Generic Drug User Fee Amendments II

Amy Bertha
Program Manager
Office of Executive Programs
CDER/FDA

CDER Small Business and Industry Assistance
Regulatory Education for Industry: Generic Drug Forum
April 4, 2017

Outline

- GDUFA Reauthorization Process
- GDUFA II Proposals - Highlights
  - Submission Review Performance Goals
  - Original ANDA Review Program Enhancements
  - Pre-ANDA Program for Complex Products
  - DMF Review Program Enhancements
  - Facility Assessment Enhancements
  - Accountability and Reporting Enhancements

GDUFA Reauthorization Process

- Public Meetings
- FDA/Industry negotiations
- Stakeholder Meetings
- User Fee package transmitted to Congress
- To effectuate reauthorization, Congress would pass and President would sign

Submission Review Performance Goals

90% FOR ALL

Original ANDA

Submission Type	Goal
Standard Original	10 months
Priority Original	10 months no PFC 8 months w/PFC

PFC = Pre-Submission Facility Correspondence

Major Amendment to an Original ANDA

Submission Type	Goal
Standard Major	10 months w/inspection 8 months no inspection
Priority Major	10 months w/ insp. no PFC 8 months w/insp. w/PFC 6 months no inspection

Minor Amendment to an Original ANDA

Submission Type	Goal
Standard Minor	3 months
Priority Minor	3 months

Prior Approval Supplement

Submission Type	Goal
Standard PAS	10 months w/inspection 6 months no inspection
Priority PAS	10 months w/insp. no PFC 8 months w/insp. w/PFC 4 months no inspection

Major Amendment to a PAS

Submission Type	Goal
Standard Major	10 months w/inspection 6 months no inspection
Priority Major	10 months w/insp. no PFC 8 months w/insp. w/PFC 4 months no inspection

Minor Amendment to a PAS

Submission Type	Goal
Standard Minor	3 months
Priority Minor	3 months

Original ANDA Review Program Enhancements

- Notification of Standard or Priority review
- Issue discipline IRs and DRLs at about the mid-point of the review
- Grant Post-Complete Response Letter t-cons – goals
- Dispute Resolution goals

IR = Information Request
DRL = Discipline Review Letter

Pre-ANDA Program for Complex Products

- Meetings for complex products
  - Product Development
  - Pre-submission
  - Mid-cycle review
- Guidance
- Regulatory Science enhancements
- Controlled Correspondence – Complex Controls
- Inactive Ingredient Database improvements

DMF Review Program Enhancements

- Communication of DMF Review Comments
- Teleconferences to Clarify DMF First Cycle Review Deficiencies
- First Adequate Letter
- No Further Comment Letter
- Guidance on Post-approval changes to Type II API DMFs

API = Active Pharmaceutical Ingredient

Facility Assessment Enhancements

- Risk-based site selection model
  - guidance
  - outreach
- Communications regarding inspections
- Facility compliance status database

Accountability and Reporting Enhancements

- FDA will build internal capacity to enable improved productivity and performance
- Third party evaluation and recommendations
- Financial Program Evaluation
- Robust Performance Reporting

Thank You!

Please complete the session survey:

surveymonkey.com/r/GDF-D1S10