

GPhA Technical Advisory Committee

Office of Generic Drugs

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Director, Office of Generic Drugs

February 16, 2006



Moves

- OGD is still projected to move to White Oak sometime in 2007
- 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**

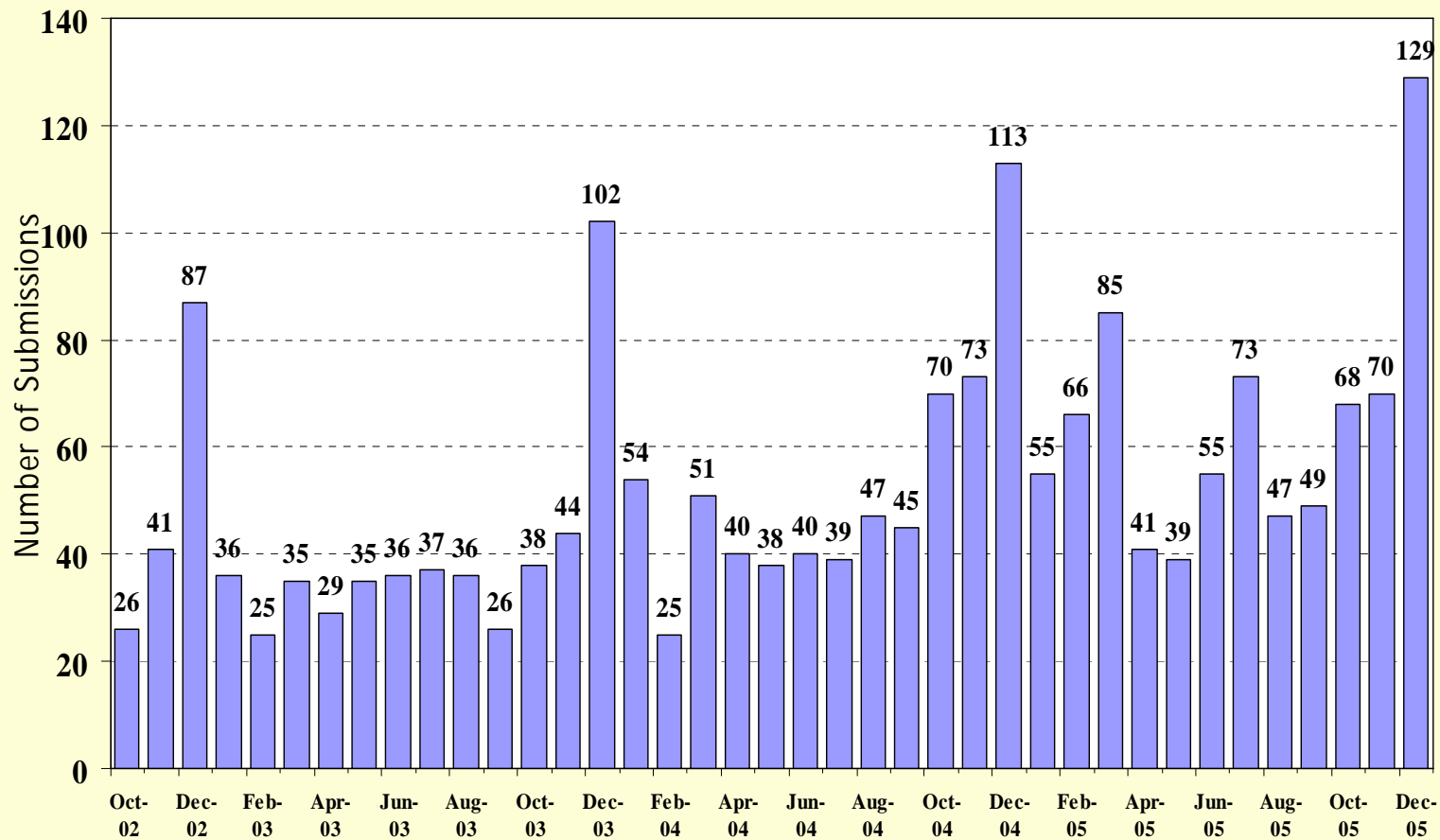


Productivity and Statistics

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

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Receipts by Month - Original ANDAs

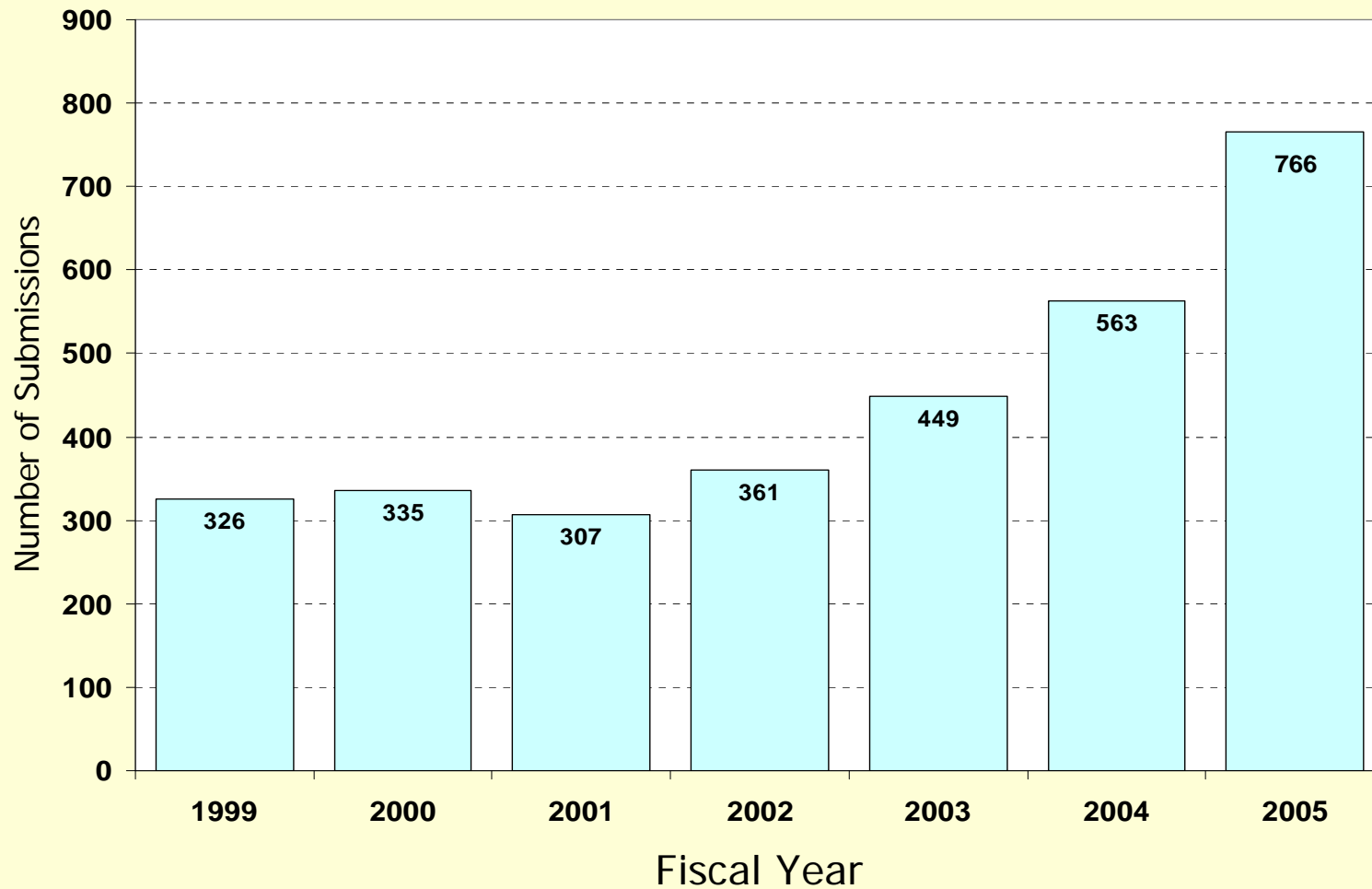


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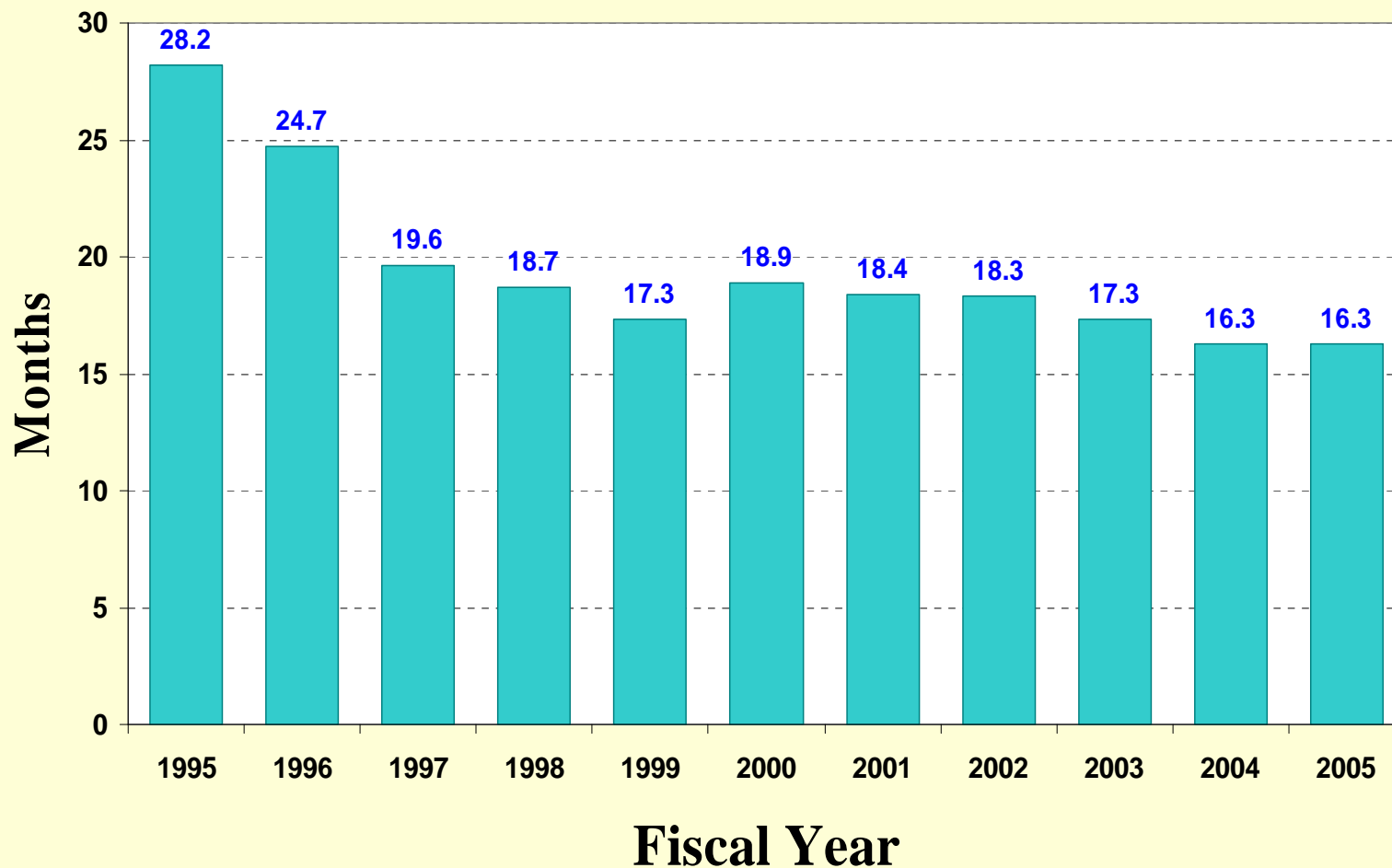
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Receipts of Original ANDAs



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ANDA Approval Times - Median



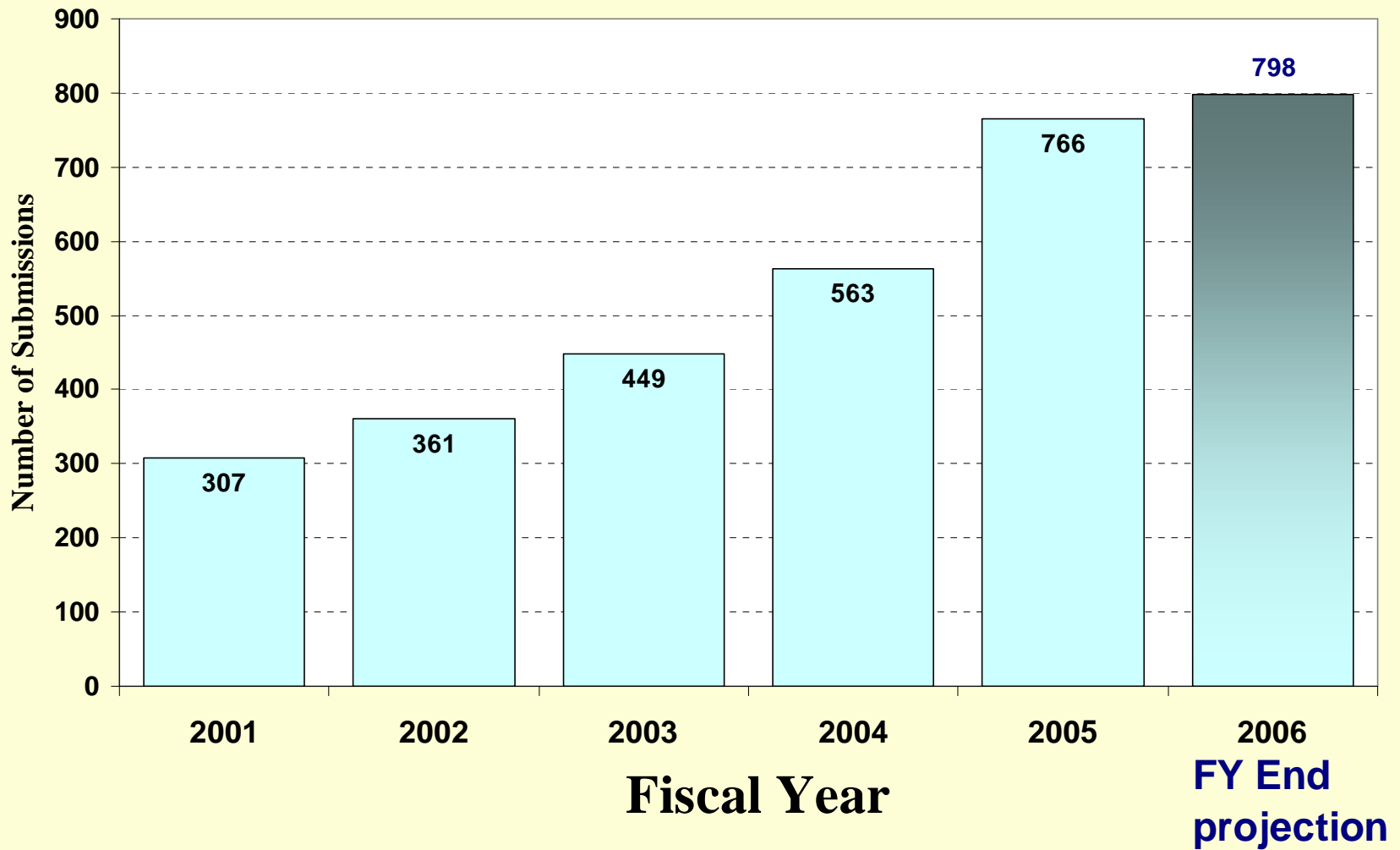
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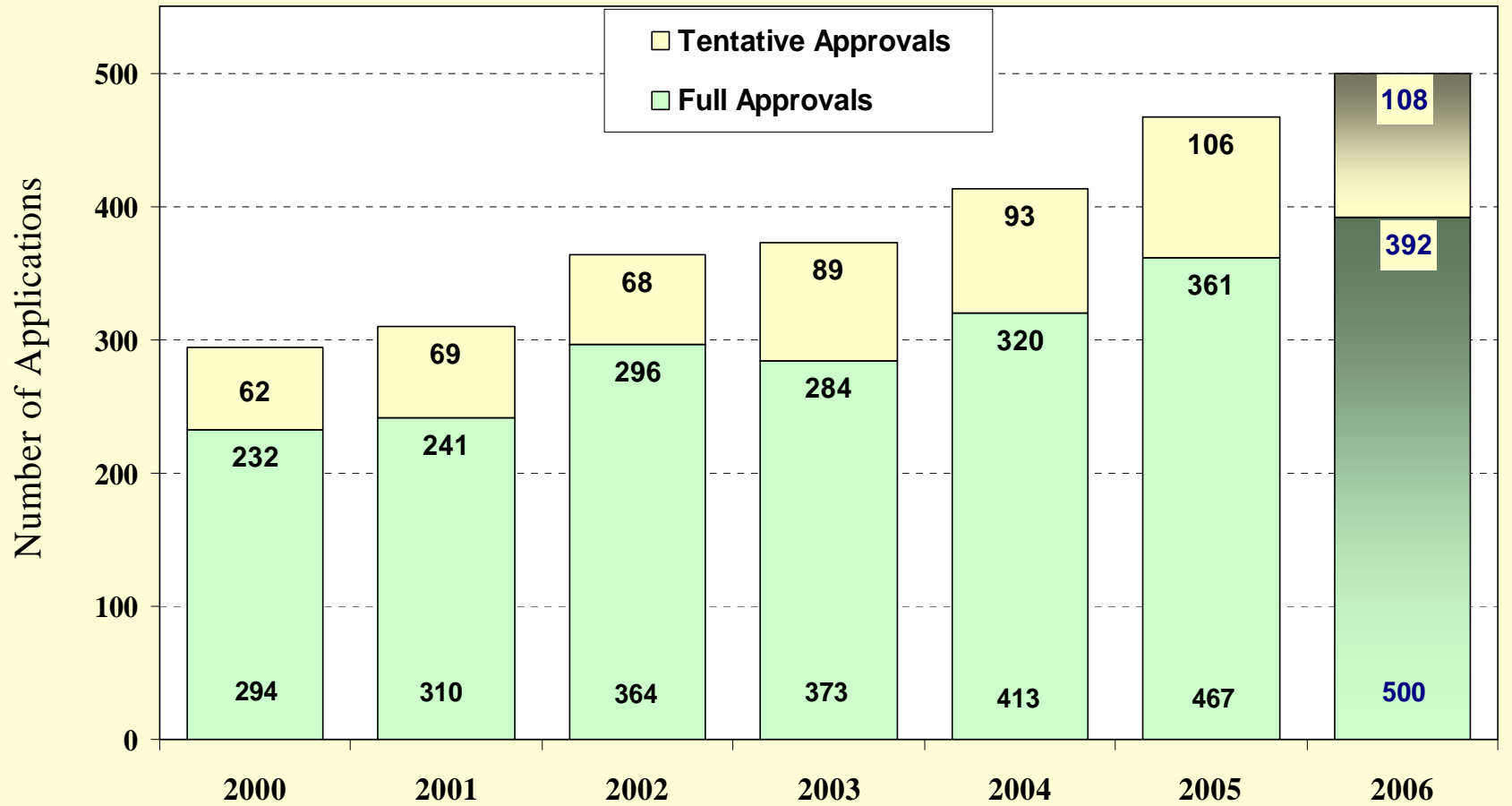
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Receipts of Original ANDAs



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Approvals and Tentative Approvals



**FY End
projection⁸**

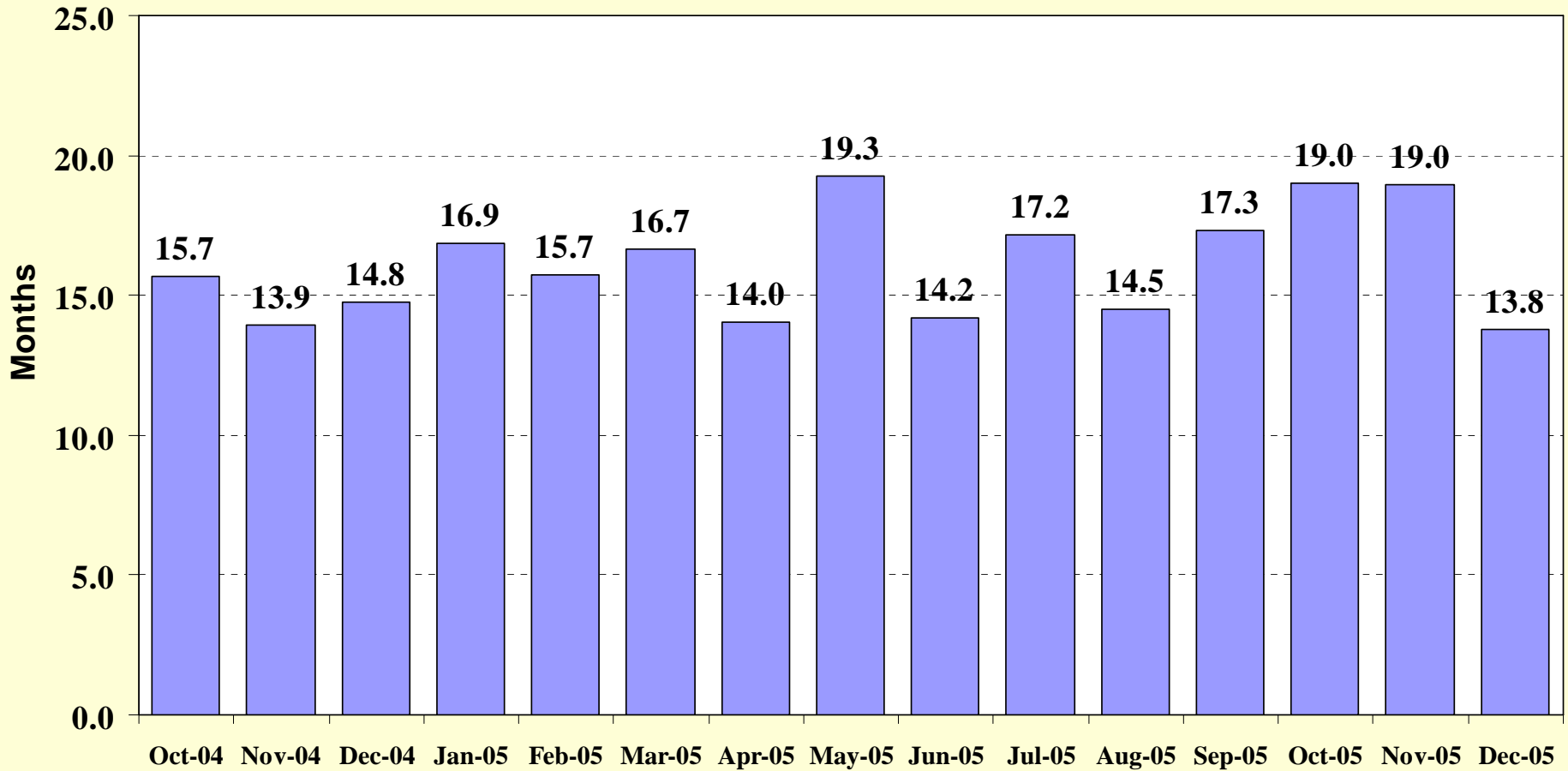
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Median Approval Times

By Month





Chemistry Review Backlog

- Division I ~ 122 days
- Division II ~ 145 days
- Division III ~ 121 days



Bioequivalence Review Backlog

● Currently ~450 days

Clinical Team Backlog

● Currently ~360 days



Microbiology Review Backlog

- Currently ~530 days for original ANDAs
- ~210 days for ANDA supplements



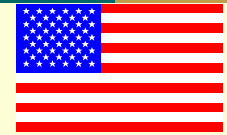
Expediting Citizen Petitions

- 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



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



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