Animal Drug User Fee Act Reauthorization(ADUFA IV)

FY 2019 – FY 2023

Public Meeting

November 2017

Welcome

Steven Solomon, DVM
Director, Center for Veterinary Medicine

FDA Goals for ADUFA IV 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.

ADUFA Benefits

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

Proposed Recommendations for ADUFA IV

Cindy L. Burnsteel, DVM

Roxanne Schweitzer

History of ADUFA Performance

- ADUFA I: FY 2004-FY 2008
  - Eliminated backlog
  - Reduced review times to 90% within statutory timeframes (from 500+ days to 180 days)
  - Created a more predictable, streamlined process
  - Met all performance goals
- ADUFA II: FY 2009-FY 2013
  - Reduced number of 2nd review cycles with end-review amendments (ERAs)
  - Developed electronic submission capability
  - Added pre-approval foreign inspection goals
  - Increased transparency by participating in 10 public workshops
  - Met performance goals for all years except for one goal in 2013

History of ADUFA Performance Cont.

ADUFA III: FY 2014-FY 2018 (Current Authorization)

- Process enhancements:
  - Added flexibility to the process by replacing End Review Amendments with 2nd cycle shortened-review process, including extensive IT enhancements
  - Fostering innovation through the early information process; working to fill the pipeline and increase drug availability
  - Made multiple enhancements for chemistry manufacturing and controls (CMC) technical section
  - Added 2 new sentinel submission types (Non-fee paying labeling supplements, Microbial Food Safety Hazard Characterizations)
- Long term goals:
  - Explore the possibility of expanding the use of conditional approval
  - Explore the feasibility of statutory revisions that may modify the current requirement that the use of multiple new animal drugs in the same medicated feed be subject to a separate approved application
- Met performance goals to date except for one goal in 2014

History of ADUFA Financials

- ADUFA I (FY 2004-FY 2008)
  - Planned 5-year revenue was $47 million
  - Collections realized were $49.5 million
- ADUFA II (FY 2009-FY 2013)
  - Planned 5-year revenue was $98 million
  - Collections realized were $88 million
- ADUFA III (FY 2014-FY 2018)
  - Planned 5-year revenue is $114 million
  - Collections estimated (with workload adjuster) to be $117 million by the end of FY 2018

ADUFA III Target Revenue					
ADUFA III $116.8M	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
	$23.600M	$22.036M	$22.818M	$23.673M	$24.641M

Reauthorization Process

May 2016

- Initial public meeting
- 30-day comment period

October 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 ADUFA package to Congress no later than January 15, 2018.

ADUFA IV Financial Recommendations

	ADUFA III	ADUFA IV Proposal
5-Year Total Revenue	$114M FY 2018: $23.5M (without workload adjuster)	$150M FY 2019: $30.3M FY 2020: $29.9M
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

- Workload Adjuster: In conjunction with eliminating the Offset Provision, which will make excess collections more readily available for use by FDA, 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.
- Shortfall: Statute continues to authorize recovery of collection shortfalls; however, proposal would provide for any fee increase to recover shortfalls to be reduced by the amount of remaining prior year excess collections not already applied for purposes of reducing workload-based fee increases.

ADUFA IV Performance Recommendations

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

Application Type	Current Goal	ADUFA IV Proposal
Administrative New Animal Drug Application (NADA)	60	60
NADA Originals/Reactivations	180	180
NADA Reactivations (Shortened Review)	135	135
Non-Manufacturing Supplemental NADAs and Reactivations (Prior Approval)	180	180
Non-Manufacturing Supplemental NADAs and Reactivations (Shortened Review Time)	135	135
Manufacturing Supplemental NADAs and Reactivations (Prior Approval)	120	120
Manufacturing Supplemental NADAs and Reactivations (Changes Being Effected)	120	180
Qualifying Labeling Supplements	60	60
Investigational New Animal Drug (INAD) Studies	180	180
INAD Studies – Microbial Food Safety Hazard Characterization	100	100
INAD Study Protocols	50	50
Categorical Exclusions (End Game)*	180	60
Animal Drug Availability Act (ADAA) Combinations*	180	60
Pre-Submission Conference*	n/a	60
Tissue Residue Method	n/a	120

**Shortened timeframes are contingent upon certain criteria or conditions being met*

ADUFA IV Performance Recommendations Cont.

- Electronic Submission
  - Require 100% electronic submission starting in FY 2019
- Foreign Inspections
  - CVM commits to working on implementation of the U.S.-EU GMP Inspection Mutual Recognition Agreement
- Technical Corrections
  - Amend the definition of “animal drug application” in ADUFA to allow user fee funds to be used for review of applications for conditional approval
  - For biopharm animals, exempt all fees except application fee
  - Revise the statutory requirement that indexed products state their unapproved status on their labels
  - Require all approved drugs to include the NADA 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

submitted at:
http://www.regulations.gov

- Electronic comments can be identify comments with Docket No. FDA-2011-N-0656
- Docket will close November 24, 2017