Center Director's Update

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Outline

- New First Generics Policy Announcement
- Improvement Initiatives
- IOM Study
- Challenges
  - Resources
  - Citizen Petitions
  - User Fees
- Looking Ahead

Generic Drug Review Continues to Be Critical Priority for CDER

- Importance to bottom line = Importance to health care of Americans
- Management continues focus on process improvements & efficiency
- Order of application review unchanged for many years

Revision of "First-In, First-Reviewed Policy"

- Remain committed to approach unless specific reasons to expedite
- Reasons to expedite:
  - First generics (never approved before as generic & no blocking petitions, exclusivities)
  - Public Health Emergencies
  - Nationwide Shortages
  - Special Review Programs – PEPFAR
- Priority review goal – 6 months

CDER/OGD Initiatives

- eCTD – Use of Quality Overall Summary; Question-based Reviews (first tentative appr)
- Structured Product Labeling
- Safety Initiatives – Risk Management Plans
- Use of Center electronic document repository
- Dissolution info on web
- BE study recommendations – web resource coming

Critical Path for Generic Products

- Bioequivalence of Locally Acting Products
  - – Inhaled Corticosteroids
  - – Topical Dermatological Products
- Quality by Design – Supplement Reduction
- Scaling Approaches for Highly Variable Drugs
- Equivalence of Complex Drug Substances

Regarding Complex Drug Substances

- More Study is Needed
- Documents in clearance
- Biologics Approved Under Different Regulations

The Report

- Culture, Structure and Management of CDER
- Quality and Quantity of the Science
- Credibility of the Science
- Regulation
- Communication
- Resources

IOM Study Impact

- Recommendations Directed to Congress; DHHS; and The Agency
- Reaction to the Recommendations will Require Internal Discussion - underway
- Report is important opportunity for improvement

Enhancements Already in Place

- Re-organization to the Office of Surveillance and Epidemiology
- Drug Safety Board
- Improved Communication to the Medical Community and The Public

Challenges

- Number of Applications
- Legal Challenges – Citizens Petitions
- Resource Uncertainty
- Increasing Complexity of Products and Issues

Citizen Petitions

- Agency Has Not Developed a Position on Proposed Legislation
- CDER/OGD Process Improvements
  - – Too Soon to See Impact
  - – Office of Regulatory Policy – Active Management of Response Development
  - – OGD Science Staff – More Expert at Drafting Responses
  - – CDER/OND – Developing Better Understanding of Input to Responses

Resources

- Overall – Tough year ahead
- FY 2007 – Continuing Resolution
- FY 2008 – Optimism
- Discussions on Potential User Fees

Future of OGD

- Continue Process Improvements – QbR; BE Abbreviated Reviews; Review Order
- Growth and Development of Review Staff
- Advising the Industry in Development of High Quality Generic Drug Products
- Continued productive work with GPhA!