# Generic Drug User Fees

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Stakeholder Update

Peter C. Beckerman, Office of Policy

Russell Wesdyk, CDER Office of Pharmaceutical Science

# Agenda

- Public Presentations (if any)
- Generic Drug User Fee – Why Now?
- Activities to Date/Current Status
- Outlines of the Agreement
- Take Away Messages
- Next Steps
- Questions?

# Public Presentations

# Generic Drug User Fee - Why Now?

- Growth in submissions has consistently outpaced FDA resources
- FDA's workload has grown
- Conditions have changed:
  - Increasingly complex products
  - Shift towards foreign manufacturing

# Activities To Date:

- Initial September 17, 2010 Public Meeting
- December, 2010 web update
- Additional stakeholder update meetings:
  - February 23, 2011
  - May 10, 2011
  - August 28, 2011
- Docket repeatedly reopened for public input
  - Docket FDA-2010-N-0381
  - Open through end of August.
- Serious consideration of all comments and proposals

# Summary of Comments to Docket

- Overwhelmingly positive – approximately 90% of comments supported some form of generic drug user fee.
- Very few requests for specific exemptions; however, multiple requests for exemption of PET drugs
- Suggestions from comments led directly to FDA reaching out to make sure there was broad representation in the negotiation.

# Activities To Date (continued):

- Materials from public meetings, speeches and FDA presentations posted on FDA's website.
- Fifteen face-to-face negotiating sessions, from February 28, 2011 to last week.
  - Participants: FDA, GPhA, EFCG and SOCMA's BPTF
  - FDA only negotiates with trade organizations, not individual companies – voices not at the negotiating table heard via public comment and at stakeholder updates.
- Minutes of these sessions posted, generally within 10 business days
- http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm

# Current Status

- Negotiation nearly complete
- Work product, as in other user fee negotiations:
  - Goals Letter
  - Legislative Language
- Recent public statements by each organization involved in the negotiation supportive of the agreement

# Considerations and Goals

FDA has said or agreed a user fee must:

- Be additive to budget appropriation
  - Industry insists fees not replace current appropriations
  - This is necessary to achieve incremental goals
- Provide resources that are:
  - adequate to fund all necessary activities
  - predictable
- Be implementable
  - Simplicity
  - Requires ramp up time

We believe we have a program that achieves these aims.

# Considerations and Goals (cont.)

- Primary goal is to advance the public health
  - Timely
  - Safe and High Quality
  - Affordable
- Increase transparency
- Help FDA address challenges of globalization
- Advance regulatory science

# Brand and Generic Industries

- The generic industry is different than the brand industry
  - Volume
  - API location and unique applicant
  - Inspection is sometimes rate limiting for generics
- User fee structured to recognize critical features of regulation related to generic drugs with implications for public health.

# Outlines of the Agreement

- Fees for:
  - Applications
    - Applications in the backlog (year 1 only)
    - Drug master file fee
    - ANDA and PAS filing fee
  - Facilities
    - involved in manufacture of generic drugs, whether API or FDF, domestic or foreign.
- Individual fees calculated/published upon implementation
  - Order of magnitude lower than PDUFA application fees
- Critical splits:
  - 80% from finished dosage form manufacturers, 20% from API manufacturers
  - 70% from facility fees, 30% from application fees
  - In year 1, $50M from backlog fee, so above splits will be slightly different

# Outlines of the Agreement (cont.)

- Four walls and a roof
  - FIFR application review policy; no separation of backlog
  - Backlog to steady state, where what comes in can go out within the review time, by end of year 5
  - Primary application review goal = 10 months in year 5
  - Resources of inflation adjusted $299 million annually
  - Risk-adjusted biennial surveillance inspection model with foreign and domestic parity in year 5
- Each element corresponds to a public health benefit

# Timely Access to Generic Drugs

- Eliminate the backlog or queue from practical perspective
  - In year 5
- Complete review response of ANDAs in 10 months
  - In year 5; there are incremental goals
- Median to approval presently about 31 months
  - Not apples to apples…
  - But useful given other considerations
    - Quality drivers
    - Reduced cycle initiatives

# Safe Generic Drugs

- Risk adjusted biannual inspection of specified facilities (manufacturing and BE)
- Parity of related inspection frequency comparing foreign and domestic facilities
- Various other initiatives
  - Funding of post market safety in OSE
  - Regulatory science initiatives

# Affordable Generic Drugs

- Both FDA and industry wanted to limit the size of the program
  - Enough to make improvements
  - Not so much as to impact prices
- Program size represents
  - About one half of one percent of sales
  - Less than ten cents per generic prescription
- Savings from reduced timeline may exceed cost

# Transparency

- Complete review / complete response letters
- Rolling review
- First cycle deficiency meetings
- Other communication tools

# Globalization

- Commitment to risk-adjusted biennial surveillance inspection model with foreign and domestic frequency parity

- A paradigm shift, recognizing the globalized nature of the industry and the locus of risk.
  - Addresses concerns highlighted by GAO about FDA coverage
  - PAI and surveillance

# Regulatory Science

- Studies to evaluate post-market safety
  - Job not done at approval
- Studies to develop standards for new generics
  - Benefits public health and industry
- Studies to develop needed Guidance

# Critical take away messages

- GDUFA is about more than just the backlog
- GDUFA is fundamentally about assuring timely access to safe and high quality generic products that are affordable.
- Questions raised in stakeholder process have been addressed
- This is a program that will advance the public health

# Next Steps

- Wrapping up goals letter and legislative language
- To HHS in September
- Then to OMB
- To Congress with FDA's other user fee packages in January

# Questions?