Update from the Office of Generic Drugs

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Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food & Drug Administration
March 2, 2004
Office of Generic Drugs

Full and Tentative Approvals of ANDAs

Fiscal Year

Number of Applications:

- 1997: (306) Full, (256) Tentative
- 1998: (249) Full, (19) Tentative
- 1999: (266) Full, (68) Tentative
- 2000: (294) Full, (232) Tentative
- 2001: (310) Full, (241) Tentative
- 2002: (364) Full, (296) Tentative
- 2003: (373) Full, (284) Tentative
Office of Generic Drugs

MEDIAN Approval Times -- ANDA ORIGINALS

As of September 30, 2003

Center for Drug Evaluation & Research
Office of Generic Drugs

Receipts of Original ANDA Applications

<table>
<thead>
<tr>
<th>Fiscal Year Totals</th>
<th>Number of Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>335</td>
</tr>
<tr>
<td>1998</td>
<td>346</td>
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<tr>
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<td>326</td>
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<tr>
<td>2000</td>
<td>335</td>
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<tr>
<td>2001</td>
<td>307</td>
</tr>
<tr>
<td>2002</td>
<td>361</td>
</tr>
<tr>
<td>2003</td>
<td>449</td>
</tr>
</tbody>
</table>

Center for Drug Evaluation & Research 4
Office of Generic Drugs

Receipts of Original ANDAs
By Month

Number of Submission:

- May-01: 15
- Jun-01: 24
- Jul-01: 22
- Aug-01: 25
- Sep-01: 26
- Oct-01: 35
- Nov-01: 62
- Dec-01: 30
- Jan-02: 19
- Feb-02: 30
- Mar-02: 24
- Apr-02: 30
- May-02: 31
- Jun-02: 30
- Jul-02: 22
- Aug-02: 29
- Sep-02: 26
- Oct-02: 41
- Nov-02: 87
- Dec-02: 36
- Jan-03: 35
- Feb-03: 35
- Mar-03: 36
- Apr-03: 37
- May-03: 36
- Jun-03: 38
- Jul-03: 38
- Aug-03: 44
- Sep-03: 26
- Oct-03: 38
- Nov-03: 55
- Dec-03: 102

Center for Drug Evaluation & Research
Office of Generic Drugs
Controlled Correspondence Documents Received

Center for Drug Evaluation & Research

*Projected for End of FY 04
## Workload Backlog and Staffing

<table>
<thead>
<tr>
<th>Chemistry</th>
<th>FY01</th>
<th>FY02</th>
<th>FY03</th>
<th>FY04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backlog</td>
<td>140-150 days</td>
<td>90-120 days</td>
<td>±100 days</td>
<td></td>
</tr>
<tr>
<td>Staffing</td>
<td>60 (at end of FY)</td>
<td>Lost 4 Gained 8</td>
<td>Lost 2 Gained 12</td>
<td>Lost 2 Gained 2</td>
</tr>
<tr>
<td>Pending</td>
<td>374</td>
<td>395</td>
<td>506</td>
<td>625*</td>
</tr>
<tr>
<td>Receipts</td>
<td>307</td>
<td>361</td>
<td>449</td>
<td>239*</td>
</tr>
</tbody>
</table>

*as of 1/31/2004
New Chemistry Review Division

Chemistry Division 1
- Team 1
- Team 2
- Team 3
- Team 4
- Team 5

Chemistry Division 2
- Team 6
- Team 7
- Team 8
- Team 9
- Team 10

Chemistry Division 3
- Team 4
- Team 6
- Team +
## Workload Backlog and Staffing

<table>
<thead>
<tr>
<th>Microbiology</th>
<th>FY01</th>
<th>FY02</th>
<th>FY03</th>
<th>FY04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backlog (Orig)</td>
<td>210 days</td>
<td>343 days</td>
<td>280 days</td>
<td>86 days*</td>
</tr>
<tr>
<td>Staffing</td>
<td>4 (at end of FY)</td>
<td>Lost TL Gained TL +1</td>
<td>Lost 0 Gained 1</td>
<td>Lost 0 Gained 1</td>
</tr>
<tr>
<td>Backlog (Supp)</td>
<td>209 days</td>
<td>110 days</td>
<td>113 days</td>
<td>90 days*</td>
</tr>
<tr>
<td>Pending</td>
<td>121</td>
<td>90</td>
<td>39</td>
<td>72*</td>
</tr>
<tr>
<td>Receipts</td>
<td>307</td>
<td>361</td>
<td>449</td>
<td>239*</td>
</tr>
</tbody>
</table>

*as of 1/31/2004
# Workload Backlog and Staffing

<table>
<thead>
<tr>
<th>Bioequivalence</th>
<th>FY01</th>
<th>FY02</th>
<th>FY03</th>
<th>FY04</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backlog</td>
<td>±49 days</td>
<td>118 days</td>
<td>200+ days</td>
<td>226 days*</td>
</tr>
<tr>
<td>Staffing</td>
<td>30 (at end of FY)</td>
<td>Lost 4 Gained 0</td>
<td>Lost 2 Gained 5</td>
<td>Lost 0 Gained 2</td>
</tr>
<tr>
<td>Pending</td>
<td>374</td>
<td>395</td>
<td>506</td>
<td>625*</td>
</tr>
<tr>
<td>Receipts</td>
<td>307</td>
<td>361</td>
<td>449</td>
<td>239*</td>
</tr>
</tbody>
</table>

*as of 1/31/2004
Scientific Staff

- FY2002
  - Lawrence Yu
- FY2003
  - Robert Lionberger
  - Sam Haider
  - Hyojong Kwon
  - Pradeep Sathe
  - Qian Li
- FY2004 - projected
  - Andre Raw
Clinical Review Staff

- **FY2002**
  - Dena Hixon, MD

- **FY2003**
  - Carol Kim
  - Krista Scardina
  - Helen Li (Statistician)
  - Sarah Ho

- **FY2004 - projected**
  - Additional MD
Other Activities

- Listed Drug Guidance
  - Directed by new law
  - Drafted; under review

- OGD/Office of Chief Counsel (OCC) determining regulation revisions or changes necessitated by new law

- OGD/GPhA Communications
Interaction to Facilitate Efficient Approval of Applications

- June 11, 2003 - Impurities - Lawrence Yu
- June 26, 2003 - General discussion - Need for dissolution database identified
- September 24, 2003 - Webcast on Impurities
- October 15, 16, 17, 2003 - Fall Technical Conference
- November 5 & 6, 2003 - First “ANDA Basics” Workshop
- February 4 & 5, 2004 - Second “ANDA Basics” Workshop
- February 10, 2004 - Webcast on cGMP
- TO COME:
  - April 20, 2004 – Preparing CTD/eCTD Workshop
Budget Outlook

- **FY2004**
  - Not yet finalized

- **FY2005**
  - Proposed the same as FY2004
  - Can’t predict what will happen
Bioequivalence Information
Availability

- Dissolution Methods database
  - Will be available March 2004
  - Will be initially populated with older products
  - Newly approved products will be added incrementally

- In-Vivo Bioequivalence Recommendations database being planned
Dissolution Methods for Drug Products

FDA-Recommended Dissolution Methods

Search for a Drug by its Generic Name

Enter at least three characters: [ben]  Search  Clear

Disclaimer for the Dissolution Methods Database
### FDA CDER Office of Generic Drugs
#### Dissolution Method Database

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosage Form</th>
<th>Apparatus</th>
<th>Speed (RPMs)</th>
<th>Medium</th>
<th>Volume (mL)</th>
<th>Recommended Sampling Times (minutes)</th>
<th>Date Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine Besylate/Benazepril HCl</td>
<td>Capsule</td>
<td>USP I (Basket)</td>
<td>100</td>
<td>0.01N HCl</td>
<td>500</td>
<td>10, 20, 30, 45 and 60</td>
<td>1/14/2004</td>
</tr>
<tr>
<td>Benazepril HCl</td>
<td>Tablet</td>
<td>USP II (Paddle)</td>
<td>50</td>
<td>Water (deaerated)</td>
<td>500</td>
<td>15, 30, 45 and 60</td>
<td>1/16/2004</td>
</tr>
<tr>
<td>Benazepril HCl/Hydrochlorothiazide</td>
<td>Tablet</td>
<td>USP I (Basket)</td>
<td>100</td>
<td>0.1 N HCl</td>
<td>500</td>
<td>15, 30, 45 and 60</td>
<td>1/16/2004</td>
</tr>
<tr>
<td>Benazepril HCl/Hydrochlorothiazide</td>
<td>Tablet</td>
<td>USP I (Basket)</td>
<td>100</td>
<td>0.1 N HCl</td>
<td>500</td>
<td>10, 20, 30, 45 and 60</td>
<td>11/18/2003</td>
</tr>
<tr>
<td>Benzonatate</td>
<td>Capsule</td>
<td>USP II (Paddle)</td>
<td>50</td>
<td>Water (deaerated) (Tier 1) or SGF with Pepsin (Tier 2)</td>
<td>900</td>
<td>15, 30, 45 and 60</td>
<td>1/16/2004</td>
</tr>
<tr>
<td>Benzphetamine HCl</td>
<td>Tablet</td>
<td>USP II (Paddle)</td>
<td>50</td>
<td>Water (deaerated)</td>
<td>900</td>
<td>10, 20, 30 and 45</td>
<td>1/16/2004</td>
</tr>
</tbody>
</table>
Orange Book Revisions

- Increased staffing to improve service
- Will go to daily patent listings ≈April 2004
- New search capability for patent listings from OB webpage
Electronic Orange Book

Approved Drug Products
with
Therapeutic Equivalence Evaluations

Current through December 2003

Preface

FAQ

Search by Active Ingredient  Search by Applicant Holder
Search by Proprietary Name  Search by Application Number

Search by Patent

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Drug questions email: DRUGINFO@CDER.FDA.GOV

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Science
Office of Generic Drugs
Electronic Orange Book Query

Query by Patent Number
Query Newly Added Patents
Query Patent Delistings

Return to the Electronic Orange Book Home Page
CDER Electronic Submission Initiatives

- Electronic-Common Technical Document
  - Pilot program has begun
  - G for I: Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions
    - ANDAs, DMFs, NDAs, BLAs, INDs
  - Efficient, flexible approach
  - Uses e-CTD Viewer System (EVS)
  - Commercial tools available for creating e-CTD
CDER Electronic Submission Initiatives

- E-Labeling Submissions
  - Implementation of a Structured Drug Label
  - A repository to house all labels
  - Develop tools to review and keep labels current
  - G for I: Providing Regulatory Submissions in Electronic Format – Content of Labeling
E-Submissions/E-CTD

Additional information and specifications
www.fda.gov/cder/regulatory/ersr/ectd.htm

CDER/Office of Information Management
ERSR Technical Support:
ESUB@CDER.FDA.GOV
CTD@CDER.FDA.GOV
For the Future:

- Continue to maximize our review efficiency
- Continue to focus resources on backlogged review areas
- Continue to interact regularly with GPhA to discuss critical issues
- Expand the Dissolution Methods database
- Create a In-Vivo Bioequivalence Recommendations database
Your generic drug is safe and effective.

And we’ve got the results to prove it.

FDA ensures that your generic drug is safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA’s high standards. We make it tough to become a generic drug in America so it’s easy for you to feel confident. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more.

Generic Drugs: Safe. Effective. FDA Approved.
February 11, 2004

- OGD approved 13 applications for Benazepril or Benazepril/HCTZ
- 2002 Sales for Lotensin® (the RLD) were $315 million (ranks 97th)
- In one week, the retail price of a month’s supply of Benazepril fell from $44 to $26 (40% decrease)
- Approximate annual savings of 100 million dollars
Final Words...

- The generic drug industry has done more to address the spiraling health costs in this country than any other industry.
- More than 50% of all prescriptions dispensed are supplied by your industry and reviewed by my office.

👍 We are making a difference...
Office of Generic Drugs