2006 GPhA Annual Meeting

Office of Generic Drugs Update

Gary J. Buehler, R.Ph, Director

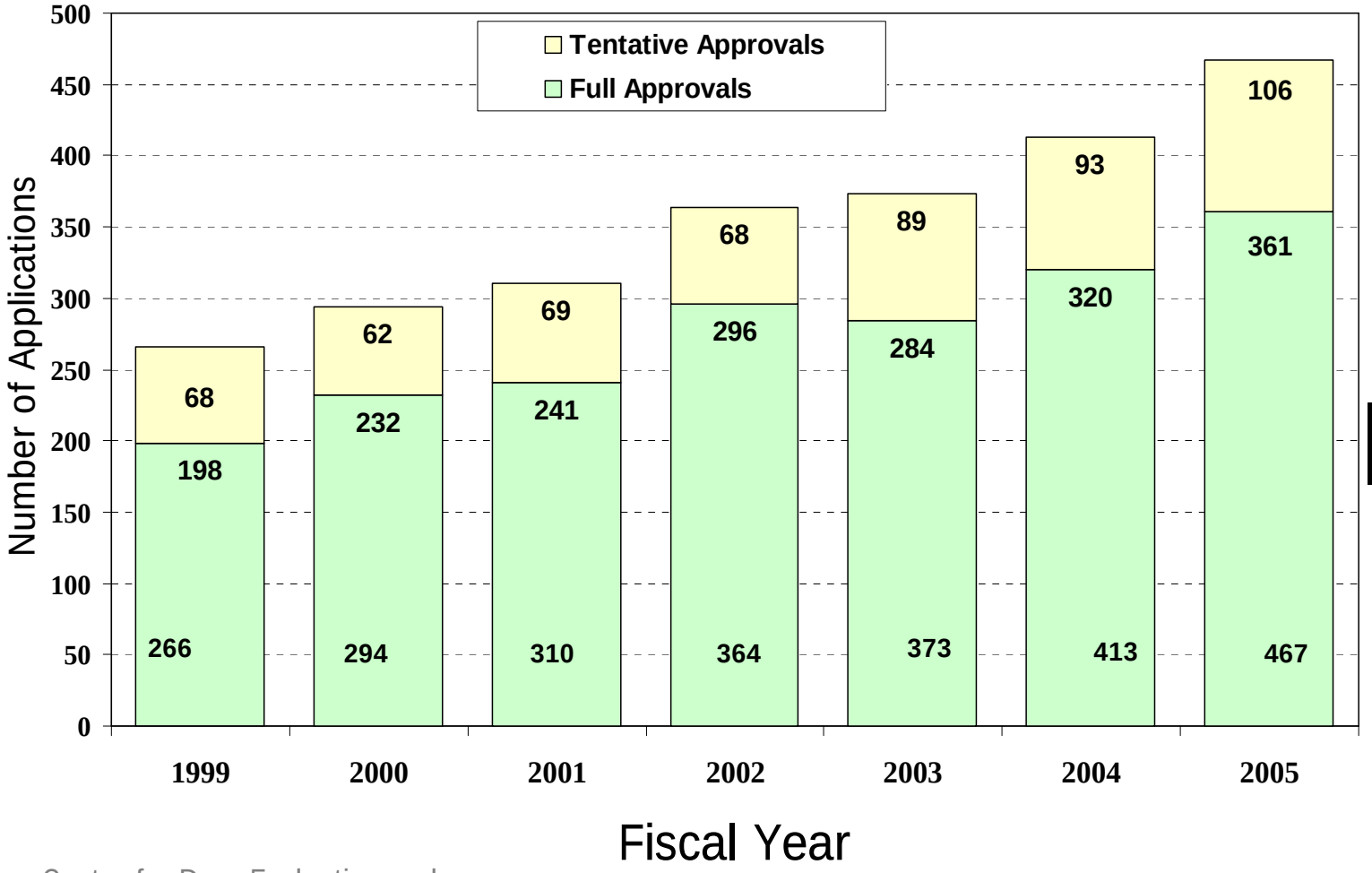
Office of Generic Drugs, FDA

February 18, 2006

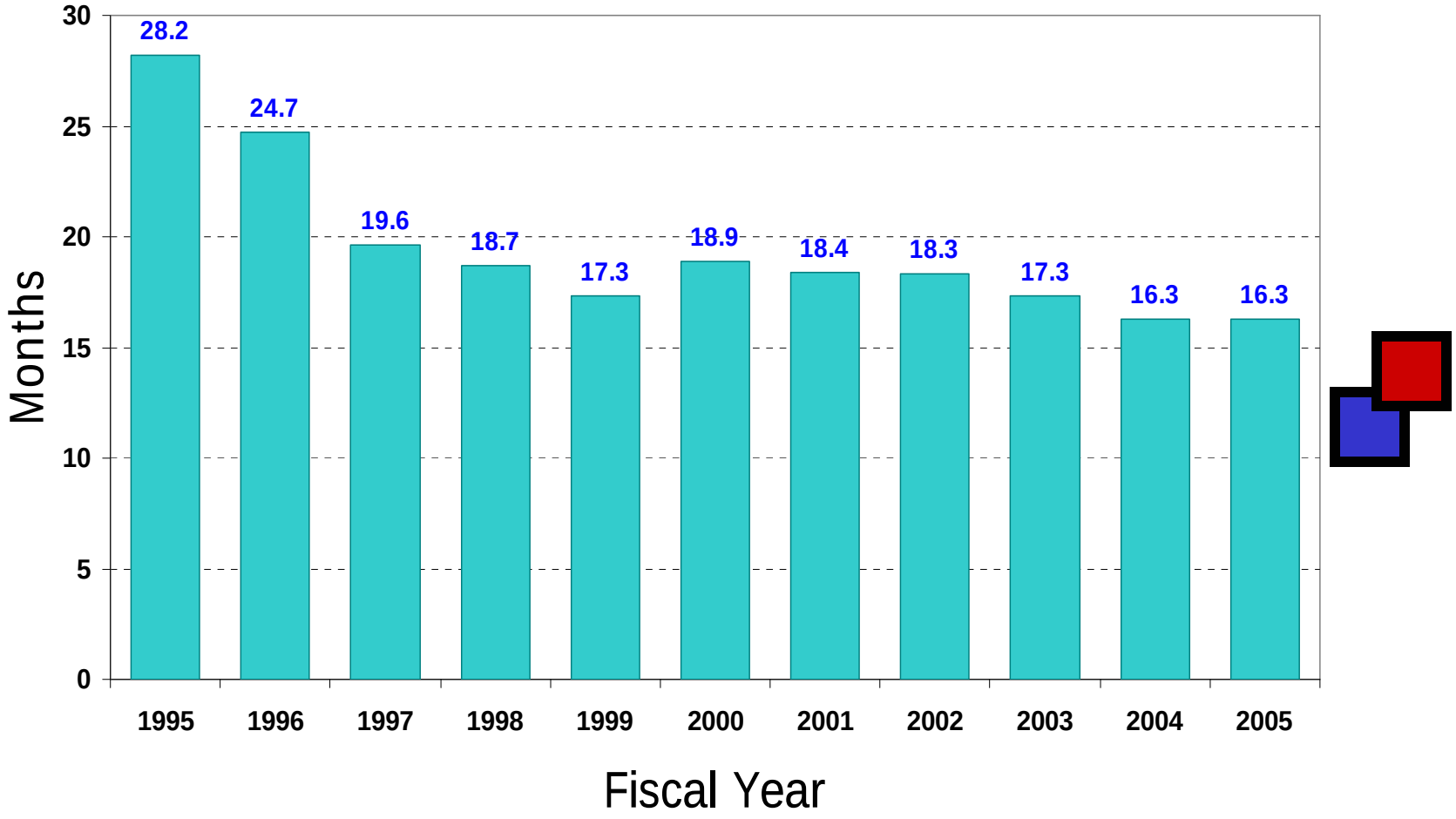
Productivity and Statistics

- Record Receipts of Applications
- Approvals (trying to keep up)

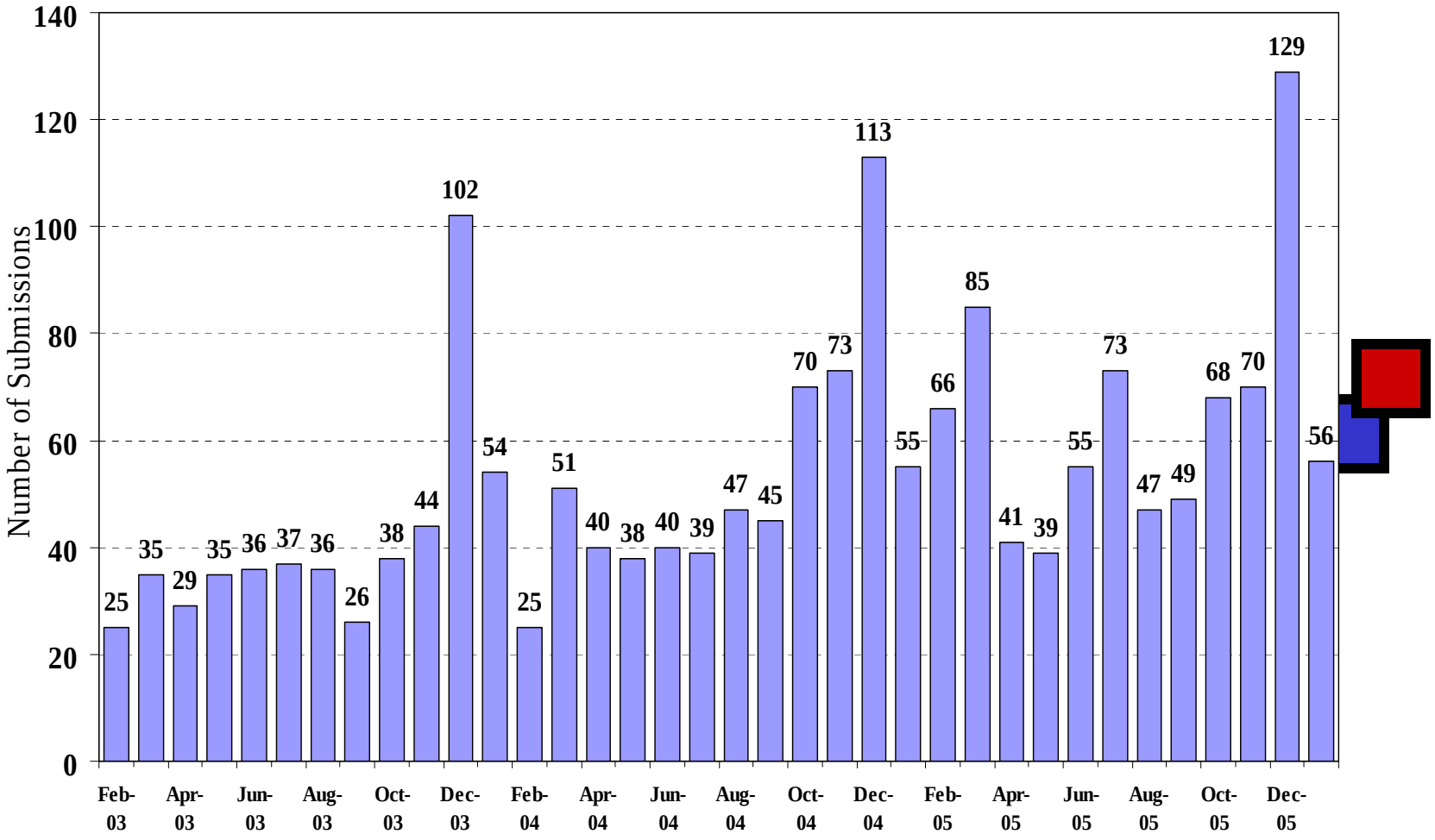
Approvals and Tentative Approvals



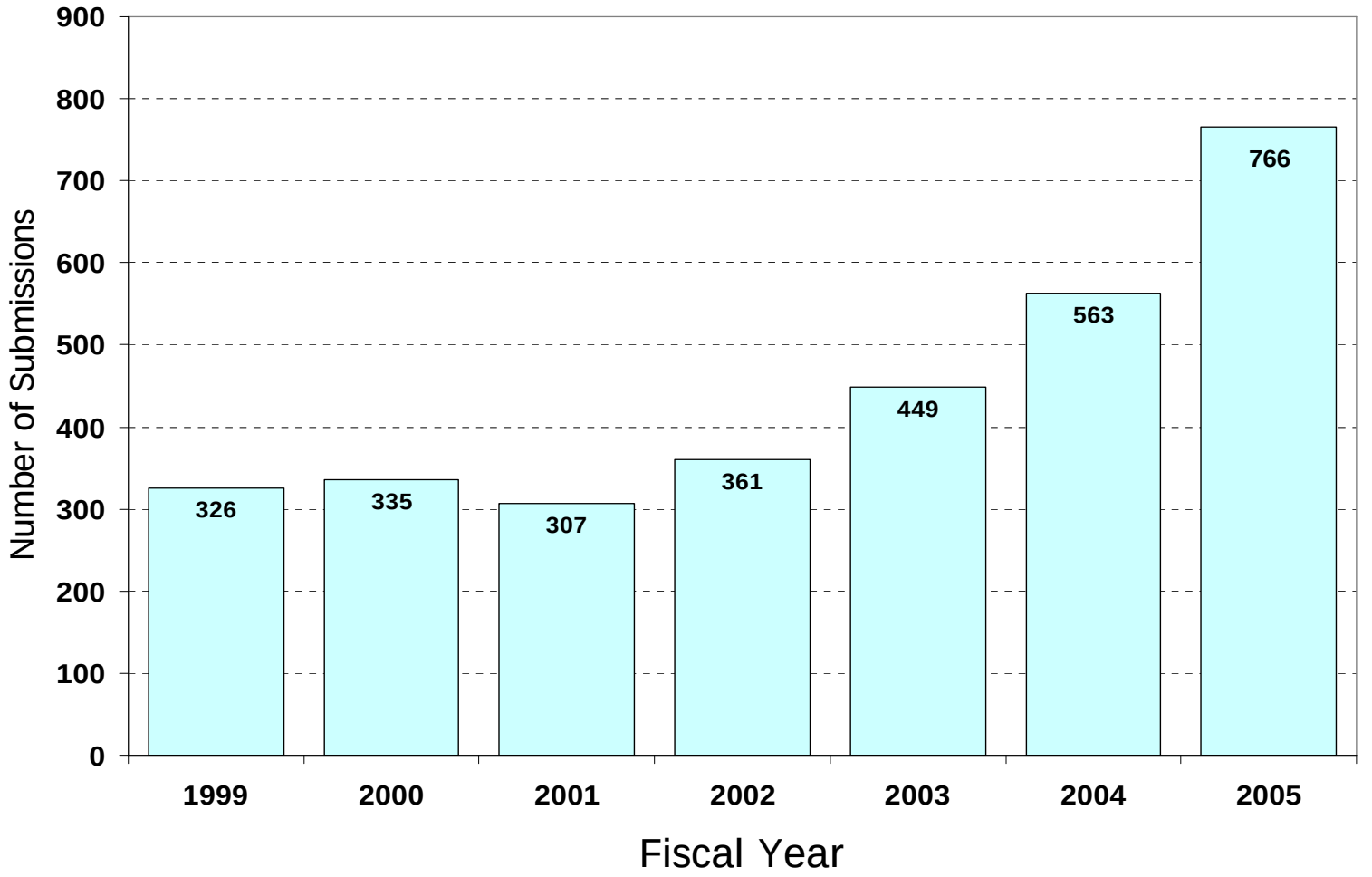
ANDA Approval Times - Median



Receipts by Month - Original ANDAs



Receipts of Original ANDAs



Research

- Ongoing topics
  - Skin Stripping Methods
  - Inhaled Corticosteroids
  - Bioequivalence of Locally Acting GI Drug
  - Extension of Bio Waivers
- Limitations expected in the future

Application Review Backlogs

- Chemistry
  - Div I - ~122 days Div II - ~145 days
    Div III - ~121 days
- Bioequivalence ~450 days
- Clinical ~360 days
- Microbiology ~530 days

(Original Applications)

Budget

- Review of generic drugs remains a high priority for the agency
- 2006
  - 10 additional FTEs were given to OGD on January 27, 2006
  - *Washington Post* article - February 4, 2006
- 2007
  - Uncertain

Moves

- OGD is still projected to move to White Oak within the next 2 years
- OGD Immediate Office has moved to 7519 Standish Place (MPN4)
- OGD received a conference room in MPN4 that can seat about 200
- OGD MAIN: **240-276-9310**

  FAX: **240-276-9327**


Crabbs Branch Way
Standish Pl
Standish Pl
E Gude Dr
E Gude Dr

Approaches to Streamline the Review Process

- Full utilization of telephone communication whenever possible
- Emphasis on fewer review cycles
- Continued use of enhancements, e.g.:
  - Early DMF review
  - Early dissolution review
  - Clustered application reviews

Approaches to Streamline the Review Process

- Internet access to dissolution and bioequivalence information (frees up reviewer time)
- Adoption of Question based Review and CTD format for ANDAs
  - Is a learning curve for industry and OGD
  - Potential to decrease supplement workload

Approaches to Streamline the Review Process

- Possible use of secure e-mail to communicate
- Revision of first-in, first-reviewed policy to utilize review expertise

Additional Demands on OGD

- President's Emergency Plan for AIDS Relief (PEPFAR)
- Structured Product Labeling Review
- Response to requests for information (over 1,550 received in 2005)

A Word About "Refuse to Receive" (RTR) Applications

- Inactive Ingredient issues causing RTR are on the decline
- Bioequivalence issues or multiple deficiencies (> 3) on the rise
- Multiple deficiencies appear to correlate with firms with few ANDAs

Expediting Citizen Petitions

- Office of Regulatory Policy (CDER) increasing early interaction and more directed questions
- Early meetings to discuss complex or controversial petitions
- Regular discussion of priorities
- Setting of goal dates
- Utilization of the OGD Scientific Staff

Electronic Submissions of ANDAs

- Analysis of receipts of originals from Sep to Dec 2005
  - 268 ANDAs with accompanying e-submission
    - Represents 77 firms
  - 15 ANDAs were fully electronic
    - Represents 6 firms
  - 6% - but still an improvement!
  - Remainder were partial, i.e., BE & Labeling

What Can You Do to Help?

- Complete applications with background of full development work
- Use the available information from the Internet
  - Dissolution
  - Bioequivalence information
  - Guidances
- Respond in a ***timely*** manner to prevent multiple cycles

Center for Drug Evaluation and Research

Office of Generic Drugs

HFD-600
7500 Standish Place
Rockville, MD 20855
240-276-9310