regulation and FDA law, regulations, and procedures completed in 1999
- Practical experience (joint inspections) - 18 conducted by FDA investigators from October 1999 to June 2000

GMP Domestic Inspections FY 96 - FY 99

No. of Inspections



1999 Device Inspections



Least Burdensome Path to Market

Interpretation

- Goal: To get the right information to support submissions -- not more, not less
- Data: Needed and appropriate to product
- Process: Interactive and transparent

Least Burdensome Path to Market

Implementation

- Comments via public meetings, industry task force, dockets, letters,
- Draft guidance released 9/1/1999
  - Focus is clinical data requirements

Least Burdensome Path to Market

Implementation

- Results of small FDA/industry WG
  - see LB web page on Center's FDAMA website: http://www.fda.gov/cdrh/modact/leastburdensome.html
- Training review staff & panel members
- Adding language to correspondence with industry to raise least burdensome concerns