FY 2021

PERFORMANCE REPORT TO CONGRESS

for the

Animal Drug User Fee Act

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Commissioner's Report

I am pleased to present to Congress the Food and Drug Administration's (FDA's or the Agency's) fiscal year (FY) 2021 Animal Drug User Fee Act (ADUFA) performance report. This report marks the 18th year of ADUFA; specifically, the third year of the third reauthorization of ADUFA, referred to as ADUFA IV (covering FY 2019 through FY 2023).

This report details FDA's preliminary performance results for FY 2021 and finalizes FDA's performance results for FY 2020. It is my pleasure to report that FDA exceeded all performance goals for FY 2020. The Agency also met performance goals for all FY 2021 cohort submissions reviewed or due for review by September 30, 2021. With some reviews still pending, FDA has the potential to exceed all performance goals for FY 2021.

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FDA is committed to improving the efficiency, quality, and predictability of the new animal drug review process. FDA is dedicated to exploring new approaches and technologies that offer high-quality, cost-effective improvements in the Agency's review of new animal drug applications and submissions. Under the leadership of the President and in collaboration with Congress and industry, FDA looks forward to the continued success of the new animal drug review process made achievable by ADUFA.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

ADAA – Animal Drug Availability Act

ADUFA – Animal Drug User Fee Act

CFR – Code of Federal Regulations

CVM – Center for Veterinary Medicine

EU – European Union

FAP – Food Additive Petition

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

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]

Information Included in This Report

This report summarizes FDA's performance results in meeting its ADUFA goals and commitments for FY 2020 and FY 2021. Specifically, this report updates and finalizes the FY 2020 performance data initially reported in the FY 2020 ADUFA Performance Report and presents preliminary data on FDA's progress in meeting its FY 2021 review goals, implementation activities, and accomplishments.

Review Performance

FDA met or exceeded the expectations of the review performance goals in the second year of ADUFA IV (i.e., FY 2020) and continued to meet or exceed expectations of the review performance goals for FY 2021. Key activities and accomplishments during FY 2021 included the following:

- FDA met review-time goals for almost all (954 of 973) of the FY 2020 cohort submissions. FDA exceeded all nine ADUFA performance goals for the FY 2020 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 (537 of 554) of the FY 2021 cohort submissions reviewed and acted on as of September 30, 2021. With 284 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all nine of the ADUFA performance goals for the FY 2021 cohort for which FDA received submissions. Please see Appendix A for more details on the submission types and related performance goals.

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

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Table of Contents

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Introduction

The Animal Drug User Fee Act (ADUFA) requires the Secretary of Health and Human Services to submit two annual reports to Congress for each fiscal year 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 the Agency's) third 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 fiscal year (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. The guidelines and definitions below apply to the information provided in the FY 2021 report.

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 2020 cohort submissions and presents FDA's preliminary performance results for the FY 2021 cohort submissions that were received early enough to be reviewed and acted on, or due for review, by September 30, 2021.

The following information refers to FDA's performance presented in this 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 2021. 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 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

[2] https://www.fda.gov/media/116001/download.

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 2021 include all submissions received in FY 2021. 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.

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

File Types Included in This Report

- **NADA** – A 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 INAD, sponsors may submit data intended to support an application for new animal drug approval. This report presents studies and protocols.

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

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Review Workload: FY 2016 to FY 2021

In the table below, preliminary review workload numbers from FY 2021 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 can also be 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 2021, the workload for two application and submission types showed a large increase from the 5-year average, two application and submission types stayed fairly consistent, and three application and submission types decreased.

Review Workload for Applications and Submissions

Application/ Submission Type	FY 16	FY 17	FY 18	FY 19‡	FY 20	FY 21§	FY 16 to FY 20 5-Year Average	FY 21 Compared to 5-Year Average
Original NADAs and Reactivations	15	11	9	4	9	4	10	-60%
Administrative NADAs	18	8	11	9	11	7	11	-36%
Non-Manufacturing Supplemental NADAs and Reactivations	0†	2	4	9	3	7	4	+75%
Manufacturing Supplemental NADAs and Reactivations	324	378	347	351	423‡	391	365	+7%
Labeling Supplements*	6	6	3	20	23	19	12	+58%
INAD Studies	181	172	157	182	160‡	175	170	+3%
INAD Study Protocols	277	282	227	360	259‡	158	281	-44%
Presubmission Conferences†	N/A	N/A	N/A	77	84	80	N/A	N/A
Tissue Residue Method Demonstration†	N/A	N/A	N/A	0	1	2	N/A	N/A

* Labeling Supplements were added as a sentinel submission type in the second year of ADUFA III (i.e., FY 2015). FY 2016 through FY 2018 totals include qualifying submissions only; the FY 2019 through FY 2021 total includes qualifying and non-qualifying submissions (see page A-1).
† Presubmission Conferences and Tissue Residue Method Demonstration were added as sentinel submission types in the first year of ADUFA IV (i.e., FY 2019).
‡ Numbers were changed to reflect updates to the data presented in the FY 2020 ADUFA Performance Report.
§ FY 2021 numbers are preliminary and will be finalized in the FY 2022 ADUFA Performance Report.

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FY 2020 and FY 2021 ADUFA Performance Results

The tables that follow present FDA's review performance results for the FY 2020 and FY 2021 ADUFA cohort submissions.

Final FY 2020 Performance Results

FDA exceeded the 90 percent performance level for all nine of the submission types for which submissions were received for the FY 2020 cohort. Across all submission types, FDA met the review-time goal for 954 of 973 submissions. The entire FY 2020 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	9	9	0	100%
Administrative NADAs	11	11	0	100%
Non-Manufacturing Supplemental NADAs and Reactivations	3	3	0	100%
Manufacturing Supplemental NADAs and Reactivations	423*	415	8	98%
Labeling Supplements	23	23	0	100%
INAD Studies	160*	158	2	99%
INAD Study Protocols	259*	258	1	99%
Presubmission Conferences	84	76	8	90%
Tissue Residue Method Demonstration	1	1	0	100%

* Numbers were changed to reflect updates to the data presented in the FY 2020 ADUFA Performance Report.

Preliminary FY 2021 Performance Results

As of September 30, 2021, preliminary performance data was available for 554 of 843 submissions filed in FY 2021. FDA is currently exceeding performance goals for all nine of the submission types which had at least one submission acted on in FY 2021. Overall, FDA met review-time goals for 537 of 554 submissions acted on. With 284 of the remaining 289 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 2021. 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	4	2	0	2	0	100%
Administrative NADAs	7	6	0	1	0	100%
Non-Manufacturing Supplemental NADAs and Reactivations	7	4	0	3	0	100%
Manufacturing Supplemental NADAs and Reactivations	391	220	11	159	1	95%
Labeling Supplements	19	12	0	7	0	100%
INAD Studies	175	89	2	81	3	95%
INAD Study Protocols	158	147	1	10	0	99%
Presubmission Conferences	80	55	3	21	1	93%
Tissue Residue Method Demonstration	2	2	0	0	0	100%

FY 2021 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, at the beginning of the calendar year, a list of foreign manufacturing facilities that are specified in a NADA, supplemental NADA, or INAD submission that may be subject to foreign PAIs for the following fiscal year.

    - **Accomplishment:** Due to staff travel restrictions implemented by FDA in response to the COVID-19 pandemic, only one foreign PAI was completed in in FY 2021; however, alternatives to in-person inspections, including records requests under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), were used where possible to inform approval decisions on applications and manufacturing supplements.[4] The table below shows the number of foreign PAIs conducted and the average time it took to complete a PAI during that fiscal year.

Fiscal Year	Number of Foreign PAIs Conducted	Average Time to Completion (in Days)
2019	10	106
2020	5	130
2021	1	159

- **Foreign Good Manufacturing Practice (GMP) Inspections.** The Agency committed to working to implement the United States-European Union (US-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 FDA's Office of Regulatory Affairs (ORA) to complete the assessments, cumulatively, of eleven EU member states (Estonia, Greece, Ireland, Slovenia, Austria, Belgium, Denmark, Finland, Luxembourg, Poland, and Spain) with dual oversight (i.e., human and animal) authority; these assessments were completed, in part, through leveraging previous human regulatory assessments. Additionally, the assessments of three single oversight authorities (i.e., France, Bulgaria, and Hungary) were completed. The EU and

[4] See FDA's Resiliency Roadmap for FDA Inspectional Oversight report (May 2021) at www.fda.gov/media/148197/download.

FDA are engaged in ongoing discussions about FDA's animal drug inspection practices and capability following an audit of CVM and ORA by the EU. A separate MRA was enacted between the US and the United Kingdom (UK) following Brexit based on capability assessments of the animal drug inspection practices of FDA and UK regulators.

- **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 three early information submissions in FY 2021.

- **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 are addressed in the performance tables above.

- **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.

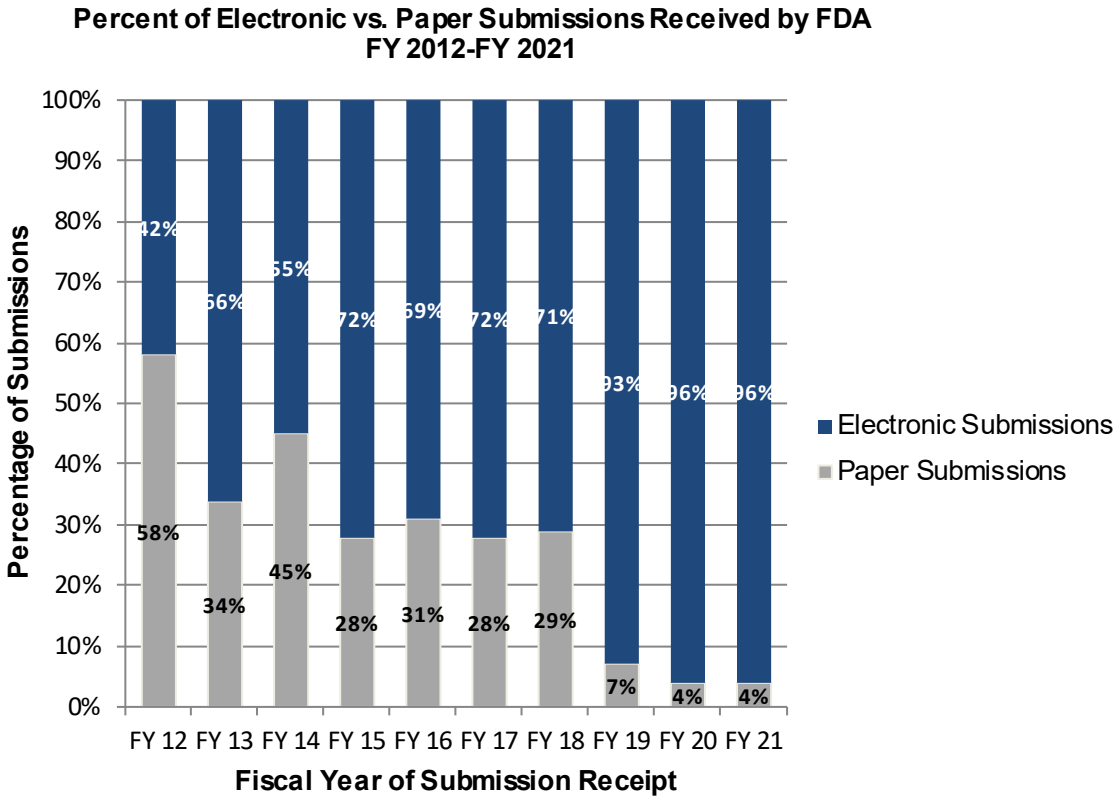
- **Presubmission Conferences.** Conduct 90 percent of qualifying presubmission conferences within a 60-day time frame when certain conditions are met.

- **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.

FY 2021 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 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 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:** CVM continues to work towards updating labeling of indexed drugs. CVM sent letters to all holders of an indexed drug asking them to update their labeling with the new labeling statement. These parties have submitted revised labeling for review, and CVM is working to update the existing Index for these drugs. In addition, CVM is taking steps to ensure that any products that will be added to the Index in the future also 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:** CVM issued an electronic message to all animal drug sponsors on September 2, 2021, reminding them of the upcoming labeling requirement and encouraging the submission of supplements to NADAs to update labeling by the end of 2022. In addition, the message was posted on CVM's website.[5] CVM continued to remind and encourage sponsors of approved pioneer and generic new animal drugs to update their products' labeling with the new statement. CVM also conducted outreach to smaller sponsors. By the end of FY 2021, the labeling of approximately one-half of the approved and marketed products was in compliance with the labeling requirement.

- **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 July 13, 2021, FDA issued the final guidance for industry (GFI) #261,[6] which defines certain terms, clarifies the eligibility criteria for expanded conditional approval, and describes the criteria CVM intends to consider when determining expanded conditional approval eligibility. On January 14, 2021, FDA granted the first conditional approval under its expanded authority

[5] https://www.fda.gov/animal-veterinary/resources-you/approved-fda-labeling-statement-approved-new-animal-drugs.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-261-eligibility-criteria-expanded-conditional-approval-new-animal-drugs.

to KBroVet-CA1 (potassium bromide chewable tablets) to control seizures in dogs with idiopathic epilepsy.

- **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:** On September 23, 2019, FDA published for public comment the draft GFI #263 to bring all dosage forms of medically important antimicrobial drugs approved for use in food-producing animals that continue to be available over-the-counter under the oversight of a licensed veterinarian. On June 10, 2021, FDA issued the final GFI #263.[7]

- **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 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 July 16, 2019, FDA held the public meeting required under this section.[8] Based on the public comments, on July 14, 2020, FDA issued four draft guidance documents[9] with draft recommendations to assist sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real-world evidence, biomarkers, and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs.

- **Section 306. Food additives intended for use in animal food.** This section of the reauthorization legislation amended section 409 of the FD&C Act to require FDA to post to the Agency website, no later than 1 year after enactment, the number of petitions for food additives (FAPs) intended for use in animal food that are pending; how long each

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals.

[8] See https://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs.

[9] See https://www.fda.gov/animal-veterinary/cvm-updates/fda-issues-draft-guidances-help-facilitate-development-new-animal-drug-submissions.

FAP has been pending, including any extensions; the number of study protocols under review by the Agency for more than 50 days; and the number of protocol reviews that have received an extension from the Agency. The legislation also directs the Agency to issue, within 18 months from enactment of the reauthorization legislation, draft guidance to assist petitioners in engaging with the Agency in a voluntary pre-petition consultation process for animal food additives. The draft guidance should be finalized, withdrawn, or reissued no later than 1 year after the close of the comment period on the draft guidance.

- **Accomplishment:** FDA met the congressional deadline by posting to FDA-TRACK in August 2019 the data for FAPs and study protocol reviews. On February 13, 2020, CVM met the congressional deadline by issuing a draft guidance on the pre-petition consultation process for animal FAPs. The final guidance was subsequently published in December 2020,[10] ahead of the congressional deadline to finalize, withdraw, or reissue guidance by April 2021.

[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-262-pre-submission-consultation-process-animal-food-additive-petitions-or-generally.

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Appendix

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.

FY 2019 to FY 2023 Under 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 was part of the ADUFA III goals letter; however, FY 2019 was the first year Non-Qualifying Labeling Supplements were reported.

FY 2015 to FY 2018 Under ADUFA III

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 were added (labeling supplements and phased data submissions MFS HC).

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

U.S. Department of Health and Human Services
U.S. Food and Drug Administration

This report was prepared by FDA's Office of Planning in collaboration with the Center for Veterinary Medicine. For information on obtaining additional copies, contact:

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