Animal Drug User Fee Act
Reauthorization Performance Goals and Procedures Fiscal Years 2024 Through 2028

The goals and procedures of the Food and Drug Administration (FDA or the Agency) as agreed to under the "Animal Drug User Fee Amendments of 2023" are summarized as follows:

I. Definitions

1. For the application/submission goals below, the term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of an animal drug application, supplemental animal drug application, or investigational new animal drug (INAD) submission which either (1) approves or conditionally approves an animal drug application or approves a supplemental application or notifies a sponsor that an INAD submission is complete or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or INAD submission and, where appropriate, the actions necessary to place such an application, supplemental application, or submission in condition for approval.

   Within 30 days of receipt, FDA shall refuse to file an animal drug application, supplemental new animal drug application, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the Agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed.

   Within 60 days of receipt, FDA will refuse to review an INAD submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110.

   A decision to refuse to file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The Agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

2. A minor amendment is understood to mean information requested by FDA during the review of the application or investigational submission. FDA may request minor amendments to animal drug applications, supplemental new animal drug applications, and INAD submissions during its review of the application or submission. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or

submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. The same policy applies for INAD submissions.

3. The term "submission date" or the date of receipt means the date the FDA Center for Veterinary Medicine (CVM) Electronic Submission System (ESS) receives an application or submission. Upon receipt of an application or submission, the CVM ESS creates an electronic receipt that contains the date of receipt and is sent to the submitter.

4. 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.

5. The term "presubmission conference" is understood to mean one or more conferences between a potential applicant and FDA as described in 21 CFR 514.5 to reach a binding agreement establishing a submission or investigational requirement.

6. The term "dosage characterization" is understood to mean a justification of the dosage (dose or dose range, dosing frequency, and the dosing duration) and a characterization of the critical aspects of the dose-response relationship related to each intended use and associated conditions of use.

II. Application/Submission Goals

All applications and submissions under the Federal Food, Drug, and Cosmetic Act sections 512(b) and 571 must be created using the CVM eSubmitter tool and submitted to the Agency through CVM's ESS.

The submissions in this section are sentinel submissions. CVM's performance toward meeting the associated goals will be included in the performance reports required by section 740A(a) of the FD&C Act.

Work Queue Review Procedures: The Agency will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Application/Submission Goal timeframe will be reviewed with the highest possible priority among those pending.

1. Original New Animal Drug Applications (NADAs), Applications for Conditional Approval (CNADAs), and Reactivations

Review and act on 90 percent of original NADAs and CNADAs within 180 days after the submission date.

An application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the issue(s) presented in the application.

The Agency will review and act on 90 percent of reactivated applications:

i. Within 180 days after the reactivated application submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;
ii. Within 135 days after the reactivated application submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the application reactivation must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and
iii. Within 180 days after the reactivated application submission date if the reactivation is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the reactivated application.

The Agency will generally favor using the shorter reactivation timeframe of 135 days, where possible. The Agency will state in the incomplete letter the appropriate timeframe for review of the reactivation. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to reactivation of the application. The shorter review time of 135 days for reactivated applications for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of an application.

2. Administrative NADAs and CNADAs

Review and act on 90 percent of administrative NADAs and CNADAs [(C)NADAs filed after all scientific decisions already have been made as part of the investigational new animal drug process] within 60 days after the filing date.

3. Non-manufacturing Supplemental NADAs

Review and act on 90 percent of non-manufacturing supplemental NADAs (i.e., supplemental NADAs for which safety or effectiveness data are required) within 180 days after the submission date.

A supplemental NADA is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the supplement and reach a decision on the issue(s) presented in the supplement.

The Agency will review and act on 90 percent of reactivated supplements:

i. Within 180 days after the reactivated supplemental NADA submission date if the Agency determines and notifies the sponsor that the

deficiencies are substantial;

ii. Within 135 days after the reactivated supplemental NADA submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the reactivation to the supplemental application must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and
iii. Within 180 days after the reactivated supplemental NADA submission date if the reactivation to the supplemental application is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the reactivated supplement.

The Agency will generally favor using the shorter reactivation timeframe of 135 days, where possible. The Agency will state in the incomplete letter the appropriate timeframe for review of the reactivation. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to the reactivation of the supplement. The shorter review time of 135 days for reactivated supplements for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of a supplemental application.

4. Prior Approval Manufacturing Supplemental Animal Drug Applications and Reactivations

Review and act on 90 percent of Prior Approval manufacturing supplemental animal drug applications within 120 days after the submission date. A Prior Approval manufacturing supplemental application includes: one or more major manufacturing changes as described in 21 CFR 514.8(b)(2)(ii) and in accordance with Guidance for Industry 83 (Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA); and, changes submitted as "Supplement-Changes Being Effected in 30 Days" that require prior approval according to 21 CFR 514.8(b)(3)(v)(A). If a Prior Approval supplement does not clearly identify any major manufacturing changes, the Prior Approval supplement will be designated by the Agency as a "Supplement-Changes Being Effected" with a 180 days review goal (see "Supplement-Changes Being Effected Manufacturing Supplemental Animal Drug Applications and Reactivations" below).

A submission is incomplete if it requires additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission. If the Agency determines that the deficiencies are not substantial for manufacturing supplements requiring prior approval, the Agency will allow the manufacturing supplements to be resubmitted as "Supplement-Changes Being Effected in 30 Days" as described in 21 CFR 514.8(b)(3) and the drug made with the change can be distributed 30 days after the resubmission according to 21 CFR 514.8(b)(3)(iv). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 180 days after the resubmission date of a complete submission. If the Agency determines that the deficiencies remain substantial or new substantial information is provided, prior-approval is required according to 21 CFR

514.8(b)(3)(v)(A). The Agency will review and act on 90 percent of these reactivated manufacturing supplements within 120 days after the resubmission date of a complete submission.

1. Supplements – Changes Being Effected Manufacturing Supplemental Animal Drug Applications and Reactivations

Review and act on 90 percent of "Supplement- Changes Being Effected" manufacturing supplemental applications and reactivations submitted according to 21 CFR 514.8(b)(3)(vi) and in accordance with Guidance for Industry 83 (Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA), including manufacturing changes not requiring prior approval according to 21 CFR 514.8(b)(3) within 180 days after the submission date.

2. Investigational New Animal Drug (INAD) Study Submissions

Review and act on 90 percent of INAD study submissions within 180 days after the submission date.

An INAD study submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission.

The Agency will review and act on 90 percent of resubmissions:

i. Within 180 days after the resubmitted INAD study submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;
ii. Within 60 days after the resubmitted INAD study submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the resubmission must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and
iii. Within 180 days after the resubmitted INAD study submission date if the resubmission is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the resubmission.

The Agency will generally favor using the shorter resubmission timeframe of 60 days, where possible. The Agency will state in the incomplete letter the appropriate timeframe for review of the resubmission. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to resubmitting the application. The shorter review time of 60 days for resubmissions for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of a submission.

Review and act on 90 percent of microbial food safety hazard characterization

submissions within 100 days after the submission date.

7. INAD Study Protocols without Data Submissions

Review and act on 90 percent of INAD submissions consisting of protocols without data, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application, within 50 days after the submission date.

An INAD protocol without data submission is incomplete if it would require additional information to enable the Agency to complete a comprehensive review of the protocol and reach a decision on the issue(s) presented in the protocol.

The Agency will review and act on 90 percent of resubmitted INAD protocol without data submissions:

i. Within 50 days after the resubmission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;
ii. Within 20 days after the resubmitted INAD protocol without data submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the resubmission must be submitted no more than 120 days after the Agency's dated non-concurrence letter to qualify for the shorter review time; and
iii. Within 50 days after the resubmission date if the resubmission is submitted after 120 days of the Agency's dated non-concurrence letter or new substantial information is provided in the resubmission.

The Agency will generally favor using the shorter resubmission timeframe of 20 days, where possible. The Agency will state in the non-concurrence letter the appropriate timeframe for review of the resubmission. Sponsors wishing to discuss the selected timeframe should contact the Agency prior to resubmission of the protocol without data. The shorter review time of 20 days for resubmitted INAD protocol without data submissions for which the deficiencies are determined not to be substantial is not intended to prevent the use of minor amendments during Agency review of a submission.

Sponsors are not required to submit study protocols for review. However, for each protocol voluntarily submitted prior to the commencement of the study that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, the Agency will issue a complete action letter providing comments resulting from a complete review of the protocol. The complete action letter will be as detailed as possible considering the quality and level of detail of the protocol submission; will include a succinct assessment of the protocol; and will state whether the Agency agrees, disagrees, or lacks sufficient information to reach a decision that the protocol design, execution plans, and data analyses are adequate to achieve the objectives of the study.

If the Agency determines that a protocol is acceptable, this represents an agreement that the data generated by the protocol can be used to support a safety or effectiveness decision regarding the subject animal drug. The fundamental agreement is that having agreed to the design, execution, or analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspectives on the issues of design, execution, or analyses unless the Agency by written order determines that a substantiated scientific requirement essential to the assessment of the study appeared after the Agency's protocol assessment, or public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

The Agency will permit comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as protocols without substantial data in an INAD file. The Agency will review and act on 90 percent of INAD submissions consisting of protocols without substantial data within 50 days after the submission date of the protocol. For potentially more complex comparability protocols, for example sterile process validation protocols, the sponsor should discuss and have Agency concurrence regarding the appropriate filing strategy.

8. Qualifying Labeling Supplements

Review and act on 90 percent of qualifying labeling supplements as described in 21 CFR 514.8(c)(2)(i)(A) and (D) within 60 days after the submission date. Qualifying labeling supplements are defined as those for which the sponsor provides and certifies a complete list of labeling changes made in the application and that CVM can determine upon initial review do not decrease the safety of drug use.

The Agency will review and act on 90 percent of non-qualifying labeling supplements within 180 days after the submission date.

9. Presubmission Conferences

Conduct 90% of qualifying presubmission conferences within a 60-day timeframe, regardless of forum, when all of the following conditions are met:

i) All background materials, including presentations, have been submitted, and
ii) A complete agenda has been agreed upon by the Agency and the sponsor.

If a sponsor requests a date beyond the 60-day timeframe for their scheduling purposes or is unable to meet with the FDA on Agency-available dates within the 60-day timeframe, the submission will be excluded from the presubmission conference cohort.

10. 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 where:

i. A Categorical Exclusion was issued;
ii. All other technical sections have been submitted; and
iii. Information contained in the other technical sections reveals a change in the conditions of use of the drug that may affect the previous determination of categorical exclusion.

11. Tissue Residue Methods

Commence 90% of tissue residue method demonstrations within 120 days of completion of the "3-hour meeting" process or equivalent process milestone where there is a single laboratory validation tissue residue method demonstration.

12. Animal Drug Availability Act (ADAA) Combination Medicated Feeds Applications

Review and act on 90 percent of qualifying ADAA Combination Medicated Feeds Applications within 60 days after the submission date. An ADAA combination application will qualify for the 60-day review timeframe only if the following criteria are met:

i. The regulatory requirements for an ADAA combination application have been met as outlined in 21 CFR 514.4(c)(2)(ii)
ii. The submission meets all of the eligibility criteria found in section II of P&P 1243.5730, "Review of 60-Day Original Animal Drug Availability Act of 1996 (ADAA) Feed Use Combination New Animal Drug Applications (NADAs)."

Review and act on 90 percent of ADAA combination applications within 100 days for those applications initially accepted for the 60-day timeframe but subsequently determined to need minor amendments.

If any of the above conditions cannot be met, the ADAA combination application will be given a 180-day review timeframe and placed in the original NADA application cohort.

III. Additional Performance Goals

Submissions in this section are not sentinel submissions unless they appear in section II, above.

A. Foreign inspections

1. Pre-Approval Foreign Inspections

a. The Agency and regulated industry are committed to improving the review and business processes that will facilitate the timely scheduling and conducting of pre-approval inspections (PAIs). To improve the timeliness and predictability of foreign PAIs, sponsors may voluntarily submit 1) at the beginning of the calendar year, a list of foreign manufacturing facilities that are specified in an animal drug application, supplemental animal drug application, or investigational animal drug submission and may be subject to foreign PAIs for the following fiscal year; and 2) a notification 30 days prior to submitting an animal drug application, a supplemental animal drug application, or INAD submission that informs the Agency that the application/submission includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the Agency, the sponsor may provide the updated information to the Agency.

b. The Agency will keep a record of the number of foreign PAIs conducted for animal drug applications, along with the average time for completing the PAIs, and include this information in its annual performance report. The time for completing the PAI is understood to mean the time from the inspection scheduling request through notification to the Center of inspectional findings.

2. Foreign GMP Inspections

The Agency commits to working to implement and maintain the United States and European Union, and the United States and United Kingdom, Good Manufacturing Practice mutual recognition agreements and future mutual recognition agreements with respect to animal drug products subject to review.

Beginning in fiscal year (FY) 2024, the Agency will report quarterly in FDA-TRACK the percentage of pre-approval inspection risk decisions which relied at least in part on information from inspections recognized under a mutual recognition agreement with a foreign regulatory authority.

B. Meetings

1. Presubmission Conferences Held Virtually

Beginning on October 1, 2023, for qualifying presubmission conferences where the sponsor requests that the conference be held virtually (not in person), the Agency will provide the following:

- At least 6 days prior to the scheduled presubmission conference date, written responses to the questions posed by the sponsor in their meeting request. Responses will be commensurate to the level of information and

complexity of questions submitted by the sponsor.
- Permit the sponsor to cancel the scheduled presubmission conference should the Agency's written responses provide all the information they were seeking from the Agency.
- Should the presubmission conference be held, provide a memorandum of conference within 30 days after the presubmission conference date.

Sponsors may request a virtual presubmission conference and opt out of the process above. The sponsor will identify their decision whether to opt out of the above process within the presubmission conference request. If the sponsor chooses to opt out, the Agency will not issue any written responses before the presubmission conference and will provide a memorandum of conference within 45 days following the presubmission conference date.

2. Stakeholder Engagement

a. The Agency is committed to engaging with all our external stakeholders in substantive ways that work for all parties. Further, the Agency commits to coordinating with AHI to identify the most appropriate forum based on topic, timing, and public health safety precautions with the understanding that it is a priority for AHI to meet in person when possible.
b. FDA will host triannual meetings (three times a calendar year) with the Animal Health Institute (AHI) members.
c. During one triannual meeting with AHI per calendar year, the Agency will dedicate up to 8 hours for an education session intended for the animal drug industry. These sessions will be open to the public and hosted in an appropriate forum. The Agency and AHI will build a plan of educational topics for the five years of the ADFUA V program period. Education sessions will be recorded and posted publicly to the Agency's "For Industry" website in a new "Education for Industry" section.

d. The Agency will conduct an industry engagement sub-meeting during each AHI triannual meeting, that includes CVM leadership and designated AHI attendees and uses a structured agenda to provide updates on metrics and performance related to the ADUFA program and resource utilization (i.e., CVM staffing).

C. H submissions

1) Supporting Information for Presubmission Conferences and INAD Protocols without Data Submissions

The Agency and the regulated industry agree that data and/or information which uniquely describes the general attributes of the new animal drug (e.g., the known characteristics of the drug that can impact safety, effectiveness

and/or quality) needs to be submitted early in the new animal drug development process in order to enable the parties to reach agreement at a presubmission conference or to begin review of a protocol. The intent of this provision is to avoid the submission of data or information between the presubmission conference and the submission of a protocol. Eligibility both for short justifications in protocols and for concurrent supporting data and protocol review described below is predicated on the sponsor submitting information early in the new animal drug development process.

The Agency will allow for the inclusion of these data and/or information in presubmission conferences and/or in an H submission prior to the presubmission conference; however, a presubmission conference may be held without such data. By October 1, 2023, the Agency will publish a Program Policy and Procedures Manual Guide (P&P) for CVM reviewers who are advising sponsors on:

- information/data included in H submissions related to presubmission conferences,
- timing of the related meeting request submission, and
- how CVM should schedule meetings, such that they occur on, or in close proximity to, the H submission due date.

The Agency will allow short justifications within INAD protocols without data submissions that are limited in scope (e.g., no more than ten pages or no more than two (peer-reviewed) journal articles).

The Agency will allow for the concurrent submission of supporting data (INAD H submissions) and protocols (INAD E submissions) provided that the protocol is not submitted until the supporting data has been in the Agency's queue for at least 50 days.

By October 1, 2023, the Agency will publish a P&P for CVM reviewers who are advising sponsors regarding the appropriate timing of a protocol submission in relation to an H submission containing information to support the protocol. The P&P will address situations where information was submitted early in the new animal drug development process, as described earlier in this section, and situations where this information was not submitted early in the animal drug development process. The P&P will provide information to CVM staff who are advising sponsors about when a protocol may or may not be submitted after the supporting data has been in the Agency's queue for at least 50 days.

2. Dosage Characterization

The Agency and the regulated industry agree that dosage characterization is part of the effectiveness technical section of an investigational new animal drug file. In instances where data and/or information about the dosage are integral to the review of a protocol, the Agency and the regulated industry

agree that these data and/or information should be submitted as supporting data (INAD H submission) well in advance of the protocol submission. Such information may be needed to ensure selection of optimal study time points and would be particularly important for novel drugs and drugs with modified-release characteristics.

3. Raw Data Submission Expectations

By October 1, 2024, the Agency will publish a draft Guidance for Industry on raw data submission expectations for non-clinical studies conducted under Good Laboratory Practice requirements and clinical studies conducted under Good Clinical Practice requirements.

By October 1, 2023, the Agency will publish a P&P for CVM reviewers reviewing H submissions in which the sponsor is seeking agreement on a proposed list of copies of raw data and documents related to their submission of a target animal safety (TAS) protocol without data submission. After publication of the P&P, CVM will permit the submission of H submissions containing a proposed list of copies of raw data and documents supporting a TAS protocol.

4. eSubmitter and H Submissions for Raw Data

By October 1, 2023, FDA will launch a new or updated eSubmitter template for TAS protocols, to facilitate efficient review of the H submissions containing proposed raw data to be included in TAS study reports, provided that industry stakeholders that use the eSubmitter tool have provided timely feedback to further the Agency's work. FDA will continue to accept stakeholder feedback on the eSubmitter template for these H submissions during ADUFA V.

The Agency and industry stakeholders will assess the benefits of the eSubmitter template for H submissions for TAS protocols before the Agency develops a template for H submissions for effectiveness protocols. If the Agency proceeds with the template for H submissions for effectiveness protocols, industry stakeholders that use the eSubmitter tool will be invited to provide timely feedback to advance the Agency's work.

D. Exploration with Industry

1. Animal Drug Availability Act (ADAA) Combination Medicated Feeds

The Agency agrees to explore, in concert with affected parties including the animal health industry, CVM P&P 1243.5730, "Review of 60-day original Animal Drug Availability Act of 1996 (ADAA) feed use combination new animal drug applications (NADAs)", to determine why the process is not being utilized and to understand how to increase utilization of the process, thereby reducing the review time for eligible ADAA combinations drug applications following the approval of a new Type A medicated article. The exploration phase will be completed by October 1, 2025. The Agency may revise P&P 1243.5730 based on the outcome of the exploration phase.

2. Residue Method Trial

The Agency agrees to explore, in concert with affected parties including the animal health industry, the drug residue analytical method trial process and its requirements as they relate to the approval of new animal drugs intended for food producing animals. If implementation of recommendations is possible, it may include modification of current processes. Implementation also may include procedural, policy, and/or guidance revisions. The exploration phase will be completed by October 1, 2025. Implementation of actionable recommendations will be completed during ADUFA V.

3. Sentinel Submission Clock Stop

Beginning on October 1, 2023, the Agency agrees to explore, in concert with industry, the feasibility of using additional review tools to enhance the efficiency of the animal drug review process, such as implementing a "clock stop" during the review of sentinel submissions. A working group will develop a written analysis and recommendations for the tools identified by September 30, 2025.

4. Feedback on Product Development Plans

The Agency agrees to explore, in concert with affected parties including the animal health industry, means for the Agency to provide feedback on a sponsor's animal drug development plan more efficiently and effectively for both industry and the Agency. By October 1, 2025, a working group will develop a report outlining suggestions for providing feedback.

E. Other

1. Chemistry, Manufacturing, and Controls

By September 30, 2024, the Agency will publish a P&P for Chemistry, Manufacturing, and Controls (CMC) reviewers to clarify when reviewers should request amendments, use shortened review time, or classify submissions as incomplete. In addition, this P&P will describe what administrative actions are appropriate when GMP status (or pending PAI) is the only comment remaining for a CMC technical section.

By September 30, 2024, the Agency will revise Guidance for Industry 227 "Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections" to define situations for which parallel submission of phased data submissions would be allowed.

IV. Reporting Metrics

A. Sentinel Submissions Filed/Submitted at Division Level

Beginning in FY 2024, as part of the annual ADUFA V performance report, FDA will report the number of certain filed/submitted sentinel submissions by review division. Performance will be reported at the program level. The sentinel submissions are:

1. Original NADAs, CNADAs and reactivations
2. Administrative NADAs and CNADAs
3. Non-manufacturing supplemental NADAs and reactivations
4. INAD study submissions
5. INAD study protocols without data submissions
6. Qualifying labeling supplements
7. Presubmission conferences

B. Time in Agency/Time in Industry

Beginning in FY 2024, in concert with industry, explore potential Agency-reported metrics regarding review time of investigational submissions that lead to approvals by the Agency and response time by industry. The exploration may include discussions on which metrics to report, what processes currently exist to calculate and report these metrics, which systems might need to be developed to facilitate reporting the metrics, what the results of the metrics mean, and how best to report the metrics.

Following publication of the third-party assessment in 2025, industry and the Agency will initiate a follow up effort, which may include a pilot period, to inform how these metrics might be collected and reported.

C. Favorable Outcomes

Beginning in the second quarter (Q2) of FY 2024, FDA will report quarterly in FDA-TRACK, for INAD protocols without data and for INAD study submissions, the number of the following outcomes: (1) favorable, (2) non-concurrence/non-accepted but shortened review offered, and (3) non-concurrence/non-accepted and shortened review not offered.

FDA and industry will work together to identify a process to annually report the cycle number for all for INAD protocols without data and INAD study submissions with favorable outcomes and whether the favorable outcomes were first, second, or third+ submissions.

FDA and industry will work together to make sustained, substantial, and incremental improvements in the annual percentage of favorable outcomes for the CMC INAD study submissions and/or to improve utilization of the shortened review process.

D. INAD H Submissions Submitted at Division Level

Beginning in Q2 of FY 2024, FDA will report quarterly in FDA-TRACK the number of H submissions submitted to ONADE by division

E. Average Review Times in Hours

Beginning in FY 2024, FDA will report in the ADUFA performance report the average review times, in hours, for protocols without data and INAD study submissions (broken down by technical section) by fiscal year.

V. Enhancing Management of User Fee Resources

FDA is committed to enhancing management of ADUFA resources and ensuring ADUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner.

A. Third-Party Assessment

The Agency will engage an independent, third-party to conduct a comprehensive assessment of the process for the review of animal drug applications. The assessment will include consultation with both the Agency and industry. The assessment will include first cycle reviews as they pertain to the ADUFA program's objective of expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions.

The assessment will examine past and current utilization and effectiveness of the review process, available resources [e.g., full-time equivalents (FTEs)], and tools used by the Agency and industry, as established through previous ADUFA authorizations to foster favorable first cycle review outcomes for sentinel submissions. The scope of this assessment will include the analysis of submissions (starting from the request to establish an INAD file and ending with approval) and include all technical section submissions (both sentinel and non-sentinel) to INAD files, NADAs, and conditional approval application files. It will also evaluate the impact of specific user fee-based enhancements from prior reauthorizations on approved original NADAs and applications for conditional approval.

The assessment will include evaluation of a random set of applications approved from FY 2009 through FY 2022. The samples will include

representation from new chemical entities, multiple animal drug sponsors, all major species, and multiple different dosage form. The evaluation will include the proposal and evaluation of the optimal process to provide data on how resources are utilized (i.e., user fee funds; headcount and process FTEs with ADUFA allowable activities by office and division) and of applicable metrics (e.g., time to approval, divided between time in agency and time with industry, for technical sections to INADs and NADAs; and favorable first cycle outcomes) that evaluate progress towards the ADUFA program's objective mentioned above.

The Agency will obtain the services of a contractor to complete this assessment. After the final assessment report is accepted by the responsible Agency official, it will be posted on FDA.gov. When publishing the final assessment report on the FDA website, the Agency will comply with requirements to protect confidential commercial information and other information exempt from disclosure.

FDA will convene a public workshop approximately three months after accepting the final assessment report to present the findings of the independent assessment, including the third-party's report of anonymized, aggregated feedback resulting from its interviews of animal drug sponsors and Agency personnel. The assessment report and the public meeting will be completed by December 31, 2025.

Following the completion of the assessment and public meeting, the Agency and industry will analyze the recommendations for improvement opportunities identified in the assessment. FDA, with input from stakeholders, will incorporate findings and recommendations, as it determines to be possible and appropriate, into its management of the process for the review of animal drug applications and Industry will incorporate findings and recommendations, as appropriate, into their filing and submission processes.

B. Financial Transparency

1. FDA will publish an ADUFA 5-year financial plan no later than the end of the second quarter of FY 2024 that aligns with the plans published for GDUFA II, PDUFA VI and BsUFA II.
2. FDA will publish updates to the 5-year plan no later than the end of the second quarter of each subsequent fiscal year.

VI. Statutory Adjustments

A. Workload Adjustment

For the purposes of calculating the workload adjustment, the base years will be a rolling average comprising the five most recently completed fiscal years. For example, beginning October 1, 2024 (FY 2025), the base will comprise FY 2019 through FY 2023. At the start of each fiscal year thereafter, the base will be adjusted upward by one year on the upper and lower ends of the range. There will be no workload adjustment for FY 2024. Workload adjustments are one-time adjustments and are calculated annually. The weighting factor is the percent of direct review time spent on each of the five component submission types over the most recent five-year period.

As stated in the Federal Food, Drug, and Cosmetic (FD&C) Act, the workload adjustment "shall be made for each fiscal year that the adjustment determined by the Secretary is greater than 3 percent, except for the first fiscal year that the adjustment is greater than 3 percent, except for the first fiscal year that the adjustment is greater than 3 percent." See section 740(c)(3) of the FD&C Act [21 U.S.C. § 379j-12(c)(3)] for the full text of the workload adjustment.

B. Operating Reserve Adjustment

The operating reserve of carryover user fees for the process for the review of animal drug applications will be used to fund the third-party assessment described in section V.A. and any ADUFA V negotiated, one-time IT enhancements.

Additionally, as stated in the FD&C Act, fee revenue amounts will be adjusted to provide an operating reserve of carryover user fees for the process of the review of animal drug applications of not less than 12 weeks and not more than 16 weeks. The reduction of the operating reserve to the 16-week maximum will be phased in over the 5-year lifecycle of ADUFA V. Section 740(c)(4) of the FD&C Act [21 U.S.C. § 379j-12(c)(4)] contains the text of the operating reserve adjustment, as follows:

> ''(4) OPERATING RESERVE ADJUSTMENT.—
>
> > ''(A) IN GENERAL.—For fiscal year 2025 and each subsequent fiscal year, after the fee revenue amount established under subsection (b) is adjusted in accordance with paragraphs (2) and (3), the Secretary shall—
> >
> > > ''(i) increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 weeks; or
> > >
> > > ''(ii) if the Secretary has an operating reserve in excess of the number of weeks specified in subparagraph (C) for that fiscal year, the Secretary shall decrease the fee revenue amount to provide not more than the number of weeks specified in subparagraph (C) for that fiscal year.

‘‘(B) CARRYOVER USER FEES.—For purposes of this paragraph, the operating reserve of carryover user fees for the process for the review of animal drug applications does not include carryover user fees that have not been appropriated.

‘‘(C) NUMBER OF WEEKS OF OPERATING RESERVES.—The number of weeks of operating reserves specified in this subparagraph is—

‘‘(i) 22 weeks for fiscal year 2025;
‘‘(ii) 20 weeks for fiscal year 2026;
‘‘(iii) 18 weeks for fiscal year 2027; and
‘‘(iv) 16 weeks for fiscal year 2028.