Generic Drug User Fees

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Stakeholder Update

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Agenda

- Why Now?
- Activities to Date
- Current Status
- Summary of What FDA Has Heard
- Differences Between Industries
- Target Structure
- Inspections
- Benefits
- Some Other Key Factors

Generic Drug User Fee - Why Now?

- Growth in submissions has consistently outpaced approvals
- FDA's workload has grown
- Conditions have changed:
  - Increased focus on safety and quality
  - Increasingly complex products
  - Shift towards foreign manufacturing

Activities To Date:

- September 17, 2010 Public Meeting
  - Valuable public input during meeting;
  - FDA posted all presentations and transcript
  - Comment period open for 30 days
- Docket subsequently reopened twice to receive additional public input
  - Docket FDA-2010-N-0381
  - Closes February 23
- Serious consideration of all comments/proposals
- In light of comments received, we reached out to additional stakeholders

Activities To Date (continued):

- Outreach to inform and assess
  - FDA has given several presentations and interviews
  - Slides posted
  - December update posted
  - Stakeholder update meeting February 23, 2011
- We have posted all meeting materials; and provided periodic updates and invitation to stakeholder meetings; will post meeting minutes during negotiation, as in PDUFA
  - http://www.fda.gov/Drugs/NewsEvents/ucm224121.htm

Current Status

- Negotiation phase begins
  - First session February 28
  - Participants: FDA, GPhA, EFCG and SOCMA
- As indicated at the September public meeting, FDA only negotiates with trade organizations, not individual companies
- Timeline

Summary of What FDA has Heard:

- Support for Generic Drug User Fee
- Traditional proposals
  - Sponsor and Review Based
- Non-traditional proposals
  - Facility and Inspection Based

Considerations and Goals

- User fee is additive to budget appropriation
- Resourcing must be:
  - adequate to fund all necessary activities
  - predictable
- Needs to be implementable
  - Simplicity
  - Requires ramp up time

Brand and Generic Industries

- The generic industry is different than the brand industry
  - Volume
  - API location and unique applicant
  - Science re PAIs
- A user fee structured differently than PDUFA could benefit the public health.
- A variety of both external and internal environmental factors support this.

Target Structure and Rationale

- Generic User Fee Structure That Focuses Not Only on Review
  - Post Market Safety
  - Inspection
- Aligns With…
  - Generic Market Share
  - Profitability
  - Fairness/Consumer Confidence

Inspections

- Inspectional goals may be best accomplished via surveillance model:
  - Better science
  - More efficient
- Meets needs of globalized world and supply chain
- Level playing field between foreign and domestic manufacturers

Benefits of User Fee

- Predictability of Review Times
- Ensure Continued Access to Generics and Expand Access By
  - Advancing regulatory science
  - Industry funding of research programs

Additional Key Factors

- Because of volume, administrative simplicity is critical
  - Focus on funding sources of primarily product fees
  - Secondary reliance on facility fees
  - Added benefit: all segments of industry pay their fair share, and small business is not disadvantaged

Questions?