U.S. Food and Drug Administration

Generic Drug User Fee Amendments of 2012

http://www.fda.gov/gdufa

New Program Management Initiatives GDUFA Briefing

Alonza Cruse, Director (Acting)
Pharmaceutical Quality Program
FDA – Office of Regulatory Affairs

Key Achievements

- GDUFA advances critical values
  - Timely access to generic drugs
  - Safe, high-quality generic drugs
  - Maintains affordability of generic drugs
  - Increases transparency
  - Addresses globalization
  - Advances regulatory science
  - Is expected to put FDA's generic drug program on a stable financial footing

Generics Success = Regulatory Challenge

- $1.07 trillion in savings (2002-2011) has resulted in continued success and growth
- Program funding has remained relatively flat
- Generics industry success has come to represent an unprecedented regulatory challenge in terms of
  - Size
  - Scope
  - Geography

GDUFA Addresses Those Challenges

- $299 million per year
  - Ten-month review cycle for 90% in year 5
  - Effectively eliminate the backlog within 5 years
  - Risk-adjusted, biennial inspections
    - parity of foreign and domestic frequency in year 5
  - Efficiency enhancements, starting day one, are a critical component of GDUFA
- 4 types of fees: backlog; DMF; ANDA/PAS; Facility
  - 70% of program revenue from facilities; 30% from applications
  - 80% of program revenue from FDF; 20% from API

FDA Commitments: ANDAs

- Abbreviated New Drug Applications (ANDAs)
  - Complete response letters
  - Division-level deficiency review
  - Prompt communication of easily correctable deficiencies
  - First cycle meetings
  - For years 1 and 2 of the program, expedite paragraph IV (Day 1 Submissions)

Selected FDA Commitments: DMFs and Inspections

- Drug Master Files (DMFs)
  - Initial completeness assessment
  - ‘Available for reference’ list on the web
  - DMF completeness letter
- Inspections
  - Release inspection classification and date
  - Third-party foreign regulator inspection program evaluation

GDUFA Outline

- Application fees
  - Applications in the backlog (year 1 only)
  - Drug master file fee (and availability for reference list)
  - ANDA and prior approval supplement (PAS) filing fee
- Facility fees
  - Involved in manufacture of generic drugs, whether active pharmaceutical ingredient (API) or finished dosage form (FDF); domestic or foreign
- Individual fees calculated/published upon implementation
- Fees not linked to types of services; rather overall goals

GDUFA Outline *(continued)*

- Identification of facilities
- Effect of failure to pay fees
- Other provisions
  - Appropriations and spending triggers
  - Streamlined hiring authority
  - Definitions
  - Exemption for positron emission tomography (PET) drugs
  - Reauthorization

GDUFA: Important Dates and Deadlines

- User Fees:
  - Incurred beginning on October 1, 2012
  - Payment amounts to be published:
    - Backlog Fee (by Oct. 31, 2012)
    - Applications Fees – DMF, ANDA, PAS (by Oct. 31, 2012)
    - Facility Fees (by mid-Jan. 2013)
  - Business entities must submit information online and generate an invoice. No bills will be sent.
- Facility Self-Identification:
  - Notice of Requirement published by Oct. 1, 2012
  - Once published, facilities have 60 days to self-identify
  - Self-ID is distinct from drug registration and listing requirement

ORA & GDUFA - New Management Model

- Centralized coordination for managing the overall generic drug program
- Staffing
  - 80 new Investigators
  - 8 Supervisors
  - 8 Compliance Officers
  - Program Support (Field & HQ)
  - Policy Analysts

GDUFA Activities (ORA)

- Daily command center meeting
- Tracking all year 3 original (electronic) ANDA's and supplements
- Developed strategy which begins to address depth & rigor
- Application metrics – ANDA's in the year 5 cohort, FDA will review & act on 90% (complete & electronic) within 10 months
- Backlog metrics – FDA will review and act upon 90 of all ANDA, pending on Oct 1, 2012 by the end of FY 2017
- cCMP Inspection metrics – FDA will conduct risk-adjusted biennial surveillance inspections of API & generic FDF manufacturers with the goal of achieving parity of inspection frequency between foreign & domestic in FY'17
- Integrated Application Review
- Regulatory Science – FDA will continue and begin undertaking regulatory sciences initiatives
- GDUFA II Negotiations

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Website: http://www.fda.gov/gdufa

Email: AskGDUFA@fda.hhs.gov

Call: (866) 405-5367