



U.S. Food and Drug Administration

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Generic Drug User Fees

Stakeholder Public Meeting

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Agenda

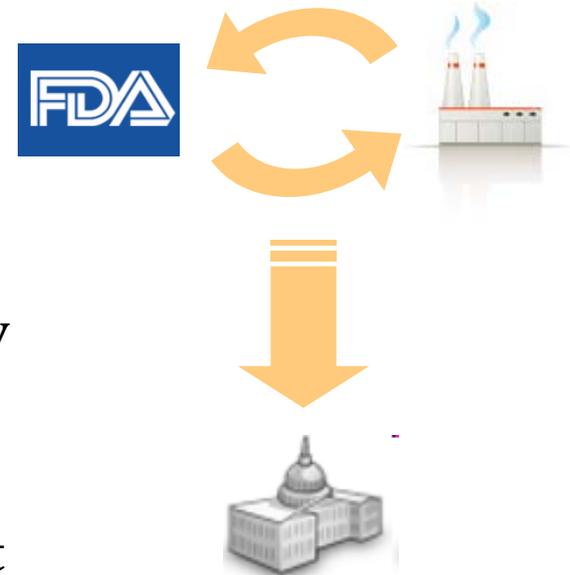
- The Process for a New User Fee
- Activities to Date
- Transparency and Inclusion
- FDA Considerations and Goals
- Key Parameters – Link to Public Health
- Effecting a Paradigm Shift

Process for a New User Fee

- Public input (continuous)
- FDA negotiation with industry trade associations, representing members who may pay the fee
- Joint recommendation to Congress
 - Legislative language
 - Goals letter from Secretary of HHS
- Enactment

How are performance goals set?

- FDA determines baseline/current performance level
- Industry and FDA discuss desired performance improvements
- FDA determines cost of the improvements
- If cost too great, levels of improvement may be adjusted until there is agreement on additive funding and performance goals
- HHS Secretary sends letter to Congress that commits FDA to these performance goals if user fee legislation is enacted
- These goals remain in effect for five years until the Act is reauthorized



Activities To Date:

- Process kicked off with September 17, 2010 Public Meeting
 - Valuable public input
 - All presentations and transcript posted
 - Docket held open for 30 days
- Docket subsequently reopened several times to permit receipt of additional public input
 - Docket FDA-2010-N-0381
 - Open for duration of the negotiations
- FDA gives serious consideration of all comments
 - In fact, in light of comments received, we reached out to additional stakeholders

Activities To Date (continued):

- Outreach to inform and assess
 - Slides, speeches and presentations posted
 - Update posted
 - Second stakeholder meeting: February 23, 2011
- <http://www.fda.gov/Drugs/NewsEvents/ucm224121.htm>
- Negotiations began February 28 and scheduled through June
 - Meeting minutes from negotiations posted 10 business days after meeting
- This third stakeholder public meeting to provide additional update, again solicit comment and to make sure all perspectives are being heard
- Docket remains open for comment

Transparency and Inclusion

- For logistical reasons, formal negotiations are with trade associations representing large industry segments
 - Physically impossible to seat all individual companies
- FDA wants to listen and include views from all parties – industry, patients, consumers, other stakeholders
 - Regular stakeholder meetings open to all
 - Docket open to all for comment throughout process
- Process transparency
 - Regular posting of meeting minutes available on FDA's GDUF webpage

Considerations and Goals

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

Negotiation Sessions

- Five meetings to date
 - February 28, March 18, March 31, April 14, April 28
 - Significant focus on mutual education
 - Progress toward alignment on program features
- Overall approach
 - Discuss goals, then resources, then fee structure

Key Parameters and Link to Public Health

- “Four walls and a roof” to guide discussion
 - 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 up to \$250-300 million as basis for discussion
 - Risk-adjusted biennial surveillance inspection model with foreign and domestic parity in year 5
- Each element corresponds to a public health benefit

Critical Components in GDUFA

Margaret Hamburg, M.D., Commissioner of Food and Drugs, Remarks to GDUFA public meeting (9/17/10), and GPHA, (2/18/11)

“review of an ANDA includes actions by agency components outside of OGD”

“building our capacity to inspect, review, and approve generic drugs as well as to provide appropriate oversight once they are on the market.”

- **Fund regulatory science**
 - To increase access and safety
- **Support all aspects of review**
 - OGD, OND, and ORP
- **Secure the supply chain (Inspection - OC/ORR)**
- **Pay fair share and fund post-market safety surveillance (OSE)**
 - Job does not end w/ approval

Review Policy and Approach to Queue

- Continued adherence to general first-in-first-reviewed application review policy
- No separation of backlog
- Benefits:
 - **Ensure continued integrity of FDA review process**
 - **Avoids creating comparative disadvantage to previously filed applications**
 - **Public timely availability of near-term generic drugs**

Queue to Steady State by End of Year 5

- Goal is not total backlog elimination, but reduction to where what comes in can go out within the agreed review goal time
- Benefits:
 - **“Right sizing” the program**
 - **Predictability of review**
 - **Ensures public of timely access to generic drugs**

Primary application review goal

- Primary application review goal is 10 months in year 5
- Benefits:
 - **Greater predictability to review process**
 - **Assure timely action on applications**
 - **Potentially reduces industry development costs**
 - Time value of money
 - **Mitigate any impact on drug costs**

Inspection

- Commitment to risk-adjusted biennial surveillance inspection model with foreign and domestic frequency parity in year 5
- A paradigm shift, recognizing the globalized nature of the industry and the locus of risk.
 - Addresses concerns highlighted by GAO about FDA coverage
- Benefits:
 - **Greater assurance of product quality for consumers**
 - **Level playing field for foreign and domestic firms**
 - **Enhanced efficiencies**

Adequate resources

- Resources of up to \$250-300 million as basis for discussion
- Recognition by all parties that FDA requires additional resources to be able to meet the parameters just discussed
- Benefits:
 - **More stable and adequate funding to accomplish goals**
 - **Affordable program that mitigates impact on drug costs**

Seeking Process Efficiencies

- **Review Process**
 - Internal and external process analysis of OGD
 - Recommendations being implemented

- **Inspection Process**
 - Surveillance focus enhances efficiency
 - Proposing to study various other enhancements

- **Improved Knowledge = Process Efficiencies**
 - Facilities database as an example

Effecting a Paradigm Shift

- Through a generic drug user fee:
 - Advance public health
 - Faster access to generic drugs
 - Provide greater predictability in review process
 - Fund the program to address challenges of a global industry
 - Level playing field between foreign and domestic
 - Extend FDA's reach to meaningfully inspect players in the generic drug industry regardless of where they are located
 - Advance regulatory science
 - Strengthen FDA's regulation of generic drugs
 - Review, Inspection and Post-market safety

Let us know what you think:

- We look forward to your presentations at today's meeting
- Please submit comments to the docket
- www.regulations.gov

