Office of Generic Drugs

Gary J. Buchler, R.Ph.
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)
Receipts of Original ANDAs

Office of Generic Drugs

Fiscal Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>326</td>
</tr>
<tr>
<td>2000</td>
<td>335</td>
</tr>
<tr>
<td>2001</td>
<td>307</td>
</tr>
<tr>
<td>2002</td>
<td>361</td>
</tr>
<tr>
<td>2003</td>
<td>449</td>
</tr>
<tr>
<td>2004</td>
<td>563</td>
</tr>
<tr>
<td>2005</td>
<td>766</td>
</tr>
</tbody>
</table>

February 16, 2006

Center for Drug Evaluation & Research
Office of Generic Drugs

ANDA Approval Times - Median

Fiscal Year

February 16, 2006

Center for Drug Evaluation & Research

6
Office of Generic Drugs

Receipts of Original ANDAs

Fiscal Year

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>307</td>
</tr>
<tr>
<td>2002</td>
<td>361</td>
</tr>
<tr>
<td>2003</td>
<td>449</td>
</tr>
<tr>
<td>2004</td>
<td>563</td>
</tr>
<tr>
<td>2005</td>
<td>766</td>
</tr>
<tr>
<td>2006</td>
<td>798</td>
</tr>
</tbody>
</table>

February 16, 2006 Center for Drug Evaluation & Research
Office of Generic Drugs

Approvals and Tentative Approvals

Fiscal Year

Number of Applications

2000 2001 2002 2003 2004 2005 2006

Fiscal Year

Tentative Approvals
Full Approvals

FY 2006 projection

Center for Drug Evaluation & Research

February 16, 2006
Office of Generic Drugs

Median Approval Times

By Month

February 16, 2006
Center for Drug Evaluation & Research
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

February 16, 2006
Center for Drug Evaluation & Research
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