U.S. Food and Drug Administration

Generic Drug User Fee Act

Agenda

- Process and Access
- Challenges and Success of Generics
- Outlines of the Act
- Legislative Language
- Goals Letter
- Next Steps
- Questions and Answers

Process and Access

Generic Industry Large & Fragmented

- Made up of both final dosage form (FDF) and active pharmaceutical ingredient (API) manufacturers
- Thousands of firms spread worldwide
- In virtually every continent and country
- Large and small

Access To All Through Multiple Vehicles

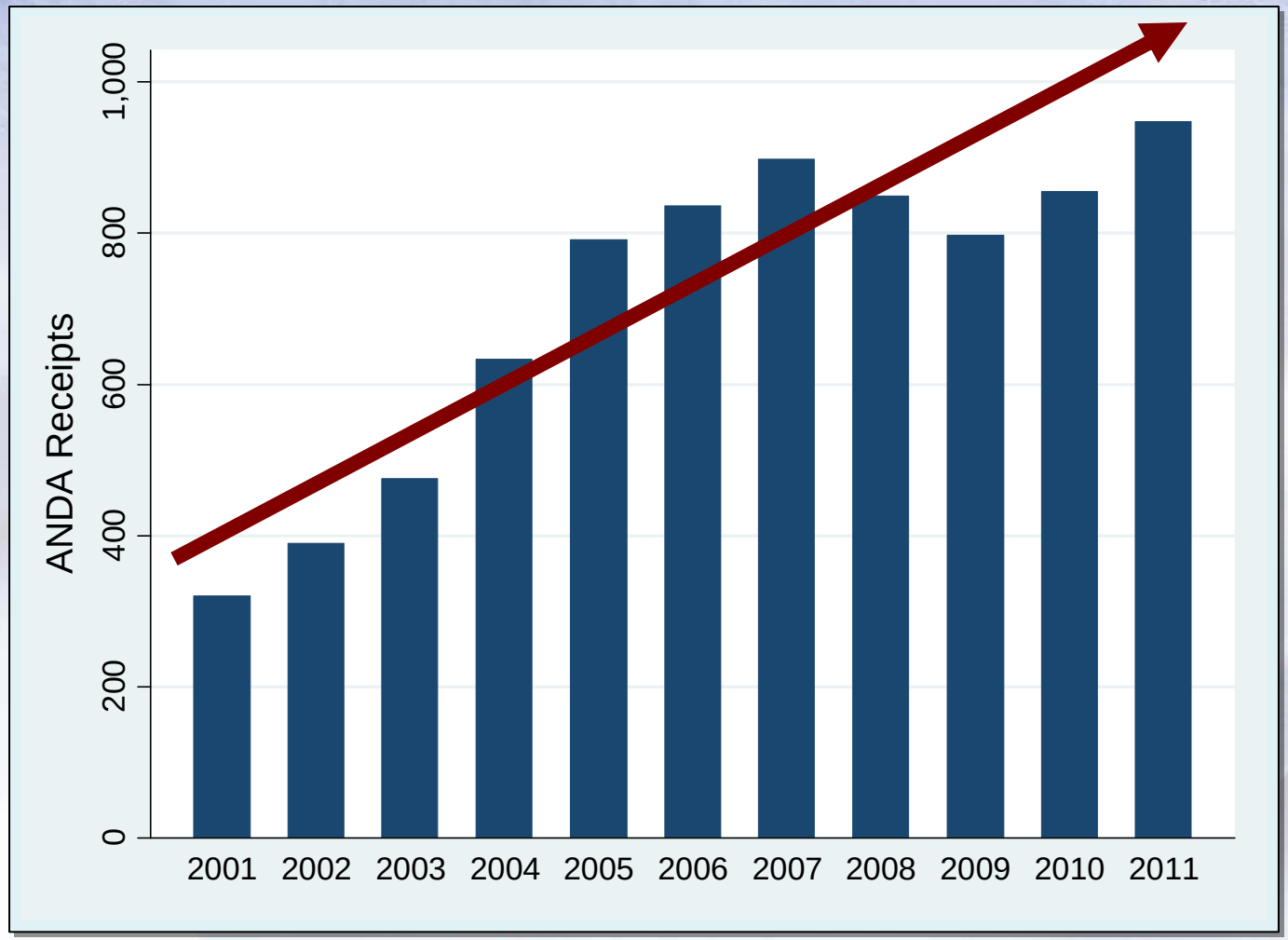
- Extensive outreach
- FDF and API trade associations at table
  - Generic Pharmaceutical Association (GPhA,) European Fine Chemicals Group (EFCG,) and the Society of Chemical Manufacturers and Affiliates' Bulk Pharmaceuticals Task Force (SOCMA's BPTF)
    - Members worldwide
  - 16 all-day negotiation sessions using a highly transparent process
    - Negotiation summaries on public Web site
- Open docket throughout
  - FDA-2010-N-0381 – Open Sept. 17, 2010 - Jan 6, 2012
- Multiple open public stakeholder meetings
  - 6 public meetings & stakeholder updates, starting Sept. 17, 2010

Environment

Generics Success = Unprecedented Regulatory Challenge

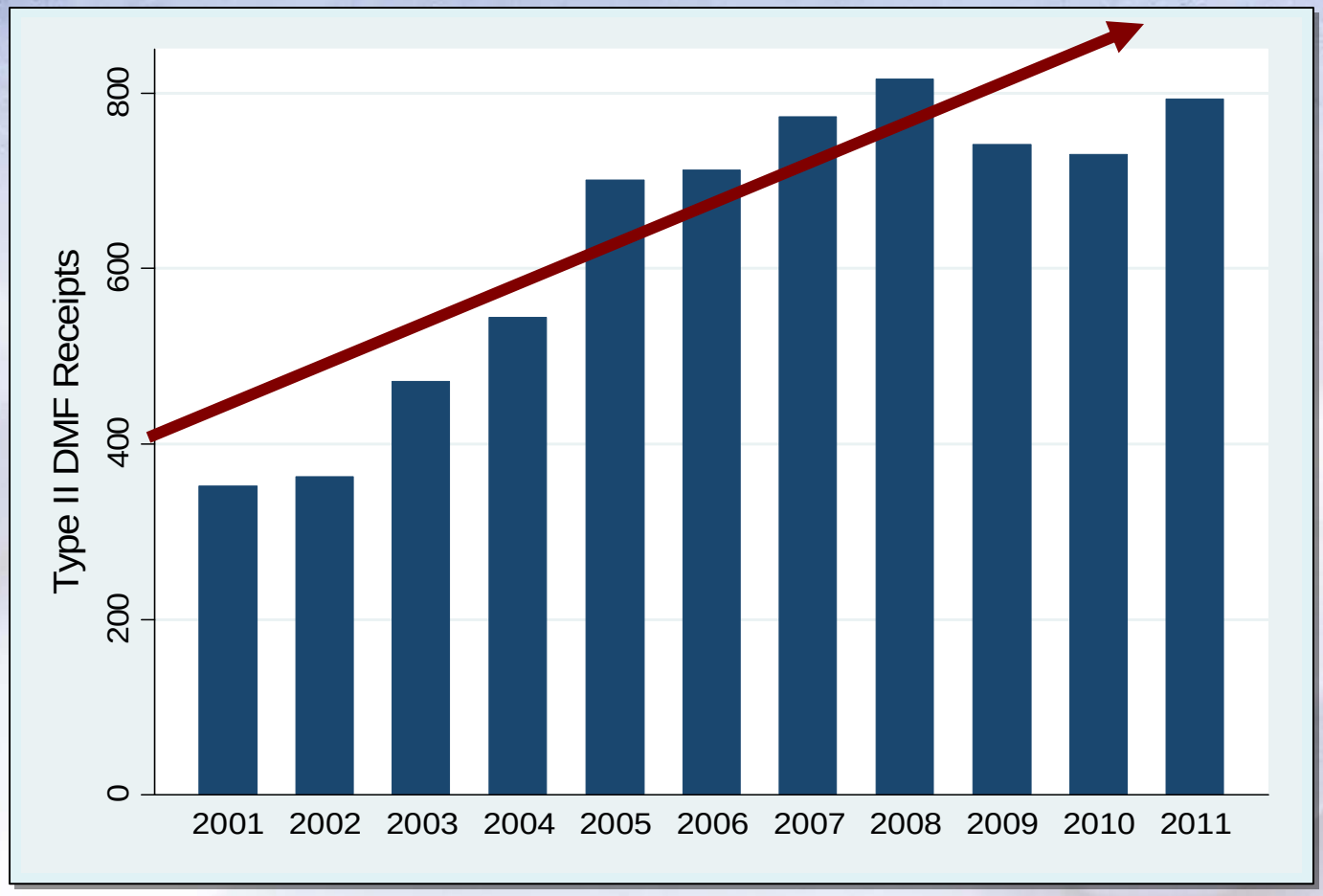
- $931 billion in savings (2001-2010) has resulted in continued success and growth
- While program funding has remained relatively flat
- Generics industry success has come to represent an unprecedented regulatory challenge in terms of
  - Size
  - Scope
  - Geography

Continued Growth in Abbreviated New Drug Applications (ANDAs)



2011 was another historic high

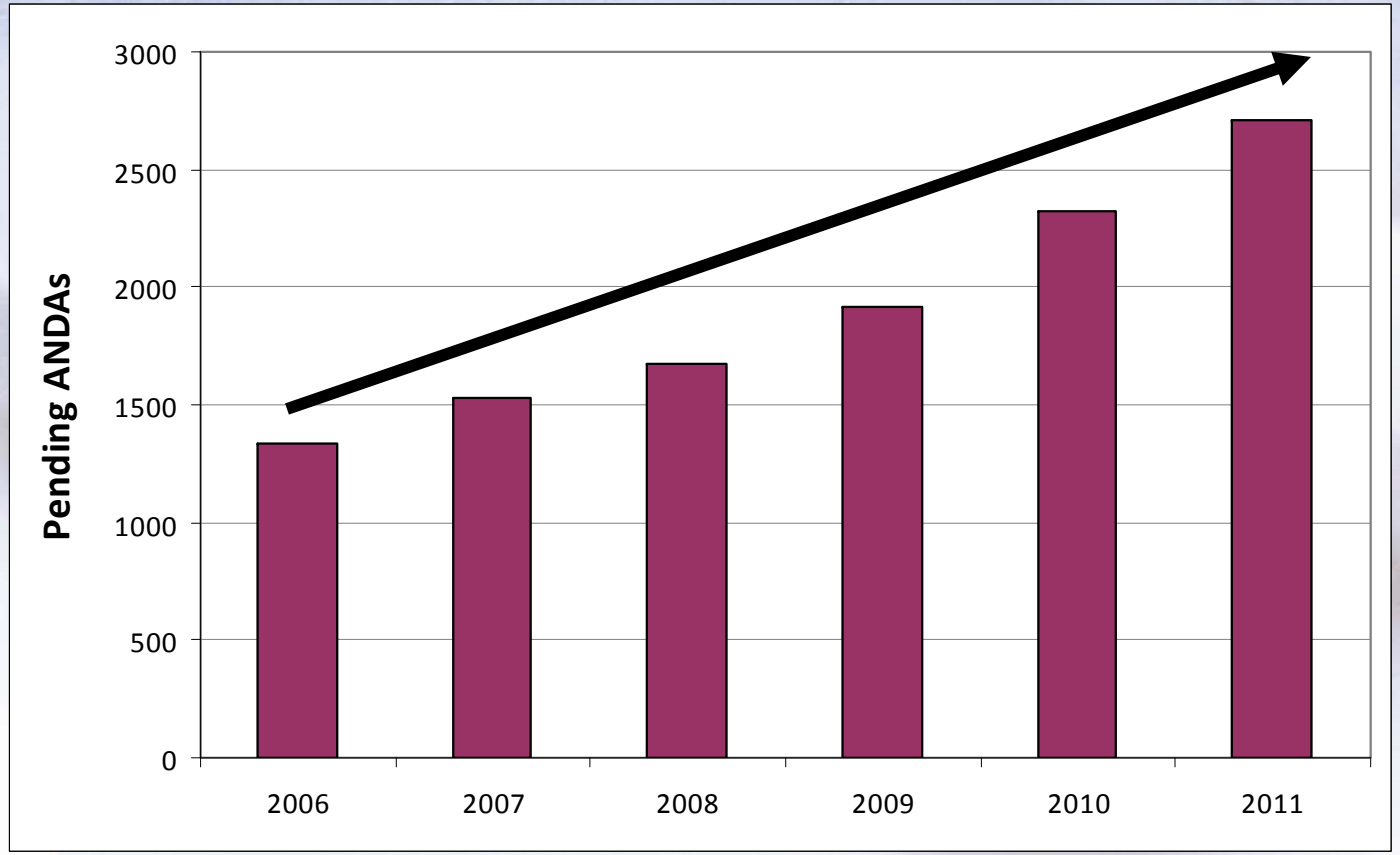
Drug Master Files (DMFs) Also Rapidly Growing



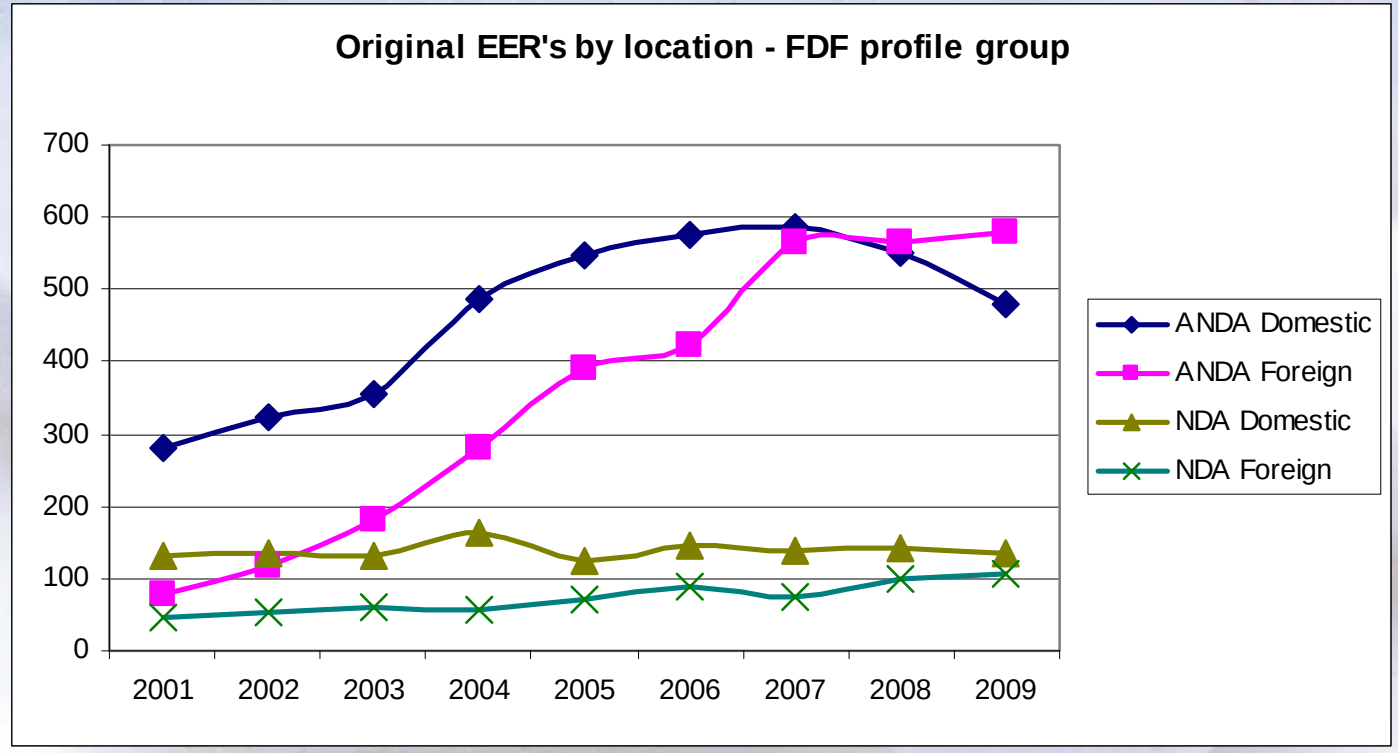
Multiple references, often years after filing

Combined, ANDAs and DMFs are approximately 10X Plus the NDA volume

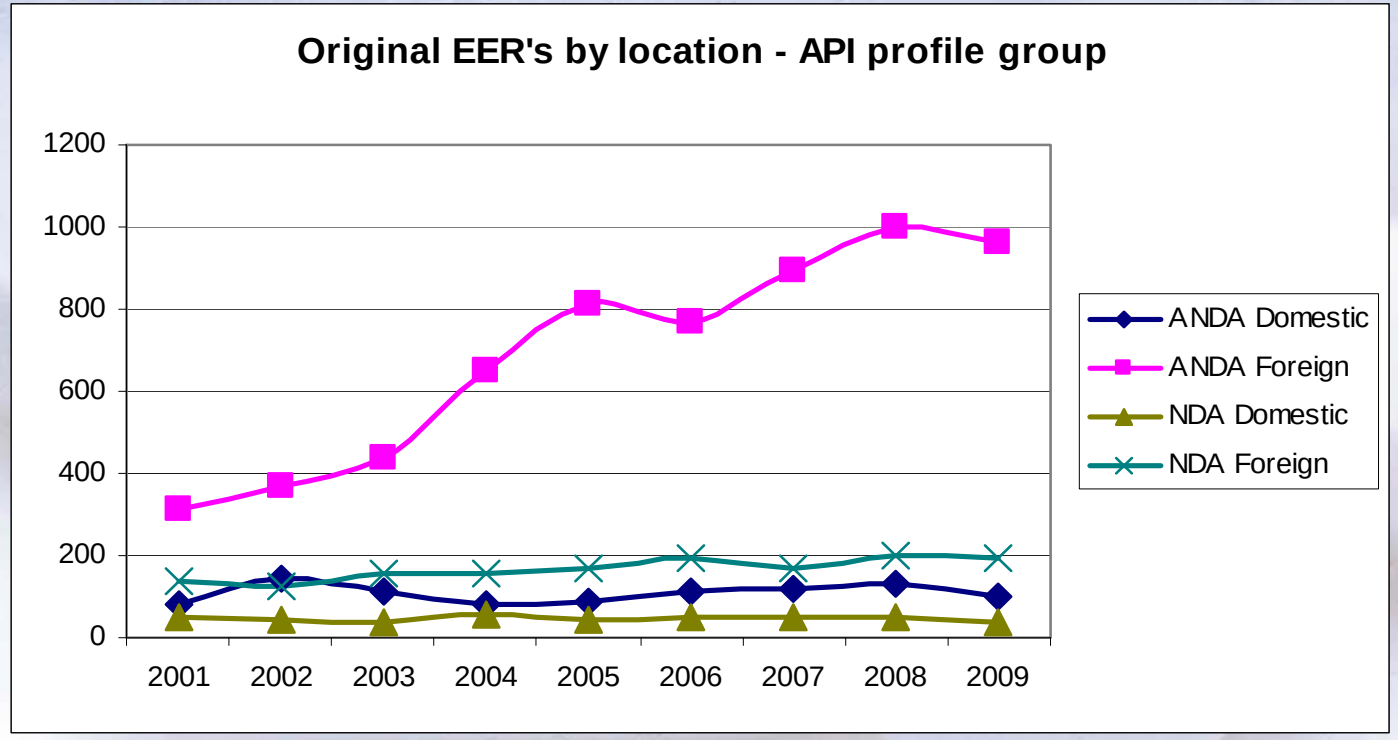
Growth Leads To Expanding Backlog



Increases in FDF Foreign Inspections



Increases in Foreign API Inspections



Focusing on Doing the Most Good

- Four walls and a roof
- Limit cost
  - $299 million/year is Less than ½ of 1% of generic drug sales
    - Expected to reduce costs, considering the reduced development/regulatory timelines
  - Less than doubling in OGD
    - Efficiency enhancements are a critical component of GDUFA
- Ten-month review cycle
- First in, first reviewed
- Eliminate the backlog
- Risk-adjusted, biennial inspection, with parity of foreign and domestic frequency

Outline of the Act

- Legislation
  - Authorizes collection of user fees
  - Establishes type of fees
  - Five year timeframe
- Goals Letter
  - Program scope, assumptions
  - Efficiency enhancements
    - ANDA, DMF, Inspection, Other
  - Regulatory science initiatives
  - Metrics/Goals
    - Human resources; submission review; controlled correspondence; inspections; backlog

Legislation

Overview

Outline of the Act

- Funding level = inflation adjusted $299 million/year
- 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 API or Finished Dosage Form, domestic or foreign
- Individual fees calculated/published upon implementation
- Fees not linked to types of services; rather overall goals

Fee Estimates: Public Stakeholder Meeting

- Estimates Only
  - Backlog ~ $25K
  - DMF ~$40K
  - ANDA ~ $60K
  - Supplement ~ $30K
    - for PAS only; $0 for changes being effected (CBE)
  - Facility ~ $85K average
    - Range estimates between $35K (API) and $150K (FDF)

Outline of the Act

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

Goals Letter

Overview

Goals Letter Overview

- Scope, assumptions, and aspirations
- Immediate efficiency enhancements
- Metrics

Scope, Assumptions & Aspirations

- Scope limited to generics
- Assumptions impacting viability
  - Streamlined hiring
  - Risk-adjusted inspection
- Aspirations (primarily during hiring period)
  - Maintaining productivity while hiring and training

Goals - Immediate Efficiency (ANDA)

- Complete Response letters
- Division-level deficiency review
- Rolling review
- First cycle meetings
  - 200 in FY 2015
  - 250 in FY 2016
  - 300 in FY 2017
- Expedite Paragraph IV (Day 1 submissions)
- Review goals (except backlog) applied to electronic submissions

Goals – Immediate Efficiency (DMFs)

- Same as ANDAs
- Initial Completeness Assessment
- Available for Reference List
- DMF Completeness Letter

Goals – Immediate Efficiency (Inspection)

- Release inspection classification and date
- Third-party foreign regulator inspection program evaluation
  - FDA will first have to determine the equivalence between a specific foreign regulator and FDA, and can then develop formal mechanisms to routinely accept the inspection of that foreign government regulatory body

Goals – Other Efficiency and Regulatory Science

- Facility, current chemistry manufacturing control (CMC) records, and other databases
- Electronic data submission standards
- Regulatory science initiatives
  - Improves access
  - Post-market safety
  - Issue guidance

Metrics

- Initially focused on staff and training
- Inspection
- Review metrics and cohorts similar to Prescription Drug User Fee Act (PDUFA) - 10 month cycle
- Quality Focus Initiative
  - Increasing review times for poor quality or unwarranted, unsolicited amendments
  - Electronic submissions

Metrics – Human Resources (HR)

- Hire and train 25% of incremental staff in FY 2013
- Hire and train 50% of incremental staff in FY 2014
- Strive to complete hiring and training in FY 2015

Metrics - ANDA

- DMF and inspection subsumed
- All applications grouped in cohort year
- Original ANDA review (review and act on):
  - 60% of submissions within 15 months for year 3 cohort
  - 75% of submissions within 15 months for year 4 cohort
  - 90% of submissions within 10 months for year 5 cohort
  - Expedite paragraph IV (Day 1 Submissions) submissions for year 1 and 2 cohorts

Metrics – ANDA Amendments

- Goals are incremental and additive
  - Pre CR application goal date adjusted
  - Post CR a new goal date from date of the new submission
  - "Delaying" amendments do not add to amendment count
- Amendments are grouped
  - Tier 1 – Solicited 1st major & 1st–5th minor, unsolicited "delaying"
    - Most favorable – (example: 90% first major within 10 months for year 5 cohort)
  - Tier 2 – Not "delaying" unsolicited
    - Less favorable – (example: 90% within 12 months for year 5 cohort)
  - Tier 3 – solicited major after 1st, unsolicited minor after 5th
    - No goals metric
  - This is a quality initiative… "get it right the first time"
  - Interim metrics apply for all – see goals letter

Metrics – PAS

- No Inspection Required
  - 60% of submissions within 6 months for FY 2015 receipts
  - 75% of submissions within 6 months for FY 2016 receipts
  - 90% of submissions within 6 months for FY 2017 receipts
- Inspection Required
  - 60% of submissions within 10 months for FY 2015 receipts
  - 75% of submissions within 10 months for FY 2016 receipts
  - 90% of submissions within 10 months for FY 2017 receipts

Metrics – Other

- Controlled correspondences
- Inspection metrics
  - Risk-adjusted surveillance inspection
    - Achieving biennial inspection rate and parity of foreign and domestic frequency in FY2017
  - Pre-approval inspections (PAIs) continue
- Backlog metrics
  - Review and act on 90% of backlog applications pending on Oct. 1, 2012, by end of FY 2017

Key Achievements

- The program advances critical values
  - Timely access to safe, high quality, affordable generic drugs
  - Increases transparency
  - Addresses globalization
  - Advances regulatory science

Next Steps

- Appropriations
- Implementation

Questions?

Web site:

http://www.fda.gov/GDUFA

Email:

AskGDUFA@fda.hhs.gov