## Performance Report to Congress

# Animal Drug User Fee Act

## FY 2024

# Executive Summary

On September 30, 2023, the fourth reauthorization of the Animal Drug User Fee Act (ADUFA), referred to as *ADUFA V*, was signed into law extending the ADUFA program for an additional 5 years (from fiscal year (FY) 2024 through FY 2028). ADUFA V includes a comprehensive set of the Food and Drug Administration's (FDA's) review performance goals and commitments designed to improve the timeliness and predictability of its review of new animal drug applications (NADAs) and reactivations, supplemental NADAs and reactivations, and some investigational new animal drug submissions.

More information on the history of ADUFA is available on FDA's ADUFA website.[1]

## A. Information Included in This Report

This report summarizes FDA's performance results in meeting its ADUFA goals and commitments for FY 2023 and FY 2024. Specifically, it updates and finalizes performance data initially reported in the FY 2023 ADUFA Performance Report and presents preliminary data on FDA's progress in meeting its FY 2024 review goals, implementation activities, and accomplishments.

## B. Review Performance

FDA met or exceeded the expectations of the review performance goals in the fifth year of ADUFA IV (i.e., FY 2023) and continued to meet or exceed expectations of the review performance goals for FY 2024. Key activities and accomplishments during FY 2024 included the following:

- FDA met review-time goals for almost all (666 of 683) of the FY 2023 cohort submissions. FDA exceeded all eight ADUFA performance goals for the FY 2023 cohort for which FDA received submissions. Please see Appendix A for more details on the submission types and related performance goals.
- Preliminary performance results indicate that FDA met review-time goals for almost all (390 of 399) of the FY 2024 cohort submissions reviewed and acted on as of September 30, 2024. With 253 additional reviews pending that may yet be completed on time, FDA has the potential to meet or exceed the eight ADUFA performance goals for the FY 2024 cohort for which FDA received submissions.

[1] www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.

Please see Appendix A for more details on the submission types and related performance goals.

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# Acronym List

| | |
|---|---|
| **ADAA** | Animal Drug Availability Act |
| **ADUFA** | Animal Drug User Fee Act |
| **AHI** | Animal Health Institute |
| **CMC** | Chemistry, Manufacturing, and Controls |
| **CNADA** | Conditional New Animal Drug Application |
| **CVM** | Center for Veterinary Medicine |
| **EU** | European Union |
| **FDA** | Food and Drug Administration |
| **FD&C Act** | Federal Food, Drug, and Cosmetic Act |
| **FY** | Fiscal Year (October 1 to September 30) |
| **GFI** | Guidance for Industry |
| **GMP** | Good Manufacturing Practice |
| **INAD** | Investigational New Animal Drug |
| **MFS HC** | Microbial Food Safety Hazard Characterization |
| **MRA** | Mutual Recognition Agreement |
| **NADA** | New Animal Drug Application |
| **PAI** | Pre-Approval Inspection |
| **P&P** | Program Policy and Procedures Manual Guide |
| **TAS** | Target Animal Safety |

# I. Introduction

The Animal Drug User Fee Act (ADUFA) requires the Secretary of Health and Human Services to submit the following two annual reports to the Committee on Health, Education, Labor, and Pensions of the Senate, and to the Committee on Energy and Commerce of the House of Representatives for each fiscal year (FY) in which fees are collected: (1) a performance report and (2) a financial report. This report is the Food and Drug Administration's (FDA's or Agency's) first annual performance report to Congress under the fourth reauthorization of ADUFA, referred to as *ADUFA V*. Under ADUFA V, FDA agreed to meet performance goals over 5 years (from FY 2024 through FY 2028) for certain submissions. Further details on FDA's commitments under ADUFA V can be found in the ADUFA V Performance Goals Letter on FDA's website.[1]

By providing FDA with supplemental funding for the review of new animal drug submissions, ADUFA was designed to provide greater predictability in review times for the animal drug industry and to accelerate the availability of safe and effective new animal products.

## A. Information Presented in This Report

In any given year, FDA's performance includes its review of applications and submissions pending from previous fiscal years along with submissions received during the current fiscal year. This report provides FDA's final performance results for the FY 2023 cohort submissions and presents FDA's preliminary performance results for the FY 2024 cohort submissions that were received early enough to be reviewed and acted on, or due for review, by September 30, 2024. The definitions below apply to the information provided in the FY 2024 report:

- The term *submission* is used to refer to new and conditional new animal drug applications (NADAs and CNADAs, respectively) and reactivations, supplemental NADAs and reactivations, investigational new animal drug (INAD) studies, and INAD protocols.

- *Review-time goal* is the targeted time period, identified in number of calendar days, within which individual submissions are to be acted on by FDA. ADUFA review-time goals range from 20 days to 180 days. FDA calculates ADUFA review times by the date of the original receipt of the application or submission. An *on-time review* indicates that FDA completed an action within the number of calendar days specified by the review-time goal.

- *Percent on time* refers to the percentage of reviews for which FDA met a review-time goal for a given type of submission. FDA's percent on time for a given type of

[1] https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.

submission is used to determine whether FDA met or exceeded the ADUFA performance goals.

- *Performance goal* refers to the percentage of total submissions, agreed to under ADUFA, for which FDA is expected to meet the review-time goal for a given type of submission. The ADUFA performance goals call for FDA to meet the review-time goals 90 percent of the time for the defined fiscal year cohort.

- For submission types with a longer review-time goal (for example, 180 days), review performance data are usually limited at the time the performance report is prepared. For submission types with a shorter review-time goal (for example, 50 days), review performance data for submissions received early in the fiscal year are available at the time the report is prepared and thus the report may provide an early indicator of review performance.

- Performance goal tables indicate the total number of submissions filed, as well as whether the submission was reviewed on time, was overdue, or is still pending and not past its due date. Submissions that FDA identified as refused to file or refused to review, as well as reviews that were stopped at the request of the sponsor, are not included in the statistics used to measure performance. However, beginning in FY 2024, FDA is reporting the numbers and types of refusals in its performance reports. (See Table 4.)

- When determining performance, FDA's calculated percentages are rounded to the nearest whole number, up to 99 percent. Percentages above 99 percent, but below 100 percent, are rounded down to 99 percent.

- The performance statistics in this report are based on submissions received during a fiscal year, known as a *receipt cohort*. The performance statistics for submissions were calculated according to the fiscal year FDA received them, regardless of the year in which FDA ultimately acted on the submissions. A result of this approach is that the statistics shown for a particular fiscal year may change from one report to the next. As more submissions are completed, the statistics for the year of receipt are adjusted to reflect the new completions. Therefore, until all submissions in a cohort are acted on or have passed the due date, whichever comes first, only a preliminary performance assessment is provided for that fiscal year cohort.

- The term *labeling supplement* is understood to mean a supplemental application for certain labeling changes as described in 21 CFR 514.8(c)(2)(i)(A) and (D) that require approval of a supplemental application prior to distribution of the drug made using the change.

**File Types Included in This Report**

- **NADA** – A new animal drug application (NADA) includes all amendments and supplements. This report presents original applications and reactivations, administrative applications, and supplemental applications and reactivations as separate goals.
- **INAD** – Under an investigational new animal drug (INAD) file, sponsors may submit data intended to support an application for new animal drug approval. This report presents studies and protocols.
- **CNADA –** An approved application for conditional approval of a new animal drug (CNADA) allows a sponsor to legally market a new animal drug after fulfilling the requirements for conditional approval and while it pursues full approval. This report includes CNADAs as a type of new animal drug application.

**Sources:**

- NADA: www.fda.gov/animal-veterinary/guidance-industry/new-animal-drug-application-guidances
- INAD: www.fda.gov/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm123818.htm
- CNADA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-261-eligibility-criteria-expanded-conditional-approval-new-animal-drugs

# II. ADUFA Review Workload

## A. Review Workload: FY 2019 to FY 2024

In the table below, preliminary review workload numbers from FY 2024 are compared to the previous 5-year averages for all ADUFA application and submission types filed. The workload counts presented for FY 2024 include all submissions received in FY 2024. The individual fiscal years that are included in the 5-year average are also referenced below. There are no performance goals associated with the workload, but the variations over time in the workload can provide context for FDA's review performance. In FY 2024, the workload for three application and submission types showed an increase from the 5-year average, and six application and submission types decreased.

**Table 1: Review Workload for Applications and Submissions**

| Application/Submission Type | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 (#) | FY 19 to FY 23 5-Year Average | FY 24 Compared to 5-Year Average |
|---|---|---|---|---|---|---|---|---|
| **Animal Drug Applications and Submissions** | | | | | | | | |
| Original NADAs, CNADAs, and Reactivations * | 4 | 9 | 4 | 5 | 2 | 6 | 5 | 20% |
| Administrative NADAs and CNADAs | 9 | 11 | 7 | 11 | 13 | 11 | 10 | 10% |
| Non-manufacturing Supplemental NADAs and Reactivations | 9 | 3 | 7 | 1 | 4 | 4 | 5 | -20% |
| Manufacturing Supplemental NADAs and Reactivations † | 351 | 423 | 389 | 294 | 317 | 359 | 355 | 1% |
| Labeling Supplements ‡ | 20 | 23 | 19 | 57 | 36 | 5 | 31 | -84% |
| INAD Study Submissions § | 182 | 160 | 170 | 138 | 156 | 121 | 161 | -25% |
| INAD Protocol Submissions ¶ | 360 | 259 | 158 | 173 | 125 | 94 | 215 | -56% |
| Presubmission Conferences | 77 | 84 | 73 | 47 | 30 | 52 | 62 | -16% |
| Tissue Residue Method Demonstration | 0 | 1 | 2 | 1 | 0 | 0 | 1 | -100% |

* Original NADAs, CNADAs, and Reactivations *include Animal Drug Availability Act (ADAA) combination medicated feeds applications.*
† Manufacturing Supplemental NADAs and Reactivations *include Prior Approval Supplements and Supplement-Changes Being Effected in 30 Days.*
‡ Labeling Supplements totals *include qualifying and non-qualifying submissions.* (See Appendix A.)

§ INAD Study Submissions *include categorical exclusions.*
¶ INAD Protocol Submissions without data.
# The FY 2024 numbers are preliminary and will be finalized in the FY 2025 ADUFA Performance Report.

# III. FY 2023 and FY 2024 ADUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2023 and FY 2024 ADUFA cohort submissions.

## A. Final FY 2023 Performance Results

FDA exceeded the 90 percent performance level for all eight of the submission types for which submissions were received for the FY 2023 cohort. Across all submission types, FDA met the review-time goal for 666 of the 683 submissions. The entire FY 2023 cohort has closed; therefore, there are no pending submissions. Please see Appendix A for more details on the submission types presented in the table below and on the ADUFA IV performance goals.

**Table 2: Final FY 2023 Performance Results**

| Application/Submission Type | Filed | On Time | Overdue | Percent on Time |
|---|---|---|---|---|
| **Animal Drug Applications and Submissions** | | | | |
| Original NADAs, CNADAs, and Reactivations | 2 | 2 | 0 | 100% |
| Administrative NADAs and CNADAs | 13 | 13 | 0 | 100% |
| Non-manufacturing Supplemental NADAs and Reactivations | 4 | 4 | 0 | 100% |
| Manufacturing Supplemental NADAs and Reactivations ** | 317 | 308 | 9 | 97% |
| Labeling Supplements | 36 | 36 | 0 | 100% |
| INAD Study Submissions ** | 156 | 149 | 7 | 96% |
| INAD Protocol Submissions | 125 | 125 | 0 | 100% |
| Presubmission Conferences ** | 30 | 29 | 1 | 97% |
| Tissue Residue Method Demonstration * | 0 | N/A | N/A | N/A |

* No performance can be calculated since there were no submissions of this type.
** The numbers were changed to reflect updates to the data presented in the FY 2023 ADUFA Performance Report.

## B. Preliminary FY 2024 Performance Results

As of September 30, 2024, preliminary performance data was available for 399 of 652 submissions filed in FY 2024. FDA is currently exceeding performance goals for the eight submission types that have at least one submission acted on in FY 2024. Overall, FDA met review-time goals for 390 of 399 submissions acted on. With 253 submissions pending within the goal, FDA has the potential to meet or exceed the 90 percent performance level for all eight of the submission types for which submissions were received in FY 2024. Please see Appendix A for more detail on the submission types in the table below and the ADUFA V performance goals.

### Table 3: Preliminary FY 2024 Performance Results

| Application/Submission Type | Filed | On Time | Overdue | Pending Within Goal | Percent on Time |
|---|---|---|---|---|---|
| **Animal Drug Applications and Submissions** | | | | | |
| Original NADAs, CNADAs, and Reactivations | 6 | 3 | 0 | 3 | 100% |
| Administrative NADAs and CNADAs | 11 | 9 | 0 | 2 | 100% |
| Non-manufacturing Supplemental NADAs and Reactivations | 4 | 1 | 0 | 3 | 100% |
| Manufacturing Supplemental NADAs and Reactivations | 359 | 184 | 6 | 169 | 97% |
| Labeling Supplements | 5 | 4 | 0 | 1 | 100% |
| INAD Study Submissions | 121 | 61 | 2 | 58 | 97% |
| INAD Protocol Submissions | 94 | 85 | 1 | 8 | 99% |
| Presubmission Conferences | 52 | 43 | 0 | 9 | 100% |
| Tissue Residue Method Demonstration * | 0 | N/A | N/A | N/A | N/A |

* No performance can be calculated since there were no submissions of this type.

A decision to refuse to file an application, or to refuse to review a submission, results in the application or submission not being included in the receipt cohort for that fiscal year, which means they are not included in the user fee goal. The numbers of refusals per fiscal year are shown in the table below.

**Table 4: Refusals to File an Application or to Review a Submission**

| Decision Type | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
|---|---|---|---|---|---|
| **Number of Decisions** | | | | | |
| Refuse to File an Application | 4 | | | | |
| Refuse to Review a Submission | 3 | | | | |

# IV. FY 2024 Process Improvements and Major Accomplishments

Under ADUFA V, FDA committed to a variety of process improvements. FDA agreed to continue to enhance and further improve the review process via the following goals and procedures:

## A. Foreign Inspections.

**1. Pre-Approval Inspections (PAIs).** Continuing under ADUFA V, to improve the timeliness and predictability of foreign PAIs, the regulated industry may voluntarily submit, 1) at the beginning of the calendar year, a list of foreign manufacturing facilities that are specified in an NADA, a CNADA, a supplemental NADA, or an INAD submission and may be subject to foreign PAIs for the following fiscal year and 2) a notification 30 days prior to submitting an NADA, a CNADA, a supplemental NADA, or an INAD submission that informs the Agency that the application/submission includes a foreign manufacturing facility.

**Accomplishment:** In FY 2024, the average time to complete a PAI improved. The table below shows the number of foreign PAIs conducted and the average time to complete a PAI during each fiscal year.

**Table 5: Number of Foreign PAIs and Average Time to Complete PAIs**

| Fiscal Year | Number of Foreign PAIs Conducted | Average Time to Completion (in Days) |
|---|---|---|
| 2019 | 10 | 106 |
| 2020 | 5 | 130 |
| 2021 | 1 | 159 |
| 2022 | 2 | 456 |
| 2023 | 11 | 186 |
| 2024 | 8 | 109 |

**2. Foreign Good Manufacturing Practice (GMP) Inspections.** The Agency commits to working to implement and maintain the United States and European Union (EU), and the United States and United Kingdom, GMP mutual recognition

agreements (MRAs) and future MRAs with respect to animal drug products subject to review. The Agency agreed that beginning in FY 2024 it would report quarterly in FDA-TRACK the percentage of PAI risk decisions that relied at least in part on information from inspections recognized under an MRA with a foreign regulatory authority.

**Accomplishment:** The Center for Veterinary Medicine (CVM) worked collaboratively with FDA's Office of Global Policy and Strategy and Office of Regulatory Affairs to enact an MRA with the EU and an MRA with Switzerland to support surveillance inspections of veterinary drug manufacturers. The U.S.-EU MRA for veterinary products was implemented for Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Slovenia, Spain, and Sweden. Capability assessments for veterinary drug inspectorates in the remaining EU Member States are currently underway for future implementation. Previously, two separate MRAs between the United States and the United Kingdom and Switzerland were implemented for both human and animal drugs; these MRAs have been in use to support surveillance inspections. For more information, please see https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra.

## B. Meetings.

**1. Presubmission conferences held virtually.** Beginning on October 1, 2023, FDA agreed to provide written responses to sponsor questions at least 6 days prior to virtual presubmission conferences and to provide a memorandum of conference within 30 days after virtual presubmission conferences. For non-virtual presubmission conferences, FDA agreed to provide a memo of conference within 45 days.

**Accomplishment:** In FY 2024, FDA received a total of 17 requests for presubmission conferences to be held virtually. These were through early response letter requests. Sixteen of the requests have been completed and one is still pending. All 16 completed requests received a written response at least 6 days prior to the presubmission conference. Of the 16 completed, 10 meetings were held, and six were cancelled by the sponsor because the written responses answered its questions.

**2. Stakeholder engagement.** FDA agreed to hold three meetings per year with Animal Health Institute (AHI) members, including a sub-meeting with CVM leadership. One meeting per year will include a public educational session for the drug industry and will be recorded for posting on FDA's website.

**Accomplishment:** FDA held three meetings with AHI members on issues of mutual concern, including the planning for and conducting of a day-long educational session on the new animal drug approval process on July 17, 2024.

The session was attended by over 680 people from 15 countries both in-person and virtually. FDA worked with AHI members to develop the agenda for the session to ensure the topics were relevant and applicable to meet stakeholder needs.

## C. H submissions.

**1. Supporting information for presubmission conferences and INAD protocols without data submissions.** FDA agreed that by October 1, 2023, it would publish a Program Policy and Procedures Manual Guide (P&P) for CVM reviewers on H submissions related to presubmission conferences and the timing and scheduling of related meeting requests. Also by October 1, 2023, FDA agreed to publish a P&P for CVM reviewers on the timing of protocol submissions in relation to H submissions to support the protocol.

**Accomplishment:** FDA published P&P 1243.4092 (H Submissions Preceding Meetings and Protocols) on September 29, 2023.

**2. Dosage characterization.** The Agency clarified that dosage characterization is part of the effectiveness technical section of the INAD file. The Agency and regulated industry agreed that if information about dosage is integral to the review of a protocol, it should be provided early to inform the review.

**Accomplishment:** The Agency continued to implement the dosage characterization process.

**3. Raw data submission expectations.** FDA agreed that by October 1, 2023, it would publish a P&P for CVM reviewers on sponsors' proposed lists of copies of raw data and documents supporting target animal safety (TAS) protocols without data submission. FDA also agreed that by October 1, 2024, it would publish a draft guidance for industry (GFI) on raw data submission expectations for non-clinical studies conducted under Good Laboratory Practice requirements and clinical studies conducted under Good Clinical Practice requirements.

**Accomplishment:** FDA published P&P 1243.4095 (Review of Raw Data Agreement H Submission for Target Animal Safety Studies) on September 29, 2023. FDA published draft GFI #287 ("Raw Data for Safety and Effectiveness Studies") on April 26, 2024.

**4. eSubmitter and H submissions for raw data.** FDA agreed that by October 1, 2023, it would launch an eSubmitter template for TAS protocols, provided that industry had provided timely feedback to further FDA's work on the template. FDA may also develop an eSubmitter template for effectiveness protocol submissions and invite industry feedback.

**Accomplishment:** FDA deployed the H submission for the raw data eSubmitter template for TAS studies on October 2, 2023.

## D. Exploration with industry.

**1. ADAA combination medicated feeds.** FDA and industry agreed to explore why the ADAA combination medicated feed review process outlined in P&P 1243.5730 is not being utilized. The exploration will be completed by October 1, 2025. FDA may revise the P&P based on the outcome of the exploration.

**2. Residue method trial.** FDA agreed to explore, in concert with affected parties including the animal health industry, the drug residue analytical method trial process and its requirements as they relate to the approval of new animal drugs intended for food-producing animals. The exploration will be completed by October 1, 2025.

**3. Sentinel submission clock stop.** FDA agreed to explore, in concert with industry, the feasibility of using additional review tools to enhance the efficiency of the animal drug review process. This exploration was to begin on October 1, 2023, and to end by September 30, 2025.

**4. Feedback on product development plans.** FDA agreed to explore, in concert with affected parties including the animal health industry, means for the Agency to provide feedback on a sponsor's animal drug development plan more efficiently and effectively for both industry and FDA. This exploration is to be completed by October 1, 2025.

**Accomplishment:** FDA established the above four working groups in conjunction with regulated industry. The working groups are meeting periodically.

## E. Other, Including Metrics

**1. Chemistry, Manufacturing, and Controls (CMC).** FDA agreed that by September 30, 2024, it would publish a P&P for CMC reviewers to clarify when reviewers should request amendments, use shortened review time, or classify submissions as incomplete. In addition, this P&P will describe what administrative actions are appropriate when GMP status (or pending PAI) is the only comment remaining for a CMC technical section. Further, FDA agreed that by September 30, 2024, it would revise GFI #227 ("Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections") to define situations for which parallel submission of phased data submissions would be allowed.

**Accomplishment:** FDA published P&P 1243.3028 (Administrative Pathways for Obtaining Additional Chemistry, Manufacturing, and Controls Information) on March 22, 2024. FDA published draft (revised) GFI #227 ("Chemistry,

Manufacturing, and Controls (CMC) Technical Section Filing Strategies") on September 16, 2024.

**2. Metrics: Time in Agency/Time in Industry.** FDA agreed that beginning in FY 2024, it would, in concert with industry, explore potential Agency-reported metrics regarding the review time of investigational submissions that lead to approvals by the Agency and response time by industry.

**Accomplishment:** FDA established this working group in conjunction with regulated industry. The working group is meeting periodically.

**3. Metrics: Favorable Outcomes.** FDA agreed to report quarterly in FDA-TRACK, beginning in the second quarter of FY 2024, for INAD protocols without data and for INAD study submissions, the number of the following outcomes: (1) favorable, (2) non-concurrence/non-accepted with shortened review offered, and (3) non-concurrence/non-accepted and shortened review not offered.

**Accomplishment:** FDA began publishing outcomes metrics on FDA-TRACK[4] in January 2024.

**4. Metrics: INAD H Submissions Submitted at Division Level.** FDA agreed that beginning in the second quarter of FY 2024, FDA will report quarterly in FDA-TRACK the number of H submissions submitted to the Office of New Animal Drug Evaluation by division.

**Accomplishment:** FDA began publishing INAD H submissions submitted at the division level on FDA-TRACK[5] in January 2024.

**5. Metrics: Average Review Times in Hours.** FDA agreed that beginning in FY 2024, it would include in the performance report the average review times, in hours, for protocols without data and for INAD study submissions (broken down by technical section) by fiscal year. The following two tables report this information.

[4] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-animal-drug-user-fee-act-animal-favorable-outcomes-inad-protocols-and-data-submissions
[5] https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-animal-drug-user-fee-act-performance-inad-h-submissions-submitted-division-level

## Table 6: Average Review Times in Hours for INAD Protocols without Data by Fiscal Year

| Technical Section | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
|---|---|---|---|---|---|
| **Average Review Time in Hours for INAD Protocols without Data by Fiscal Year** | | | | | |
| Effectiveness | 31 | | | | |
| Target Animal Safety | 29 | | | | |
| Manufacturing Chemistry | 23 | | | | |
| Human Food Safety | 50 | | | | |
| Environmental Impact | 26 | | | | |

## Table 7: Average Review Times in Hours for INAD Study Submissions by Fiscal Year

| Technical Section | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
|---|---|---|---|---|---|
| **Average Review Time in Hours for INAD Study Submissions by Fiscal Year** | | | | | |
| Effectiveness | 212 | | | | |
| Target Animal Safety | 186 | | | | |
| Manufacturing Chemistry | 85 | | | | |
| Human Food Safety | 59 | | | | |
| Environmental Impact | 100 | | | | |

**6. Metrics: Sentinel Submissions Filed/Submitted at Division Level.** FDA agreed that beginning in FY 2024, it would include in the performance report the number of certain filed/submitted sentinel submissions by review division. The following table reports this information. A key to the review division abbreviations follows Table 8.

### Table 8: Number of Filed/Submitted Sentinel Submissions by Review Division

| Sentinel Submission | Review Division | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
|---|---|---|---|---|---|---|
| **Sentinel Submissions Filed/Submitted by Division Level** | | | | | | |
| Original NADAs, CNADAs and react.. | DFAD | 6 | | | | |
| Administrative NADAs and CNADAs | DCAD | 6 | | | | |
| | DFAD | 5 | | | | |
| Non-manufacturing supplemental NADAs and reactivations | DCAD | 4 | | | | |
| INAD study protocols without data submissions | DABCT | 3 | | | | |
| | DCAD | 49 | | | | |
| | DFAD | 11 | | | | |
| | DHFS | 7 | | | | |
| | DMT | 24 | | | | |
| INAD study submissions | DABCT | 5 | | | | |
| | DCAD | 34 | | | | |
| | DFAD | 22 | | | | |
| | DHFS | 13 | | | | |
| | DMT | 23 | | | | |
| | DSS | 24 | | | | |
| Qualifying labeling supplements | DCAD | 2 | | | | |
| | DFAD | 3 | | | | |
| Presubmission conferences | DBISM | 37 | | | | |
| | DCAD | 4 | | | | |
| | DFAD | 3 | | | | |
| | DHFS | 6 | | | | |
| | DMT | 1 | | | | |
| | DSS | 1 | | | | |

## Key To Review Division Abbreviations Used in Table 8

| | |
|---|---|
| DABCT | Division of Animal Biotechnology and Cellular Therapies |
| DBISM | Division of Business Information Science and Management |
| DCAD | Division of Companion Animal Drugs |
| DFAD | Divison of Food Animal Drugs |
| DHFS | Division of Human Food Safety |
| DMT | Division of Manufacturing Technologies |
| DSS | Division of Scientific Support |

# Appendix A: Progression of ADUFA Performance Goals

The table in this appendix shows the ADUFA IV (FY 2019 to FY 2023) performance goals and the current ADUFA V (FY 2024 to FY 2028) goals.

| Submission Type | Performance Goal: Act on 90 Percent Within (Days) | |
|---|---|---|
| | ADUFA IV | ADUFA V |
| **Original NADAs and Reactivations** | | |
| Original NADAs and Reactivations | 180 | 180 |
| Shortened Review Original NADA Reactivations | 135 | 135 |
| ADAA Combinations | 60 | 60 |
| **Administrative NADAs** | 60 | 60 |
| **Non-Manufacturing Supplemental NADAs and Reactivations** | | |
| Non-Manufacturing Supplement NADAs | 180 | 180 |
| Non-Manufacturing Supplemental Reactivations | 180 | 180 |
| Shortened Review Non-Manufacturing Supplemental Reactivations | 135 | 135 |
| **Manufacturing Supplemental NADAs and Reactivations** | | |
| Manufacturing Supplements and Reactivations (Prior Approval) | 120 | 120 |
| Manufacturing Supplements and Reactivations (Changes Being Effected) | 180 | 180 |
| **Labeling Supplements** | | |
| Qualifying Labeling Supplements | 60 | 60 |
| Non-Qualifying Labeling Supplements* | 180 | 180 |
| **INAD Study Submissions** | | |
| Phased Data Submissions | 180 | 180 |
| Phased Data Resubmissions | 180 | 180 |
| Phased Data Submissions Microbial Food Safety Hazard Characterization (MFS HC) | 100 | 100 |

| Submission Type | Performance Goal: Act on 90 Percent Within (Days) | |
|---|---|---|
| | ADUFA IV | ADUFA V |
| Shortened Review Phased Data Resubmissions | 60 | 60 |
| Phased Data Submissions End Game Categorical Exclusions | 60 | 60 |
| **INAD Protocol Submissions** | | |
| Protocol Submissions | 50 | 50 |
| Protocol Resubmissions | 50 | 50 |
| Shortened Review Protocol Resubmissions | 20 | 20 |
| **Presubmission Conference** | 60 | 60 |
| **Tissue Residue Method** | 120 | 120 |

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