Animal Generic Drug User Fee Program (AGDUFA) II

User Fee Program Performance Update

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New Animal Drug Program Mission

To expeditiously approve quality, safe, and effective new animal drug products through a science-based approach in a regulatory environment. To communicate with our stakeholders and understand the forces that affect them. Our actions protect human and animal health and promote a safe and abundant food supply.

User Fee Program Background
AGDUFA I: 2009 - 2013

- Eliminated backlog
- Reduced review times from 700+ days to review times ranging from 100 to 270 days for most submission types
- Created a more predictable, streamlined process

AGDUFA II: 2014 – 2018 (Current Authorization)

- Added flexibility to the process by developing and implementing a shortened-review process for resubmission of incomplete applications, data submissions, including extensive IT enhancements
- Implemented multiple enhancements for the chemistry, manufacturing and controls (CMC) technical section
- Develop Question-based Review (QbR) process for bioequivalence submissions
- Added pre-approval foreign inspection goals

AGDUFA II: Performance Goals

(Act on 90% of submissions within the days specified below)

Submission Type	FY14–18
ANADA Submissions	
Administrative ANADAs	100
Original ANADAs and Reactivations	270
Shortened Review ANADA Reactivations	190
Manufacturing Supplemental ANADAs and Reactivations	270
JINAD Submissions	
JINAD Studies	270
Shortened Review JINAD Studies Resubmissions	90
JINAD Study Protocols	100

Program Performance

- In AGDUFA I, FDA met most performance goals outlined in the Performance Goals Letters for all submission types.
- So far in AGDUFA II, FDA has met all performance goals outlined in the Performance Goals Letters for all submission types (see following 2 slides).

Program Performance: AGDUFA II (Final FY14)

Submission Type	Filed	Performance Goal: Act on 90 Percent Within	On Time	Overdue	Percent On Time
Original ANADAs and Reactivations	27	270 days	27	0	100%
Administrative ANADAs	1	100 days	1	0	100%
Manufacturing Supplemental ANADAs and Reactivations	151	270 days	151	0	100%
JINAD Studies	59	270 days	59	0	100%
JINAD Protocols	48	100 days	48	0	100%

Program Performance: AGDUFA II (Preliminary FY15)

Submission Type	Filed	Performance Goal: Act on 90 Percent Within	On Time	Overdue	Percent On Time	Pending Within Goal	Highest Possible Percent On Time
Original ANADAs and Reactivations	23	270 days	12	0	100%	11	100%
Administrative ANADAs	1	100 days	1	0	100%	0	100%
Manufacturing Supplemental ANADAs and Reactivations	156	270 days	53	0	100%	103	100%
JINAD Studies	56	270 days	22	0	100%	34	100%
JINAD Protocols	12	100 days	10	0	100%	2	100%

Program Performance: Other Accomplishments

- Implemented IT enhancements to support new performance goals
- The QbR for bioequivalence protocol submissions is complete and progress is being made on the QbR for bioequivalence study submissions. Both will be available in the Center for Veterinary Medicine's eSubmitter tool when completed.