FY 2019

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 or the Agency) Fiscal Year (FY) 2019 Animal Drug User Fee Act (ADUFA) performance report. This report marks the 16th year of ADUFA and the first year of the third reauthorization of ADUFA, referred to as ADUFA IV (FY 2019 through FY 2023).

This report details FDA's preliminary performance for FY 2019 and finalizes performance results for FY 2018. It is my pleasure to report that FDA exceeded all performance goals for FY 2018. The Agency also met performance goals for all FY 2019 cohort submissions reviewed or due for review by September 30, 2019. With some reviews still pending, FDA has the potential to exceed all performance goals for FY 2019.

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 in the new animal drug review process made achievable by ADUFA.

Stephen M. Hahn
Commissioner of Food and Drugs

Acronyms

ADAA – Animal Drug Availability Act

ADUFA – Animal Drug User Fee Act

CFR – Code of Federal Regulations

CMC – Chemistry Manufacturing and Controls

CVM – Center for Veterinary Medicine

ERA – End-Review Amendment

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

HHS – U.S. Department of Health and Human Services

INAD – Investigational New Animal Drug

MFSHC – Microbial Food Safety Hazard Characterization

MUMS – Minor Use or Minor Species

NADA – New Animal Drug Application

PAI - Pre-Approval Inspection

QLS – Qualifying Labeling Supplements

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 (through FY 2023). ADUFA IV includes a comprehensive set of FDA review performance goals and commitments designed to improve the timeliness and predictability of the review of new animal drug applications (NADAs) and reactivations, supplemental NADAs and reactivations, investigational new animal drug (INAD) submissions, and qualifying labeling supplements.

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

Information Included in this Report

This report summarizes FDA's performance in meeting ADUFA goals and commitments for FY 2018 and FY 2019. Specifically, it updates and finalizes performance data initially reported in the FY 2018 ADUFA Performance Report and presents preliminary data on FDA's progress in meeting FY 2019 review goals, implementation activities, and accomplishments.

Review Performance

FDA met or exceeded the expectations of the review performance goals in the first year of ADUFA IV and continued to meet or exceed expectations of the review performance goals established under ADUFA III for FY 2018. Key activities and accomplishments during FY 2019 included the following:

- FDA met review-time goals for almost all (751 of 758) of the FY 2018 cohort submissions. FDA exceeded all seven ADUFA performance goals for the FY 2018 cohort. 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 (706 of 712) of the FY 2019 cohort submissions reviewed and acted on as of September 30, 2019. With 310 additional reviews pending that may yet be completed on time, FDA has the potential to exceed all eight of the ADUFA performance goals for the FY 2019 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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Introduction

The Animal Drug User Fee Act (ADUFA) requires the Secretary of the Department of Health and Human Services (HHS) 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 or the Agency) first 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 for certain submissions over 5 years (FY 2019 through FY 2023). Further details on FDA's commitments under ADUFA IV can be found in the ADUFA IV Performance Goals Letter on the FDA website.[2] By providing FDA with supplemental funding for the review of new animal drug submissions, ADUFA is 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 2019 report.

Information Presented in This Report

In any given year, FDA performance includes reviews 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 for the FY 2018 cohort and presents FDA's preliminary performance with respect to performance goals for the FY 2019 cohort submissions that were received early enough to be reviewed, or due for review, by September 30, 2019.

The following information refers to FDA 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 when referencing the fiscal year cohort.

- *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 2018 and FY 2019. An *on-time review* indicates that FDA completed action within the number of calendar days specified by the review-time goal.

- *Percent on time* refers to the percentage of reviews where 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 III and ADUFA IV performance goals call for FDA to meet the review-time goals 90 percent of the time for the defined fiscal year cohort.

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

- The performance statistics in this report are based on submissions received during a fiscal year (known as a receipt cohort). This methodology calculates performance statistics for submissions 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 2019 include all submissions received in FY 2019. For ADUFA review times, FDA calculates from 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 development of products for treatment of minor species or for treatment of animal diseases and conditions of major species that occur infrequently or in limited geographic areas. Further details on MUMS can be found on the FDA website at www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies.

- 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-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 certain applications 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** – An *NADA* is a new animal drug application including 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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ADUFA Review Workload

Review Workload: FY 2014 to FY 2019

In the table below, preliminary review workload numbers from FY 2019 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 workload, but the variations in workload over time can provide context for review performance. As of October 1, 2014 (i.e., the beginning of FY 2015), the Agency agreed to discontinue end-review amendment (ERAs) procedures and to replace them with a shorter review time process for sponsors providing electronic NADA and INAD submissions. The shortened review submissions are not a subcategory but are now included in the overall submission numbers. The FY 2014 submission numbers include ERAs, when applicable, in order to make an accurate comparison of the change in workload. Please see Appendix A for more detail of the application and submission types included in the table below.

Application/ Submission Type	FY 14	FY 15	FY 16	FY 17	FY 18*	FY 19§	FY 14 to FY 18 5-Year Average	FY 19 Compared to 5-Year Average
Original NADAs and Reactivations	3	3	15	11	9	4	8	-50%
Administrative NADAs	21	16	18	8	11	9	15	-39%
Non-Manufacturing Supplemental NADAs and Reactivations	9	6	10	2	4	9	6	+45%
Manufacturing Supplemental NADAs and Reactivations	340	327	324	378	347‡	353	343	+3%
Labeling Supplements*	N/A	3	6	6	3‡	20	*	*
INAD Studies	280	147	181	172	157‡	189	187	+1%
INAD Study Protocols	215	248	277	282	227‡	360	250	+44%
Presubmission Conferences†	N/A	N/A	N/A	N/A	N/A	78	N/A	N/A
Tissue Residue Method Demonstration†	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A

* Labeling Supplements were added as a sentinel submission type in the second year of ADUFA III (i.e., FY15). FY 2015 through FY 2018 totals include qualifying submissions only; the FY 2019 total includes qualifying and non-qualifying submissions (see A-3).
† Presubmission Conferences and Tissue Residue Method Demonstration were added as sentinel submission types in the first year of ADUFA IV (i.e., FY19).
‡ Numbers were changed to reflect updates to data presented in the FY 2018 ADUFA Performance Report.
§ FY 2019 numbers are preliminary and will be updated in the FY 2020 ADUFA Performance Report.

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FY 2018 and FY 2019 ADUFA Performance

The tables that follow present FDA's review performance for the FY 2018 and FY 2019 ADUFA cohort submissions.

Final FY 2018 Performance

FDA exceeded the 90 percent performance level for all seven of the review performance goals for submission types for which submissions were received in FY 2018. Across all submission types, FDA met the review-time goal for 751 of 758 submissions. The entire FY 2018 cohort has closed, therefore there are no pending submissions.

Application/ Submission Type	Filed	On Time	Overdue	Percent on Time
Original NADAs and Reactivations	9	9	0	100%
Administrative NADAs	11	10	1	91%
Non-Manufacturing Supplemental NADAs and Reactivations	4	4	0	100%
Manufacturing Supplemental NADAs and Reactivations	347*	345	2	99%
Labeling Supplements	3*	3	0	100%
INAD Studies	157*	156	1	99%
INAD Study Protocols	227*	224	3	99%

* Numbers were changed to reflect updates to data presented in the FY 2018 ADUFA Performance Report.

Preliminary FY 2019 Performance

As of September 30, 2019, preliminary performance data was available for 712 of 1,022 submissions filed in FY 2019. FDA is currently exceeding performance goals for all eight of the submission types received in FY 2019. Overall, FDA met review-time goals for 706 of 712 submissions acted on. With 308 of remaining 310 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 2019. 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	3	0	1	0	100%
Administrative NADAs	9	8	0	1	0	100%
Non-Manufacturing Supplemental NADAs and Reactivations	9	5	0	4	0	100%
Manufacturing Supplemental NADAs and Reactivations	353	201	2	150	0	99%
Labeling Supplements	20	20	0	0	0	100%
INAD Studies	189	83	2	103	1	98%
INAD Study Protocols	360	323	0	36	1	100%
Presubmission Conferences	78	63	2	13	0	97%
Tissue Residue Method Demonstration	0	0	0	0	0	*

* Performance cannot be calculated as there were no submissions for this application type.

FY 2019 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. 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		
2021		
2022		
2023		

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

    - **Accomplishment:** The Center for Veterinary Medicine (CVM) worked collaboratively with FDA's Office of Global Policy and Strategy (OGPS) and Office of Regulatory Affairs (ORA) to successfully complete four Joint Audit Programme-observed audits for the following EU member states: United Kingdom, France, Bulgaria, and Hungary. FDA developed and sent questionnaires to 14 EU member states with dual-oversight (human and animal) authority. These questionnaires will be assessed as part of an overall process for opportunities to leverage previous human regulatory assessments. CVM was audited by the EU, and the final report is pending.

- **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 11 early information submissions in FY19.

- **Dosage Characterization.** The Agency clarified that dosage characterization is part of the effectiveness technical section of the INAD file. If information about dosage is integral to the review of a protocol, this information will be provided early to inform the review.

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

Five New Sentinel Submissions Included in ADUFA IV. Performance for the below sentinel submissions is 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.

- **Labeling Supplements.** The Agency agreed to review and act on 90 percent of qualifying labeling supplements (QLS) within 60 days after the submission date. *QLS* are defined as those for which the sponsor provides and certifies a complete list of label changes made in the application and that FDA can determine upon initial review will not decrease the safety of the drug. The Agency will review and act on 90 percent of non-qualifying labeling supplements within 180 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.

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

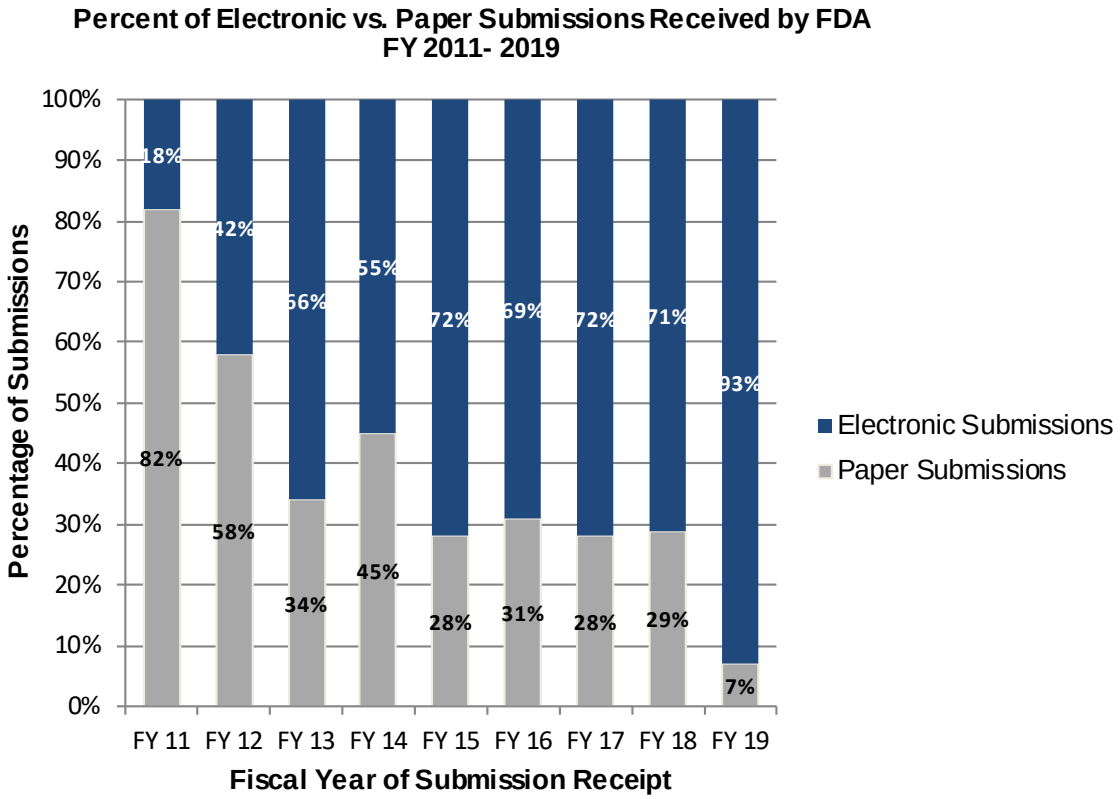
- **Tissue Residue Method.** Commence 90 percent of tissue residue method demonstrations within 120 days of completion of the “3-hour meeting” process or equivalent process milestone when there is a single laboratory validation tissue residue method demonstration.

FY 2019 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 ADUFA from FY 2019 through FY 2023 (in ADUFA IV).

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

    - **Accomplishment**: CVM provided training and support documentation to industry users to facilitate its 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 mandate that all products that are listed on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) are no longer required to carry the statement "Not approved by the FDA." Instead, they will carry 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 worked towards the requirement of updating labeling of legally marketed unapproved new animal drugs for minor species. CVM sent letters to all holders of an indexed drug asking them to update their labeling with the new labeling statement. In addition, CVM is using the new labeling statements on the products that are in the process of being added to the Index.

- **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 worked towards the requirement of updating labeling across all NADAs to carry the updated approval statement by September 30, 2023. Internally, CVM updated polices and documentation to prepare its review staff for reviewing supplemental labeling applications. Externally, CVM delivered an eSubmitter broadcast to all eSubmitter users on May 16, 2019, outlining the new labeling requirement. The broadcast is now posted on CVM's website.

- **Section 304. Conditional approval of new animal drugs.** This section of the reauthorization legislation has 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.

  - **Accomplishment:** FDA published draft guidance for industry (GFI) #261 on September 26, 2019, that describes the eligibility criteria for expanded conditional approval. The public was invited to comment on this draft guidance by January 28, 2020, to ensure their input would be considered before FDA began work on the final version of the guidance.

- **Section 304. Report on incorporating veterinary oversight.** This section of the legislation also 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 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. The public was invited to comment on this draft guidance by December 24, 2019, to ensure their input would be considered before FDA began work on the final version of the guidance.

- **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. It also requires FDA to issue a draft guidance no later than 1 year after the date of the public meeting and the final guidance document no later than 1 year after the public comment period on the draft guidance ends.

  - **Accomplishment:** CVM held the public meeting required under this section on July 16, 2019, to seek public input on 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. CVM has begun preparing the draft guidance document to be published by July 16, 2020.

- **Section 306. Food additives intended for use in animal food.** This section of the reauthorization legislation amends 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 intended for use in animal food (FAPs) that are pending; how long each 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 receive 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.

  - **Accomplishment:** FDA met the congressional deadline by posting to FDA-TRACK in August 2019 the data for FAPs and study protocol reviews. As of the end of FY 2019, CVM has cleared the pre-petition GFI, putting the guidance on track to meet the congressional deadline of February 2020.

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Appendix

Appendix A: Progression of ADUFA Performance Goals

The tables in this appendix will show how the ADUFA performance goals have progressed from FY 2014 to the current ADUFA IV goals.

FY 2014 Goals Under ADUFA III

The FY 2014 goals were a continuation of the ADUFA II goals while waiting for the IT contract funding so that the reviews could be changed from ERAs to Shortened Review.

Submission Type	Performance Goal: Act on 90 Percent Within
Original NADAs and Reactivations	
Original NADAs and Reactivations	180 days
ERAs for Original NADAs and Reactivations	135 days
Administrative NADAs	60 days
Non-Manufacturing Supplemental NADAs and Reactivations	
Non-Manufacturing Supplement NADAs and Reactivations	180 days
ERAs for Non-Manufacturing Supplemental NADAs and Reactivations	135 days
Manufacturing Supplemental NADAs and Reactivations	120 days
INAD Study Submissions	
Phased Data Submissions	180 days
ERAs for INAD Data Submissions	60 days
INAD Protocol Submissions	
Protocol Submissions	50 days
ERAs for INAD Protocols	20 days

FY 2015 to FY 2018 Under ADUFA III

In the last 4 years of ADUFA III, the shortened review process replaced the ERA process for all applicable submission types, and two new sentinel submission types were added (i.e., labeling supplements and phased data submissions Microbial Food Safety Hazard Characterization (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

FY 2019 to FY 2023 Under ADUFA IV

In 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 day
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 day
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 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 is the first year we will be reporting on it.

Department of Health and Human Services
Food and Drug Administration

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

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