CDRH Overview

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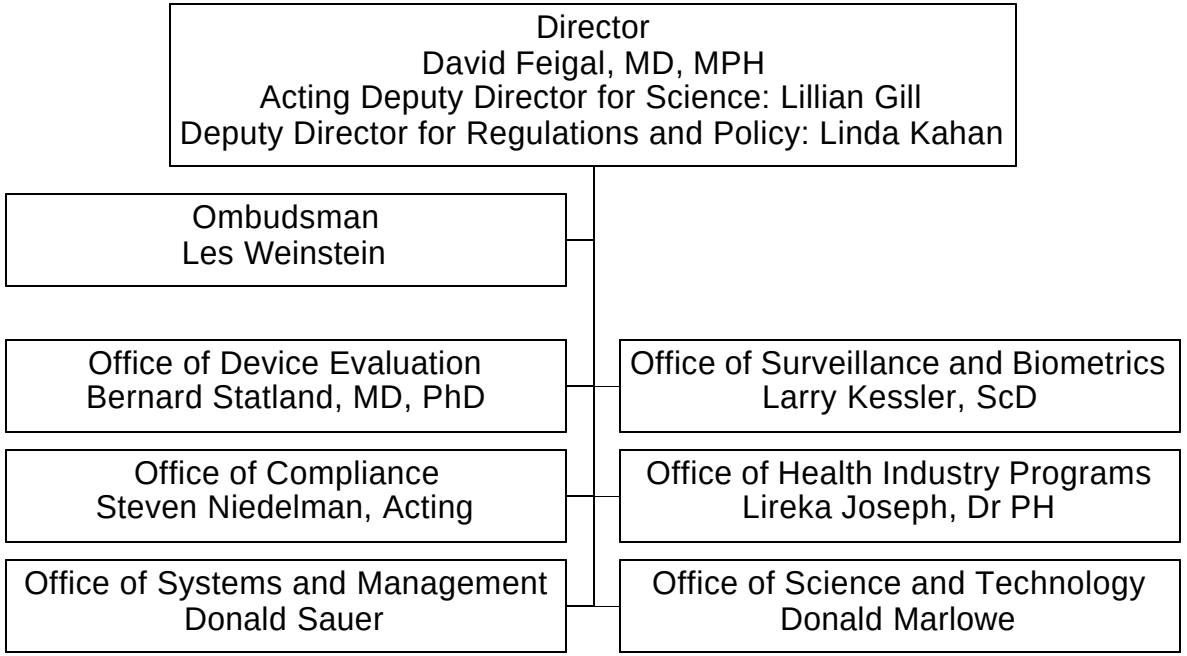
Center for Devices and Radiological Health



CDRH: The Goals

Transparent

Adequately Resourced

Re-engineered

FDAMA-ed

Science Based

Partners with all stakeholders

A Resource Snapshot: Where are we now?

FY 2000: Budget for Center

- $114 million
- 956 employees, excluding MQSA
- expect almost 10,000 submissions for year
- More than 50% of Center resources devoted to reviews

Impact of FY 2000 Appropriations

- **Center absorbs $3.7M pay raise**
- **$6.2M CDRH increase for device review**
- **$1M mandate on reuse of devices (unfunded)**
- **Floor of [3] $55.5M / 522 FTEs FDA-wide for premarket review**
- **Further reduction in Device Field Force**
- **Specific performance goals for faster review**
- **No increase for MedSun, standards, or science**

Our FY99 Performance for Submissions

- **PMAs and HDEs**
  - **First actions for PMAs within 180 days, for HDEs within 75 days - 74 %**
- **PMA supplements**
  - **Final action within 180 days - 100 %**
- **510(k)s**
  - **Completed final action within 90 days - 76 %**
  - **Completed first action within 90 days - 100 %**
- **IDEs**
  - **Approvals made during 1st review cycle - 68 %**

Performance: 510(k)s - Alternatives

Type of 510(k)	FY99 Reviews Completed 12 months	Average Total Time (days)	FY00 Reviews Completed 1st 9 months	Average Total Time (days)
Abbreviated	75	99	75	60
Special	361	29	389	33
3rd party	29	57	33	60
Traditional	4155	108	2637	115

FY 01 Budget Outlook

Congressional actions so far

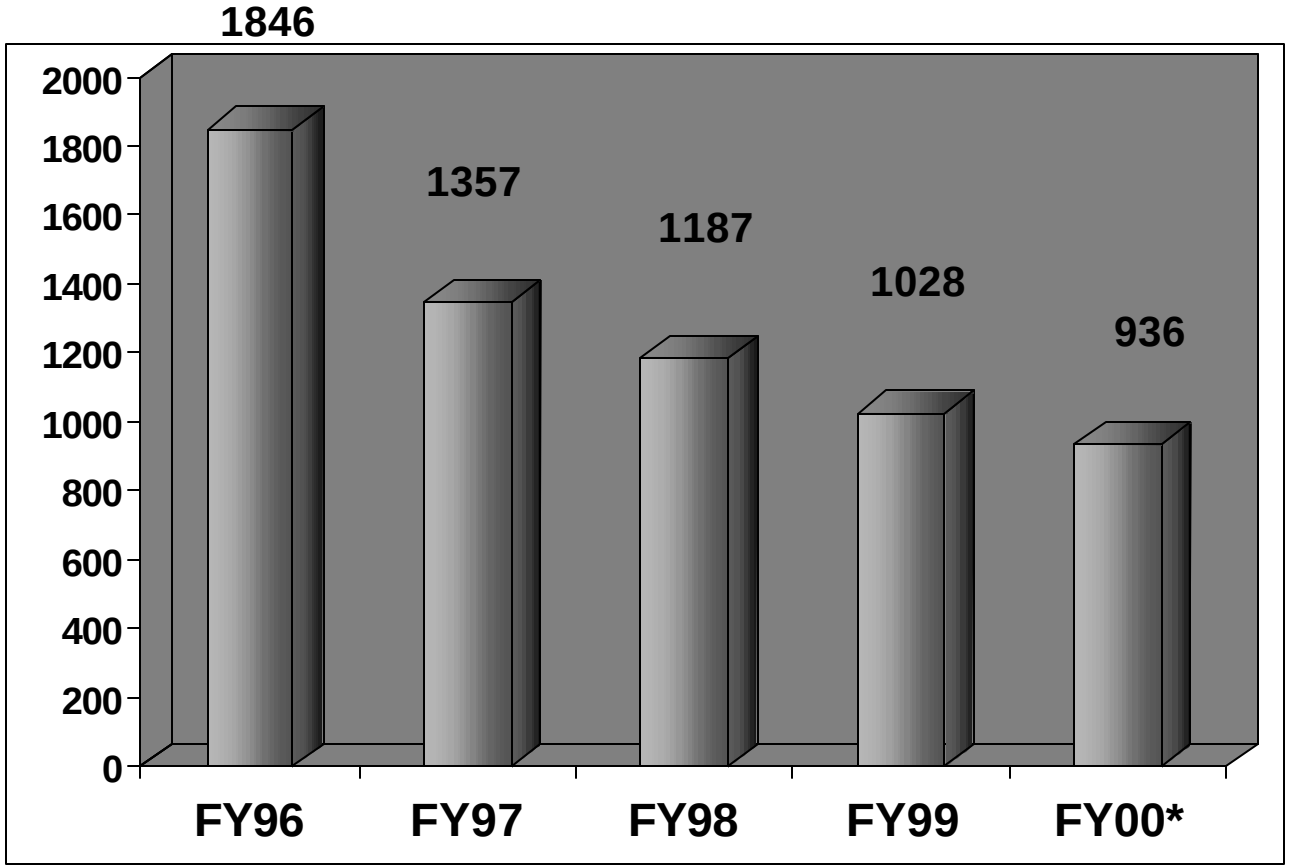
- $5.4M increase for device review targeted for reuse of single use devices, genetic testing
- $2.3M for standards
- Only $2M for inspections
- Increases small -- we still have to absorb a 3.5% payraise and other inflation costs
- No increase for MedSun

Resource Challenges

- **Resource erosion from recent years of relatively flat budgets**
- **Payroll and inflation costs cut operating budget below acceptable minimum**
- **10% fewer CDRH employees since FY96**
- **Performance improvements in device review bought at the expense of other programs**
- **Major performance gaps in other areas: reuse, human research protections, bioterrorism**

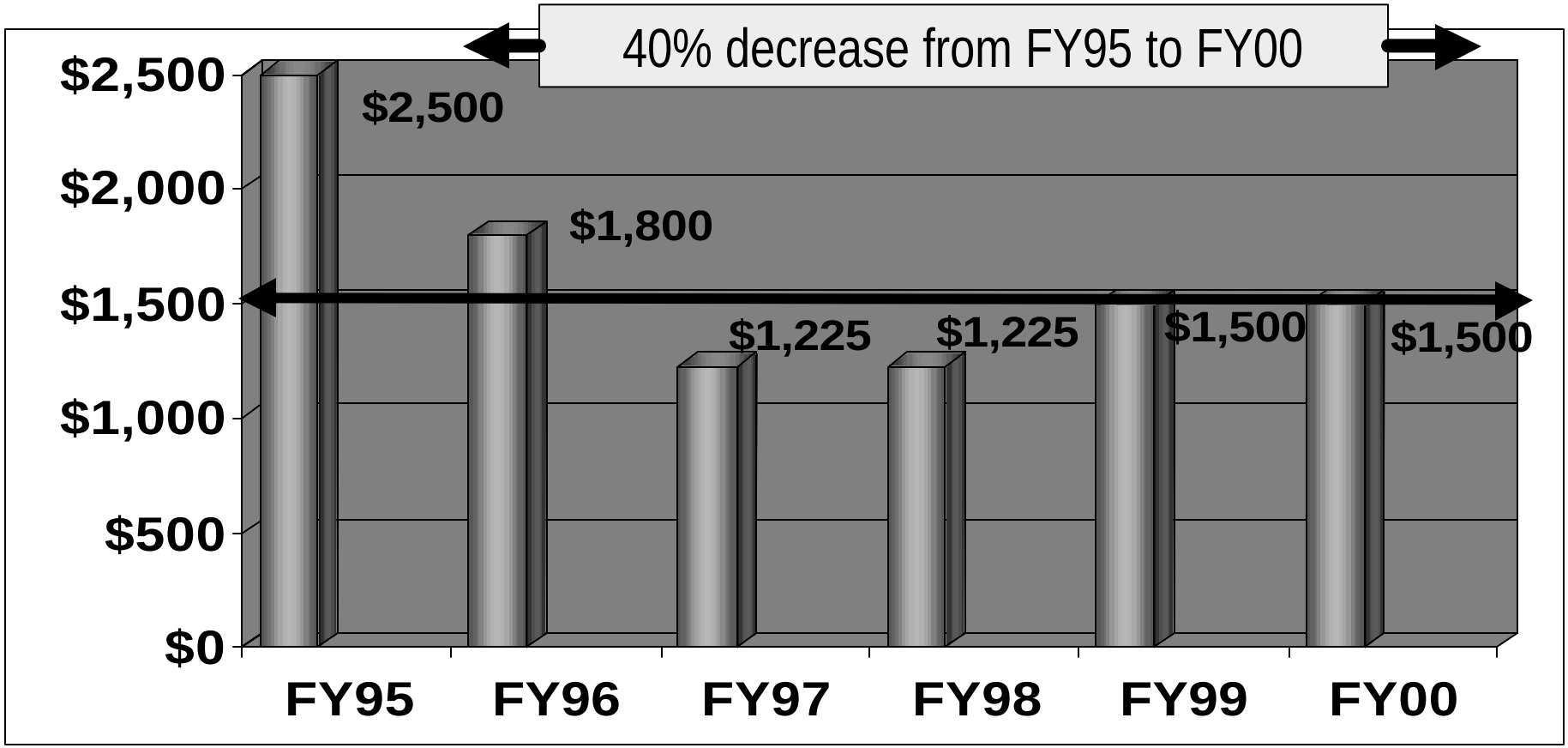
GMP Domestic Inspections FY 96 - FY 00

No. of Inspections



*Projected

CDRH Has Reduced Its Operating Support for Office FTEs by 40% FY95-FY00



Performance Goals

Goal	FY98 Perf.	FY 99 Perf.	FY00 Goal	FY01 Goal w/ increase
PMAs & HDEs Complete review: ▪ **PMAs 1st action w/in 180 days** ▪ **HDEs action within 75 ays**	**80%**	**63%**	**85%**	**90%**
PMA supplements • **Complete final action w/in 180 days**	**100%**	**100%**	**85%**	**90%**
510(k)s ▪ **Complete final actions w/in 90 days**	**69%**	**76%**	**65%**	**75%**

Performance Goals

Goal	FY98 Perf.	FY 99 Perf.	FY00 Goal	FY01 Goal w/ increase
Inspections: ▪ **Improve domestic class II & III inspection coverage**	**33%**	**30%** **(no class I)**	**24%** **(no class I)**	**28%** **(no class I)**
▪ **Improve foreign class II & III manufacturer device coverage**	**14%**	**10%**	**9%**	**10%**
Reporting adverse events **Develop MedSun System for injury reporting based on representative user facilities**	**Evaluate pilot**	**0**	**Start phase 1** **(no action)**	**Start phase 1, expand concept**

How Do We Get From Here to There?

- **Build on FDAMA and reengineering initiatives to efficiently regulate all aspects of the device life cycle**
- **Continue quality and training initiatives to build our capacity**
- **Develop new ways to share information so that we can be sure all our decisions are based on good science**

For example…
Improve submissions process:

- **Fully implement least burdensome provisions**
- **Encourage use of determination, agreement, and 100-day meetings**
- **Develop & use standards**
- **Build third party review program**
- **Expand use of reengineered, nontraditional submission mechanisms**
- **Enhance credibility of dispute resolution**
- **Leverage and partner to build our capacity**

We’re in this together