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# PDUFA IV Public Meeting

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**November 14, 2005**

**Natcher Center**

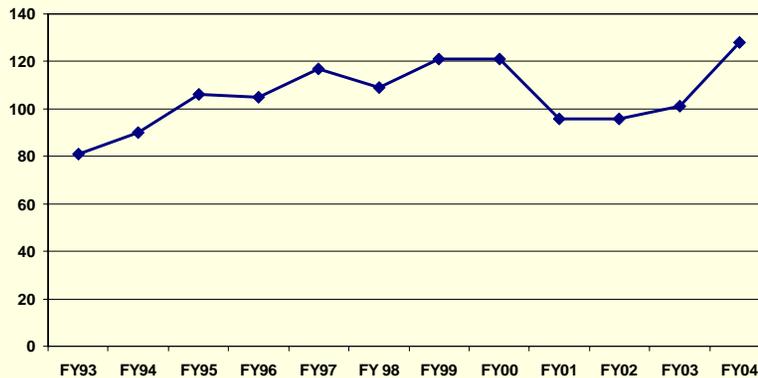
# Outline

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- CDER Submission Trends
- Agency/Sponsor Meetings – Impact
- New life-saving drugs - Faster
- CDER expert staff – More and better
- Speed vs. Safety – The evidence

# CDER: Increases in all types of applications & supplements have resulted in increase in amount of work over duration of PDUFA program – PDUFA III more stable

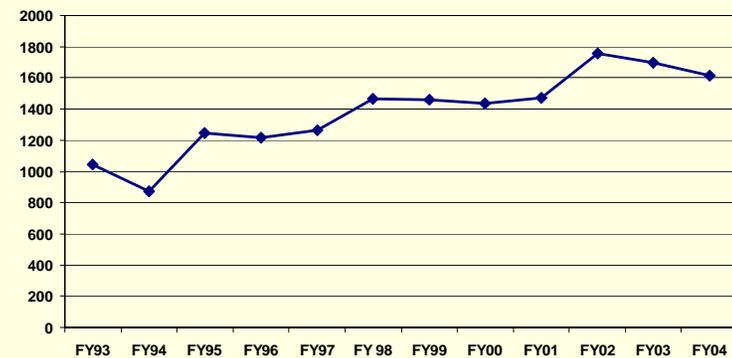
### NDA's Filed



### Efficacy Supplements

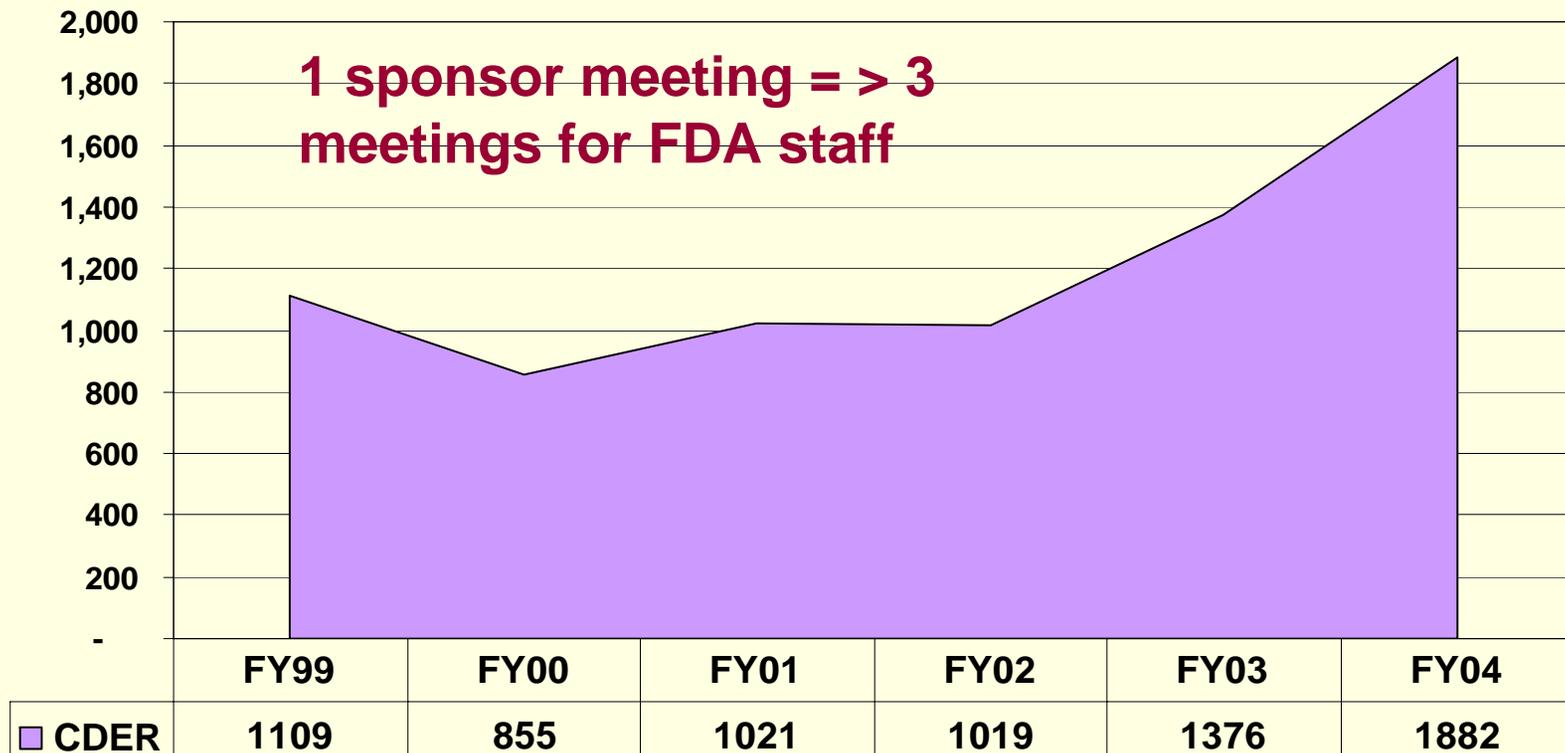


### Manufacturing Supplements



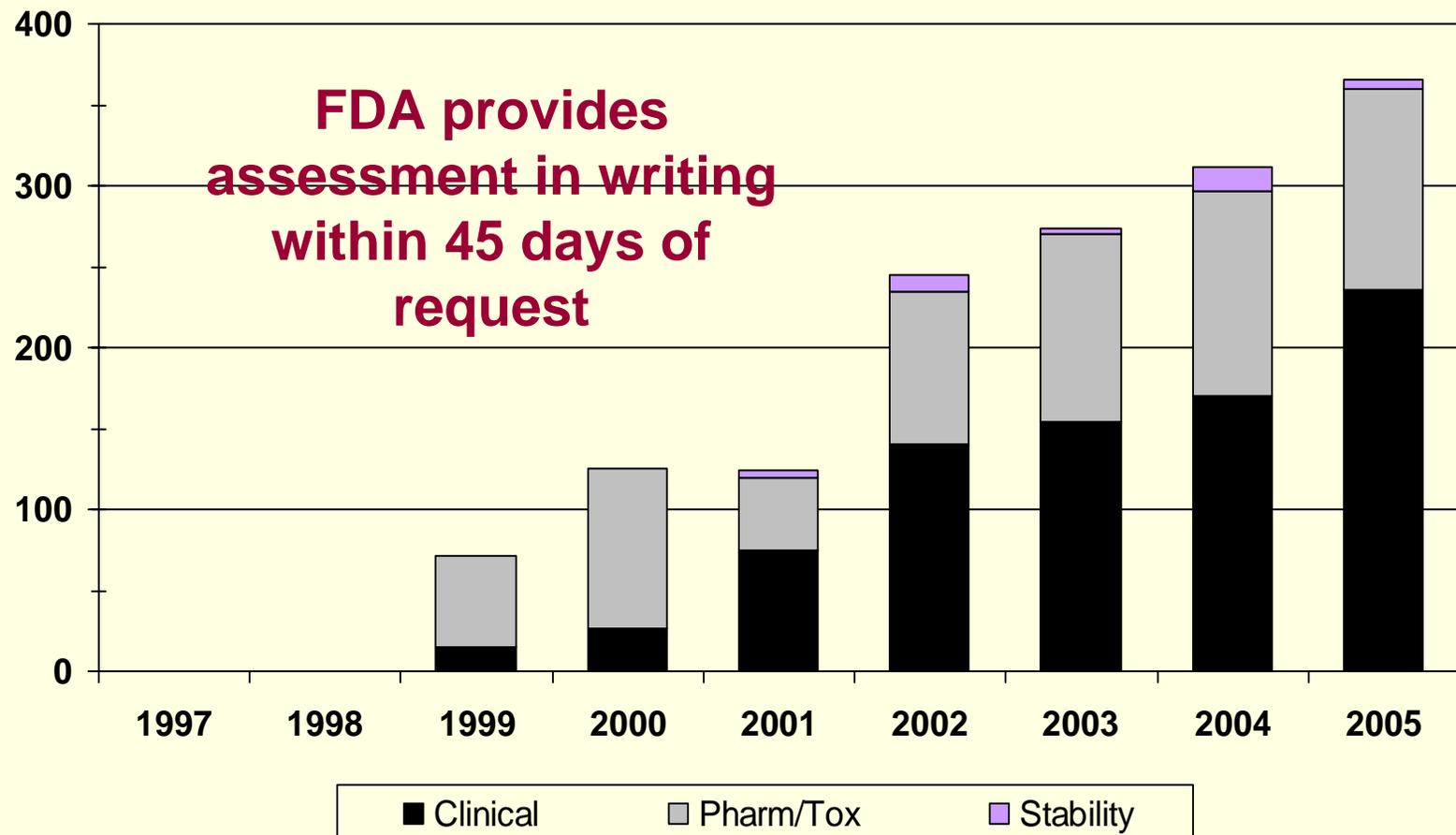
# Sponsor-Requested Meetings Have Increased by > 50% Under PDUFA III

## Number of Meetings Scheduled



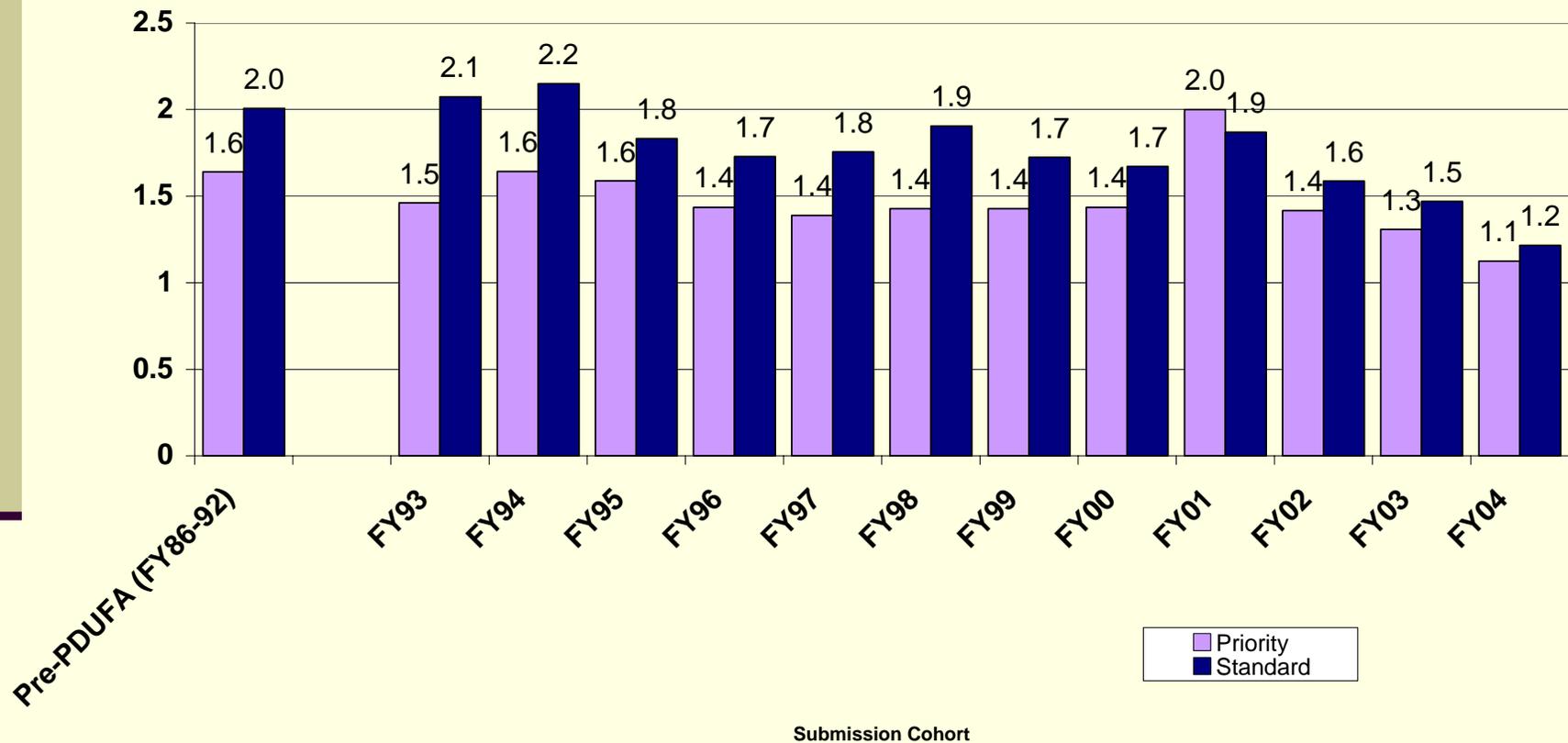
# CDER Base Workload Data

## Special Protocol Assessment By Type



# FDA Guidance and Consultation Has Improved Quality; Fewer Review Cycles Needed

## Average Cycles to NDA Approval



# New life-saving drugs have reached patients sooner

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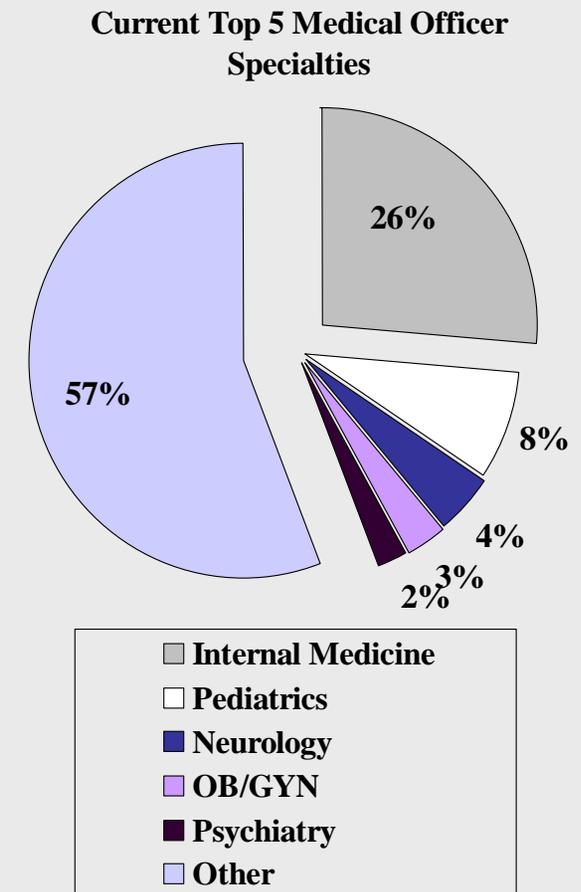
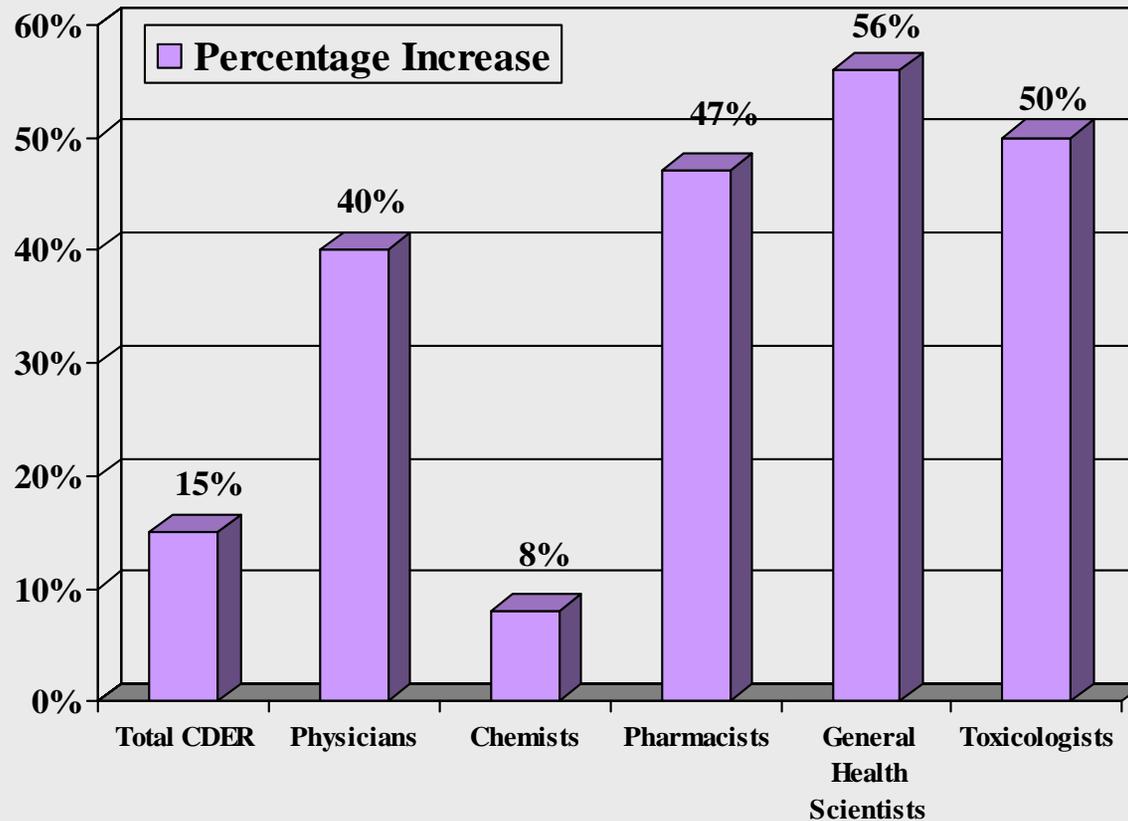
- The public has gained access to 1,010 new products under PDUFA.
- Of these products, 226 were priority drugs that represent significant therapeutic advancements.
- CDER approvals included:
  - 59 Cancer-related products
  - 144 Drugs for infections
  - 63 Drugs HIV and Hepatitis viruses
  - 73 Cardiovascular Drugs

# PDUFA III- examples of progress

## Better drugs for health

Gleevec Arranon	Chronic Myeloid Leukemia Leukemia & Lymphoma
Radiogardase	Radiation Contamination
Nameda	Alzheimer's Disease
Fuzeon Reyataz	HIV in children, once-daily HIV treatment
Campral	Alcoholism
Bidil	Heart Failure in Blacks

# PDUFA has allowed CDER to dramatically increase scientific expertise across all professional areas



# PDUFA Safety Investments

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- 50 % of CDER resources spent on drug safety activities
- Lots more to do, but safety investments have increased under PDUFA program
- CDER reorganization, appropriated funding earmarks and increased focus on safety in PDUFA IV will result in continued improvements in pre and post-market safety.
- Scientific investments needed for fundamental improvements.
- Researchers find no difference pre and post-PDUFA in drug withdrawal (Tufts, MIT)

# Summary

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- PDUFA program has dramatically contributed to public health and improved drug review
- CDER expertise substantially improved
- Advances in safety made but more needed
- No evidence of relationship between advances in speed and safety