Animal Generic Drug User Fee Act Reauthorization (AGDUFA III)

FY 2019 – FY 2023

Public Meeting

November 2017

Welcome

Steven Solomon, DVM

Director, Center for Veterinary Medicine

FDA Goals for AGDUFA III Negotiations

- Ensure predictable and sustained revenue to have the capacity to meet and exceed performance goals and to continue to invest in quality program improvements.

- Smart/sustainable long-term financial planning.

AGDUFA Benefits

- To the public:
  - Earlier access to safe and effective drugs
- To the industry:
  - Predictable review process

Proposed Recommendations for AGDUFA III

Julie Bailey, Ph.D.
Roxanne Schweitzer

History of AGDUFA Performance

- AGDUFA I: FY 2009-FY 2013
  - Eliminated backlog
  - Reduced review times to 90% within statutory timeframes (from 700+ days to 270 days)
  - Created a more predictable, streamlined process
  - Met performance goals for all years except for one goal in 2009
- AGDUFA II: FY 2014-FY 2018 (Current Authorization)
  - Added flexibility to the process with 2nd cycle shortened-review process, including extensive IT enhancements
  - Multiple enhancements for Chemistry, Manufacturing, and Controls technical section
  - Developed electronic submission capability
  - Added pre-approval foreign inspection goal
  - Developing question-based-review for bioequivalence
  - Met all performance goals to date

History of AGDUFA Financials

- AGDUFA I (FY 2009-FY 2013)
  - Planned 5-year revenue was $27 million
  - Collections realized were $30 million
- AGDUFA II (FY 2014-FY 2018)
  - Planned 5-year revenue is $38 million
  - Collections estimated (with workload adjuster) to be $49 million by the end of FY 2018

AGDUFA II Target Revenue					
AGDUFA II $49.4M	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
	$7.328M	$8.250M	$9.705M	$11.341M	$12.822M

Reauthorization Process

May 2016

- Initial public meeting
- 30-day comment period

August 2016 – October 2017

- Negotiations with regulated industry
- Publication of minutes
- Periodic meetings with stakeholders
- Industry clearance
- Agency clearance
- HHS clearance
- OMB clearance

October – December 2017

- Hill Briefing
- Publication of recommendations in FR Notice
- **30-day comment period***
- **Public Meeting***
- Revise recommendations as needed
- Final industry, HHS and OMB clearance

** Where we are now*

January 2018

- Submit AGDUFA package to Congress no later than January 15, 2018.

AGDUFA III Financial Recommendations

	AGDUFA II	AGDUFA III Proposal
5-Year Total Revenue	$38.1M FY 2018: $8.5M (without workload adjuster)	$95M FY 2019: $18.3M
Annual Inflation Adjuster	4% fixed rate	Variable
Workload Adjuster: Base Years *see below for more detail	FY 2009 – FY 2013	FY 2014 – FY 2018
Offset Provision *see below for more detail	Excess collections in the first 4 years of the authorization must be offset in the 5th year	Eliminated

In conjunction with eliminating the Offset Provision, any year the Workload Adjuster is invoked in which FDA had excess collections in the second preceding fiscal year, the workload adjusted fee revenue will be reduced by the amount of excess collections.

- If FDA did not have excess collections in the second preceding fiscal year, FDA will collect the full amount of the workload-adjusted fee revenue.

AGDUFA III Performance Recommendations

Performance Goal Review Times (Complete 90% within the following number of days)

Application Type	Current Goal	AGDUFA III Proposal
Administrative Abbreviated New Animal Drug Application (ANADA)	100	60
ANADA originals/reactivations	270	240 (180 day review + 60 day admin)
ANADA reactivations (shortened review)	190	120 (60 day review + 60 day admin)
Prior Approval supplements (Chemistry, Manufacturing, and Controls)	270	180
Generic Investigational New Animal Drug (JINAD) data submissions	270	180
JINAD data submissions (shortened review)	90	60
JINAD protocols	100	75

AGDUFA III Performance Recommendations Cont.

- Electronic submission
  - Require 100% electronic submission starting in FY 2019
- Technical Corrections
  - Amend the definition of “process for the review of abbreviated applications for generic new animal drugs” to include Freedom of Information Act (FOIA) activities
  - Require all approved drugs to include the ANADA number on the labeling

Comments

- We look forward to hearing your comments, whether you share them here today, in writing, or via electronic submission.

Written comments :
Dockets Management Staff
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Electronic comments:
http://www.regulations.gov

- Identify comments with Docket No. FDA-2011-N-0655
- Docket will close November 24, 2017