Performance Report to Congress

Animal Drug User Fee Act
FY 2023

Executive Summary

On August 14, 2018, the third reauthorization of the Animal Drug User Fee Act (ADUFA), referred to as *ADUFA IV*, was signed into law extending the ADUFA program for an additional 5 years (i.e., from fiscal year (FY) 2019 through FY 2023). ADUFA IV 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 (INAD) 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 2022 and FY 2023. Specifically, it updates and finalizes performance data initially reported in the FY 2022 ADUFA Performance Report and presents preliminary data on FDA's progress in meeting its FY 2023 review goals, implementation activities, and accomplishments.

B. Review Performance

FDA met or exceeded the expectations of the review performance goals in the fourth year of ADUFA IV (i.e., FY 2022) and continued to meet or exceed expectations of the review performance goals for FY 2023. Key activities and accomplishments during FY 2023 included the following:

- FDA met review-time goals for almost all (711 of 727) of the FY 2022 cohort submissions. FDA exceeded all nine ADUFA performance goals for the FY 2022 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 (411 of 418) of the FY 2023 cohort submissions reviewed and acted on as of September 30, 2023. With 284 additional reviews pending that may yet be completed on time, FDA will meet one of the ADUFA performance goals and has the potential to meet or exceed the remaining eight of the ADUFA performance goals for the FY 2023 cohort for which FDA received submissions. Please see

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

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
ANADA	Abbreviated 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
MUMS	Minor Use or Minor Species
NADA	New Animal Drug Application
ORA	Office of Regulatory Affairs
PAI	Pre-Approval Inspection

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) fifth annual performance report to Congress under the third reauthorization of ADUFA, referred to as *ADUFA IV*. Under ADUFA IV, FDA agreed to meet performance goals over 5 years (i.e., from FY 2019 through FY 2023) for certain submissions. Further details on FDA's commitments under ADUFA IV can be found in the ADUFA IV Performance Goals Letter on FDA's Website.[2]

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 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 2022 cohort submissions and presents FDA's preliminary performance results for the FY 2023 cohort submissions that were received early enough to be reviewed and acted on, or due for review, by September 30, 2023. The definitions below apply to the information provided in the FY 2023 report:

- The term *submission* is used to refer to new animal drug applications (NADAs) 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 for FY 2023. An *on-time review* indicates that FDA completed an action within the number of calendar days specified by the review-time goal.

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

- *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 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 IV performance goals call for FDA to meet the review-time goals 90 percent of the time for the defined fiscal year cohort.

- 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.

- For submission types with a longer review-time goal (for example, 180 days), review performance data are usually limited. 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.

- The workload counts presented in this report for FY 2023 include all submissions received in FY 2023. FDA calculates ADUFA review times by the date of the original receipt of the application or submission.

- Minor Use or Minor Species (MUMS) conditional approvals are not counted as NADAs. Therefore, review performance on them is not presented in this report. The goal of MUMS is to encourage the development of products for the treatment of minor species or for the treatment of animal diseases and conditions in major

species that occur infrequently or in limited geographic areas. Further details on MUMS can be found on FDA's MUMS website.[3]

- 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.

- 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 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.

Sources:

- NADA: www.fda.gov/animal-veterinary/guidance-industry/new-animal-drug-application-guidances
- INAD: www.fda.gov/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm123818.htm

[3] www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies.

II. ADUFA Review Workload

A. Review Workload: FY 2018 to FY 2023

In the table below, preliminary review workload numbers from FY 2023 are compared to the previous 5-year averages for all ADUFA application and submission types filed. 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 2023, the workload for two application and submission types showed an increase from the 5-year average, and seven application and submission types decreased.

Review Workload for Applications and Submissions

Application/ Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22‡	FY 23	FY 18 to FY 22 5-Year Average	FY 23 Compared to 5-Year Average
Original NADAs and Reactivations	9	4	9	4	5	2	6	-67%
Administrative NADAs	11	9	11	7	11	13	10	30%
Non-Manufacturing Supplemental NADAs and Reactivations	4	9	3	7	1	4	5	-20%
Manufacturing Supplemental NADAs and Reactivations	347	351	423	389	294	336	361	-7%
Labeling Supplements*	3	20	23	19	57§	36	24	50%
INAD Studies	157	182	160	170	138	158	161	-2%
INAD Study Protocols	227	360	259	158	173	125	235	-47%
Presubmission Conferences	N/A	77	84	73	47	32	70	-54%
Tissue Residue Method Demonstration	N/A	0	1	2	1	0	1	-100%

* Labeling Supplements were added as a sentinel submission type in the second year of ADUFA III (i.e., FY 2015). The FY 2018 total includes only qualifying submissions; the FY 2019 through FY 2023 total includes qualifying and non-qualifying submissions (see Appendix A).
Presubmission Conferences and Tissue Residue Method Demonstration were added as sentinel submission types in the first year of ADUFA IV (i.e., FY 2019).
‡ The FY 2023 numbers are preliminary and will be finalized in the FY 2024 ADUFA Performance Report.

[§] This large increase was due to the requirement in section 502(w)(3) of the Federal Food, Drug, and Cosmetic Act, which had a deadline of September 30, 2023. Sponsors have been submitting supplements to comply with this requirement.

III. FY 2022 and FY 2023 ADUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2022 and FY 2023 ADUFA cohort submissions.

A. Final FY 2022 Performance Results

FDA exceeded the 90 percent performance level for all nine of the submission types for which submissions were received for the FY 2022 cohort. Across all submission types, FDA met the review-time goal for 711 of the 727 submissions. The entire FY 2022 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 performance goals.

Application/ Submission Type	Filed	On Time	Overdue	Percent on Time
Original NADAs and Reactivations	*5	5	0	100%
Administrative NADAs	11	11	0	100%
Non-Manufacturing Supplemental NADAs and Reactivations	*1	1	0	100%
Manufacturing Supplemental NADAs and Reactivations	*294	285	9	97%
Labeling Supplements	*57	55	2	96%
INAD Studies	*138	136	2	99%
INAD Study Protocols	173	173	0	100%
Presubmission Conferences	*47	44	3	94%
Tissue Residue Method Demonstration	1	1	0	100%

*The numbers were changed to reflect updates to the data presented in the FY 2022 ADUFA Performance Report

B. Preliminary FY 2023 Performance Results

As of September 30, 2023, preliminary performance data was available for 418 of 706 submissions filed in FY 2023. FDA will meet one performance goal and is currently exceeding performance goals for the other seven submission types which have at least one submission acted on in FY 2023. Overall, FDA met review-time goals for 411 of 418 submissions acted on. With 284 submissions pending within the goal, FDA has the potential to meet or exceed the 90 percent performance level for all nine of the submission types for which submissions were received in FY 2023. Please see Appendix A for more detail on the submission types in the table below and the performance goals.

Application/ Submission Type	Filed	On Time	Overdue	Pending Within Goal	Pending Overdue	Percent on Time
Original NADAs and Reactivations	2	2	0	0	0	100%
Administrative NADAs	13	9	0	4	0	100%
Non-Manufacturing Supplemental NADAs and Reactivations	4	2	0	2	0	100%
Manufacturing Supplemental NADAs and Reactivations	336	152	4	179	1	99%
Labeling Supplements	36	33	0	3	0	100%
INAD Studies	158	74	3	80	1	97%
INAD Study Protocols	125	115	0	10	0	100%
Presubmission Conferences	32	24	0	6	2	94%
Tissue Residue Method Demonstration	0	0	0	0	0	*

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

IV. FY 2023 Process Improvements and Major Accomplishments

Under ADUFA IV, 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:

- **Foreign Pre-Approval Inspections (PAIs).** Continuing under ADUFA IV, 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 a NADA, supplemental NADA, or INAD submission and may be subject to foreign PAIs for the following fiscal year and 2) a notification 30 days prior to submitting a NADA, supplemental NADA, or INAD submission that informs the Agency that the application/submission includes a foreign manufacturing facility.

    - **Accomplishment:** During the COVID-19 pandemic, remote regulatory assessments[4] were used, when appropriate, to support risk-based PAI decisions[5] when travel restrictions limited foreign travel. In FY 2022, FDA initially resumed prioritized foreign travel and later resumed routine foreign travel as travel restrictions eased. The average time to complete a PAI increased in FY 2022 because FDA resumed inspections that had been pending due to prior COVID-19 public health emergency travel restrictions. In FY 2023, the average time to complete a PAI improved as foreign inspection travel was mostly normalized; however, this average time still reflects some delays that were attributed to the inspections initiated during the pandemic. The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during each fiscal year.

[4] https://www.fda.gov/media/160173/download.

[5] See FDA's Resiliency Roadmap for FDA Inspectional Oversight report (November 2021) at https://www.fda.gov/media/154293/download.

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

- **Foreign Good Manufacturing Practice (GMP) Inspections.** The Agency committed to working to implement the United States-European Union (EU) GMP Inspection Mutual Recognition Agreement (MRA) starting in FY 2019 for establishments manufacturing animal drugs. The Agency agreed to provide annual progress updates to industry.

    - **Accomplishment:** The Center for Veterinary Medicine (CVM) worked collaboratively with FDA's Office of Global Policy and Strategy and Office of Regulatory Affairs (ORA) to enact a Mutual Recognition Agreement (MRA) with the European Union 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, Greece, Hungary, Ireland, 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, a separate MRA between the United States and the United Kingdom was implemented for both human and animal drugs; this MRA has been in use to support surveillance inspections. For more information, see https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra.

- **Supporting Information for Presubmission Conferences and INAD Protocols Without Data Submissions.** The Agency agreed to improve the new animal drug development process to allow data that uniquely describe the general attributes of the new animal drug to be submitted earlier in the process to support more effective and efficient pre-submission conferences and INAD protocol review processes.

- **Accomplishment:** The Agency received 13 early information submissions in FY 2022.

- **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.

- **Four New Sentinel Submissions Included in ADUFA IV.** Performance results for the sentinel submissions listed below, which are a subset of the submission types, are addressed in the performance tables above. The table in the appendix shows the submissions and their subsets.

    - **Animal Drug Availability Act (ADAA) Combinations.** Review and act on 90 percent of qualifying ADAA Combination Medicated Feeds Applications within 60 days after the submission date.

    - **Categorical Exclusions.** Review and act on 90 percent of resubmissions of a previously completed Environmental Impact Technical Section within 60 days after the resubmission date when certain conditions are met.

    - **Presubmission Conferences.** Conduct 90 percent of qualifying presubmission conferences within a 60-day time frame when certain conditions are met.

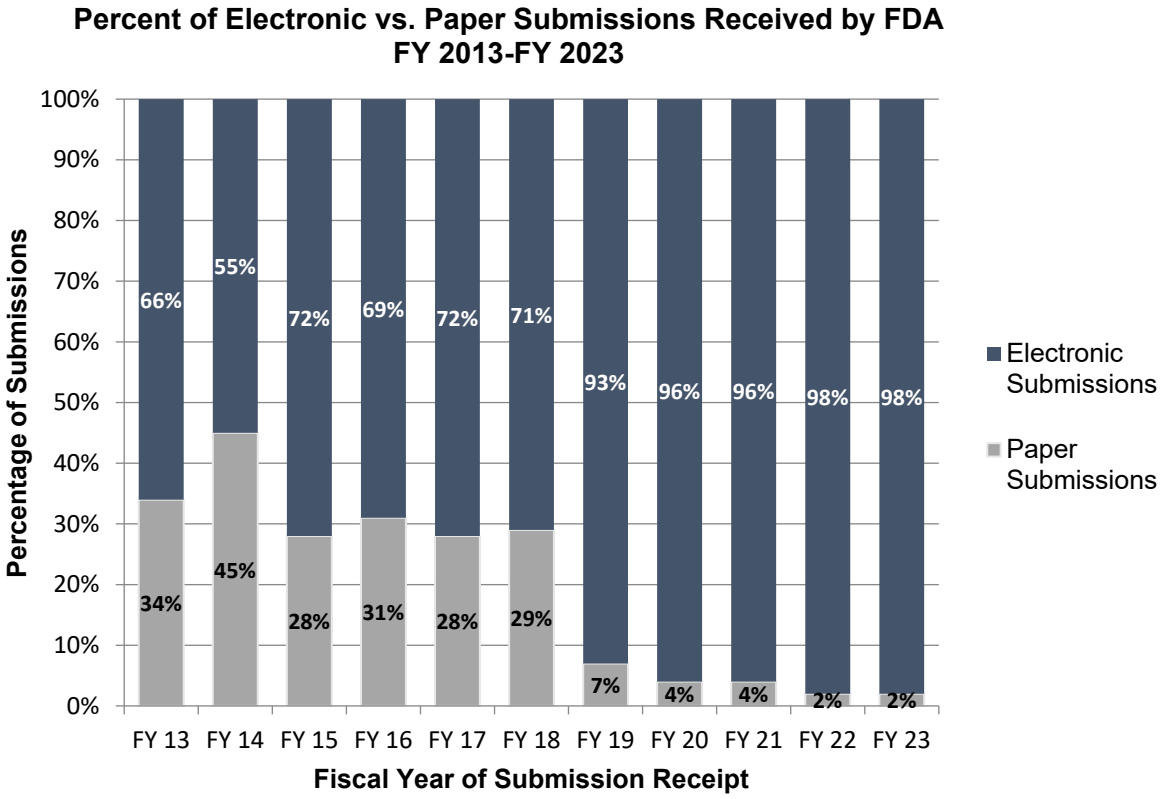
    - **Tissue Residue Method.** Commence 90 percent of tissue residue method demonstrations within 120 days of completion of the “3-hour meeting” process or equivalent process milestone when there is a single laboratory validation tissue residue method demonstration.

V. FY 2023 Additional Activities Toward Compliance with ADUFA IV

The following sections are found in Title III of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, the legislation reauthorizing the ADUFA program from FY 2019 through FY 2023 (ADUFA IV).

- **Section 301. Electronic submissions.** This section of the reauthorization legislation states that, beginning October 1, 2018, all applications and submissions under sections 512(b) and 571(a) of the Federal Food, Drug, and Cosmetic (FD&C) Act must be created using the eSubmitter tool and submitted to the Agency through CVM's Electronic Submission System.

    - **Accomplishment**: CVM provided support to industry users to facilitate their transition to using eSubmitter for all submissions to CVM.



- **Section 302. Index of legally marketed unapproved new animal drugs for minor species.** This section of the reauthorization legislation amended section 572(h) of the FD&C Act to eliminate the requirement for products that are listed

on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) to include the statement "Not approved by the FDA" on their labeling. Instead, the labeling for these products shall include the following statement:

> LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF#" (followed by the applicable minor species index file number and a period) "Extra-label use is prohibited."

- **Accomplishment:** The labeling for all drugs currently on the Index are revised to include the new statutory language. CVM is working to make the revised labeling compliant with the electronic and information technology requirements of section 508 of the Rehabilitation Act of 1973, (29 U.S.C. 794d(a)) so that the index listings that are posted on the FDA.gov website can be updated to include the new labeling. CVM will continue to ensure that the labeling for any new drug added to the Index will include the new labeling statement.

- **Section 303. Misbranded drugs and devices.** This section of the reauthorization legislation mandates that, with limited exceptions, pioneer and generic new animal drugs approved under section 512 of the FD&C Act must include the statement, "Approved by FDA under (A)NADA #," followed by their application number on their labeling, by September 30, 2023, or else such drugs will be considered misbranded under section 502(w) of the FD&C Act.

  - **Accomplishment:** By the end of FY 2023, 665 of the 668 (99.5%) actively marketed and approved (A)NADAs were fully compliant with the ADUFA IV/AGDUFA III requirement and now carry the "approved by" statement to clearly identify new animal drug products approved by FDA/CVM, distinguishing them from the products on the market that are unapproved.

- **Section 304. Conditional approval of new animal drugs.** This section of the reauthorization legislation expanded the conditional approval pathway in section 571 of the FD&C Act to allow certain additional drugs that are not MUMS drugs to qualify, provided that certain criteria are met.

- **Accomplishments:**

  - On November 15, 2022, FDA granted conditional approval under its expanded authority to Panoquell-CA1 (fuzapladib sodium for injection)[6] for the management of clinical signs associated with acute onset of pancreatitis in dogs.

  - On May 1, 2023, FDA granted conditional approval under its expanded authority to Varenzin-CA1 (molidustat oral suspension)[7] for the control of nonregenerative anemia associated with chronic kidney disease (CKD) in cats.

  - On September 6, 2023, FDA granted conditional approval under its expanded authority to Fidoquel-CA1 (phenobarbital tablets)[8] for the control of seizures associated with idiopathic epilepsy in dogs.

- **Section 304. Report on incorporating veterinary oversight.** This section of the legislation includes a requirement for FDA to submit a report to Congress by September 30, 2019, identifying how the Agency will incorporate veterinary oversight for all approved medically important antimicrobial drugs administered to animals that are not already subject to veterinary oversight.

  - **Accomplishments:** During FY 2023, FDA received and reviewed labeling supplements from animal drug sponsors willing to voluntarily align affected applications with Guidance for Industry (GFI) #263, Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter. As of May 5, 2023, supplements for 100 percent of affected applications (NADAs and Abbreviated New Animal Drug Application (ANADAs)) had been received. As of June 30, 2023, 100 percent of affected products either were approved with prescription marketing status or had otherwise been voluntarily aligned with the recommendations in GFI #263.

- **Section 305. Guidance addressing investigation designs.** This section of the reauthorization legislation requires the Agency to issue guidance addressing the use of complex adaptive and other novel investigation designs, data from

[6] See https://www.fda.gov/news-events/press-announcements/fda-conditionally-approves-first-drug-manage-acute-onset-pancreatitis-dogs
[7] See https://www.fda.gov/news-events/press-announcements/fda-conditionally-approves-first-drug-anemia-cats-chronic-kidney-disease.
[8] See https://www.fda.gov/animal-veterinary/cvm-updates/fda-conditionally-approves-phenobarbital-tablets-control-seizures-dogs-idiopathic-epilepsy.

foreign countries, real-world evidence, biomarkers, and surrogate endpoints in the development and regulatory review of new animal drugs. The provision calls for FDA to hold a public meeting with stakeholders prior to issuing the guidance. This section also requires FDA to issue a draft guidance no later than 1 year after the date of the public meeting and the final guidance no later than 1 year after the public comment period on the draft guidance ends.

- **Accomplishment:** On October 5, 2021, FDA issued final GFIs intended to assist sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence, biomarkers, and surrogate endpoints into protocols and study designs. In FY 2022, FDA presented information to industry stakeholders related to the following four GFIs: how to use real-world evidence (GFI #266) (presented in April 2022), how to use data from foreign countries (GFI #265) (presented in July 2022), how to use biomarkers and surrogate end-points (GFI #267), and how to use adaptive designs (GFI #268) (presented in November 2022).

Appendix A: Progression of ADUFA Performance Goals

The tables in this appendix show how the ADUFA performance goals have progressed from FY 2015 (ADUFA III) to the current ADUFA IV goals.

ADUFA IV

Under ADUFA IV, new sentinel submission types were added (i.e., ADAA combinations, presubmission conferences, phased data submissions end game categorical exclusions, and tissue residue methods).

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

Shortened Review Phased Data Resubmissions	60 days
Phased Data Submissions End Game Categorical Exclusions	60 days
INAD Protocol Submissions	
Protocol Submissions	50 days
Protocol Resubmissions	50 days
Shortened Review Protocol Resubmissions	20 days
Presubmission Conference	60 days
Tissue Residue Method	120 days

*This sentinel submission was part of the ADUFA III goals letter; however, FY 2019 was the first year Non-Qualifying Labeling Supplements were reported.

ADUFA III[9]

Submission Type	Performance Goal: Act on 90 Percent Within
Original NADAs and Reactivations	
Original NADAs and Reactivations	180 days
Shortened Review Original NADA Reactivations	135 days
Administrative NADAs	60 days
Non-Manufacturing Supplemental NADAs and Reactivations	
Non-Manufacturing Supplement NADAs	180 days
Non-Manufacturing Supplemental Reactivations	180 days
Shortened Review Non-Manufacturing Supplemental Reactivations	135 days
Manufacturing Supplemental NADAs and Reactivations	120 days
Qualifying Labeling Supplements	60 days
INAD Study Submissions	
Phased Data Submissions	180 days
Phased Data Resubmissions	180 days
Phased Data Submissions MFS HC	100 days
Shortened Review Phased Data Resubmissions	60 days
INAD Protocol Submissions	
Protocol Submissions	50 days
Protocol Resubmissions	50 days
Shortened Review Protocol Resubmissions	20 days

[9] In the last 4 years of ADUFA III (from FY 2015 to FY 2018), the shortened review process replaced the end-review amendment process for all applicable submission types, and two new sentinel submission types (i.e., labeling supplements and phased data submissions MFS HC) were added.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management. For information on obtaining additional copies, please contact:

Office of Planning, Evaluation, and Risk Management
Office of the Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Phone: 301-796-4850
E-mail: OPERM_ADMIN_Team@fda.hhs.gov

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