# Animal Drug User Fee Act (ADUFA) III

## 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

- ✓ **ADUFA I: 2004 – 2008**
  - Eliminated backlog
  - Reduced review times to or below statutory timeframes
  - Created a more predictable, streamlined process
- ✓ **ADUFA II: 2009 – 2013**
  - Reduced number of 2nd review cycles with end-review amendments (ERAs)
  - Developed electronic submission and review capability
  - Added pre-approval foreign inspection goals
  - Increased transparency by participating in 10 public workshops

# ADUFA III: 2014 – 2018 (Current Authorization)

Process enhancements:

- Added flexibility to the process by replacing ERAs with 2nd cycle shortened-review process, including extensive IT enhancements
- Fostered innovation through the early information process; working to fill the pipeline and increase drug availability
- Implemented multiple enhancements for the chemistry, manufacturing and controls (CMC) technical section
- Established two new sentinel submission types (Non-fee labeling supplements, Microbial Food Safety Hazard Characterizations)

# ADUFA III: 2014 – 2018 (Current Authorization)

Long Term Goals:

- Conditional Approval: CVM agrees to explore, in concert with industry, the feasibility of pursuing statutory revisions that may expand the use of conditional approvals to other appropriate categories of new animal drug applications.
- ADAA Combinations: CVM agrees to explore, in concert with affected parties, the feasibility of pursuing statutory revisions that may modify the current requirement that the use of multiple new animal drugs in the same medicated feed be subject to an approved application.

# ADUFA III: Performance Goals

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

| Submission Type | FY15–18 |
|---|---|
| **NADA Submissions** | |
| Administrative NADAs | 60 |
| Original NADAs and Reactivations | 180 |
| Shortened Review NADA Reactivations | 135 |
| Non-Manufacturing Supplemental NADAs and Reactivations | 180 |
| Shortened Review Non-Manufacturing Supplemental NADA Reactivations | 135 |
| Manufacturing Supplemental NADAs and Reactivations | 120 |
| Qualifying Labeling Supplements | 60 |
| **INAD Submissions** | |
| INAD Studies | 180 |
| Shortened Review INAD Studies Resubmissions | 60 |
| INAD Studies (Microbial Food Safety Hazard Characterization) | 100 |
| INAD Study Protocols | 50 |
| Shortened Review INAD Study Protocol Resubmissions | 20 |

# Program Performance

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

# Program Performance: ADUFA III (Final FY14)

| Application/ Submission Type | Filed | ERA Status | Performance Goal: Act on 90 Percent Within | On Time | Overdue | Percent On Time |
|---|---|---|---|---|---|---|
| Original NADAs and Reactivations | 3 | None Requested | 180 days | 3 | 0 | 100% |
| | | Requested Not Submitted | 220 days | 0 | 0 | |
| | | Requested And Submitted | 345 days | 0 | 0 | |
| Administrative NADAs | 21 | | 60 days | 21 | 0 | 100% |
| Non-manufacturing Supplemental NADAs and Reactivations | 9 | None Requested | 180 days | 8 | 1 | 89% |
| | | Requested Not Submitted | 220 days | 0 | 0 | |
| | | Requested And Submitted | 345 days | 0 | 0 | |
| Manufacturing Supplemental NADAs and Reactivations | 340 | | 120 days | 340 | 0 | 100% |
| INAD Studies | 235 | None Requested | 180 days | 187 | 1 | 99% |
| | | Requested Not Submitted | 220 days | 3 | 0 | |
| | | Requested And Submitted | 270 days | 42 | 2 | |
| INAD Study Protocols | 140 | None Requested | 60 days | 61 | 0 | 100% |
| | | Requested Not Submitted | 75 days | 6 | 0 | |
| | | Requested And Submitted | 60 to 80 days | 73 | 0 | |

# Program Performance: ADUFA III (Preliminary FY15)

| Application/ Submission Type | Filed | Goal: Act on 90 Percent Within | On Time | Overdue | Percent On Time | Pending Within Goal | Highest Possible Percent On Time |
|---|---|---|---|---|---|---|---|
| Original NADAs and Reactivations | 3 | 180 days | 1 | 0 | 100% | 2 | 100% |
| Administrative NADAs | 16 | 60 days | 14 | 0 | 100% | 2 | 100% |
| Non-manufacturing Supplemental NADAs and Reactivations | 6 | 180 days | 4 | 0 | 100% | 2 | 100% |
| Manufacturing Supplemental NADAs and Reactivations | 334 | 120 days | 233 | 1 | 99% | 100 | 99% |
| Qualifying Labeling Supplements | 3 | 60 days | 2 | 0 | 100% | 1 | 100% |
| INAD Studies | 149 | 180 days | 95 | 0 | 99% | 54 | 99% |
| INAD Study Protocols | 247 | 60 days | 224 | 0 | 100% | 23 | 100% |

# Program Performance: Other Accomplishments

- Implemented IT enhancements to support new performance goals.
- **Animal Drug Availability Act (ADAA) Combinations** and **Conditional Approval -** The Agency held public meetings on March 16, 2015 to discuss these issues with stakeholders.