Office of Generic Drugs Update

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Productivity and Statistics

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

Office of Generic Drugs

Center for Drug Evaluation and Research  FDA
Office of Generic Drugs

ANDA Approval Times - Median

- Median approval times from 1995 to 2005:
  - 1995: 28.2 months
  - 1996: 24.7 months
  - 1997: 19.6 months
  - 1998: 18.7 months
  - 1999: 17.3 months
  - 2000: 18.9 months
  - 2001: 18.4 months
  - 2002: 18.3 months
  - 2003: 17.3 months
  - 2004: 16.3 months
  - 2005: 16.3 months

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Receipts by Month - Original ANDAs

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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
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

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