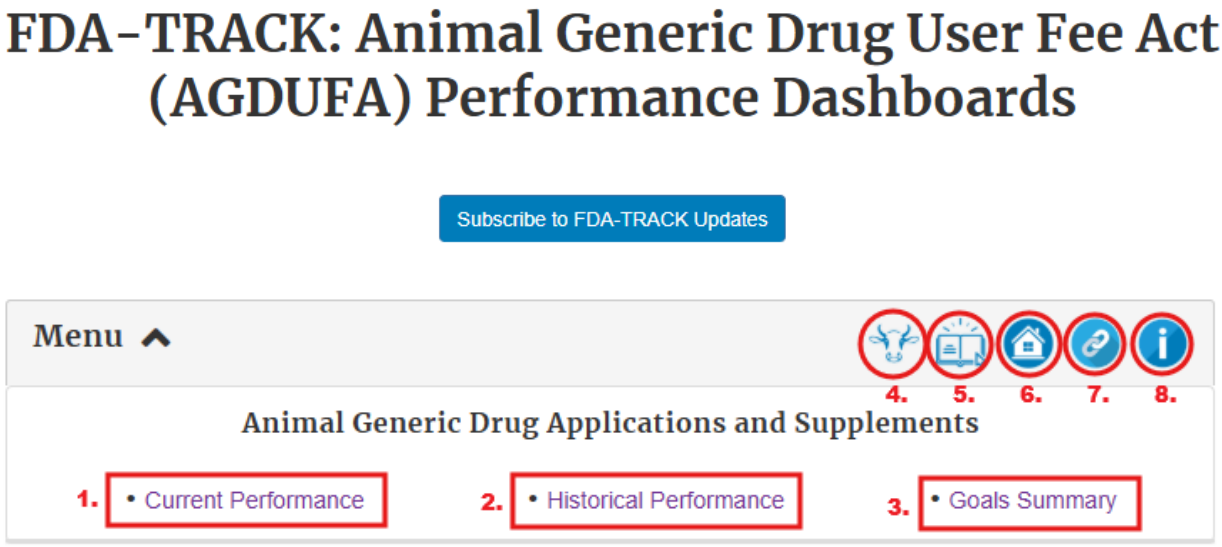
FDA-TRACK: Animal Generic Drug User Fee Act (AGDUFA) Performance Dashboard User Guide

FDA-TRACK: AGDUFA Performance Navigation

Each FDA-TRACK: AGDUFA Performance webpage includes a navigation menu and icons with the following information:

1. AGDUFA Current Performance – includes the three most recent years of performance
2. AGDUFA Historical Performance – includes historical performance
3. AGDUFA Goals Summary
4. Animal and Veterinary Homepage
5. AGDUFA Performance Dashboard User Guide
6. FDA-TRACK Home
7. Relevant Links about AGDUFA
8. Information about AGDUFA



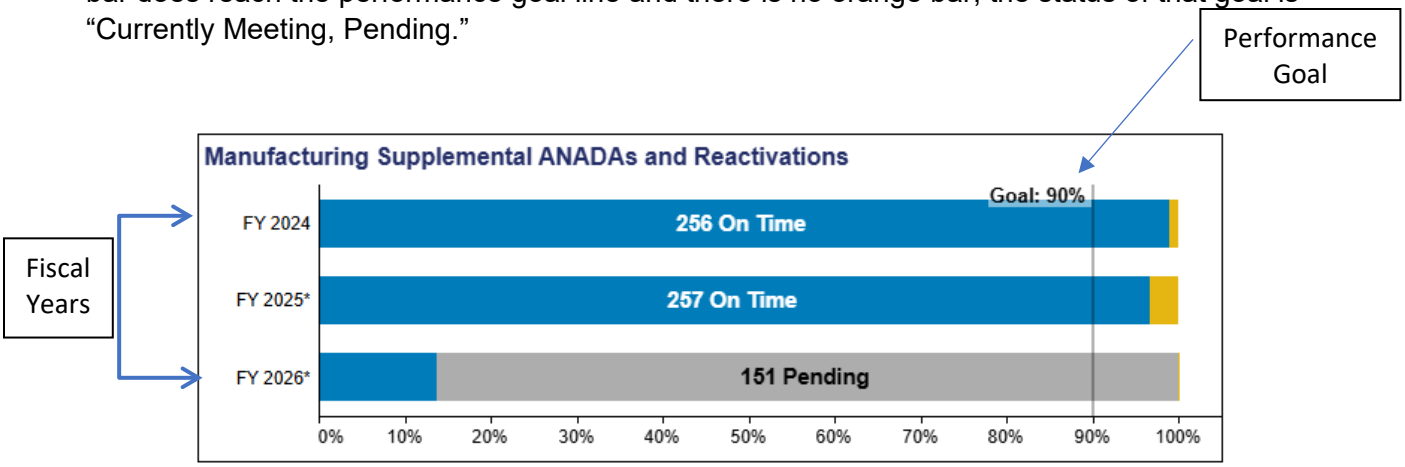
AGDUFA Current Performance

The Current Performance page of the AGDUFA Performance Dashboard shows the three most recent years of performance under AGDUFA IV for each established goal with the current fiscal year representing performance year-to-date. When more than one year of data is reported, the first year's data is final, and the second- and third-year's data is preliminary with actions still pending.

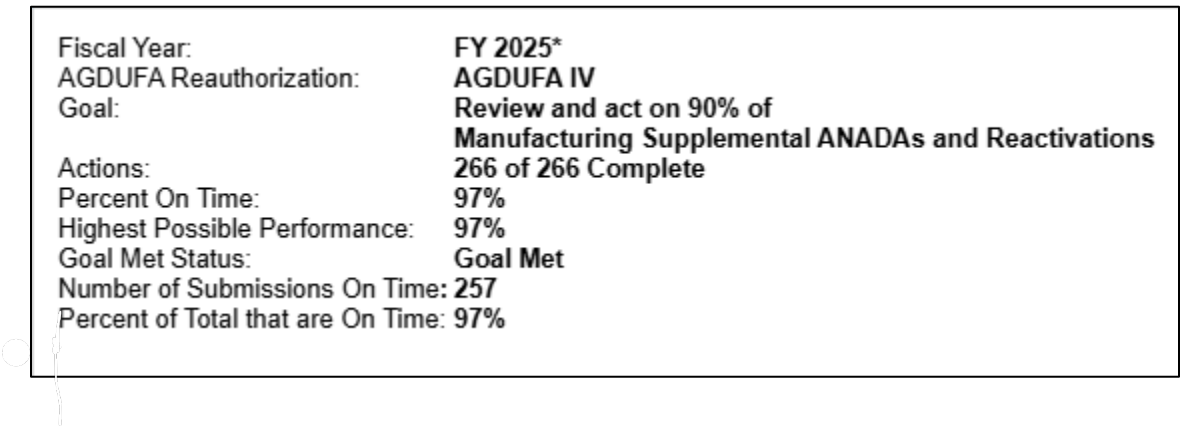
The Current Performance page displays a stacked bar chart for each year of performance:

- The color of each segment of the bar represents status:
  - Blue represents actions completed "On Time," or within goal;
  - Gray represents actions "Pending," or within goal and where no action has been taken;
  - Orange represents actions "Overdue," where action was taken after the goal date, or no action was taken and is past the goal date.
- Each bar is labeled with the number of actions in that status, except in cases where the volume of actions with that status is extremely small. In some instances, the label for the review status will not display in the graph due to space. This is an automatic default setting in the software. If you hover over the section of the graph where the label is missing, the label details will appear in the Tooltip.
- The "Performance Goal" is shown as a solid vertical line on the graph:
  - If the blue bar reaches the performance goal line, the goal status is "Goal Met", or "Will Meet Goal".
  - If the gray bar reaches the goal line, the goal status is "Currently Meeting, Pending".
  - If the orange bar reaches the goal line, the goal status is "Goal Not Met" or "Will Not Meet Goal".

In the example below, 259 submissions were filed in FY 2024. Of those submissions, 99% (256) met the performance goal, while 1% (3) did not. Since the orange bar does not reach the performance goal line, the status of that goal is "Goal Met." In FY 2025, 266 submissions were filed; 97% (257) were on time and 3% (9) are overdue. Since the orange bar does not reach the performance goal line, the status of that goal is "Goal Met." In FY 2026, 175 submissions have been filed year-to-date; 14% (24) were on time and 151 (86%) are still pending. Since the grey bar does reach the performance goal line and there is no orange bar, the status of that goal is "Currently Meeting, Pending."



To see a "tooltip" that displays additional information, hover the cursor over each status on a bar, as shown in the example below.



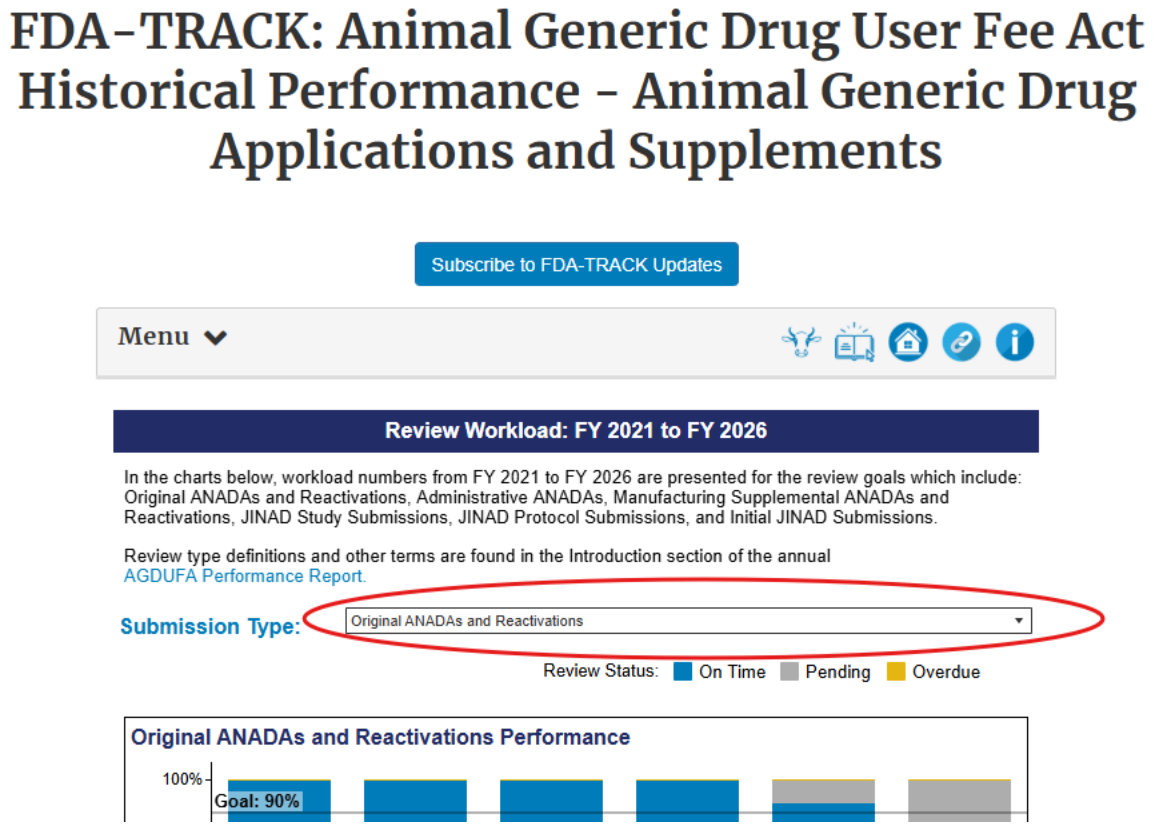
The tooltip provides several useful pieces of information. These include:

- Fiscal Year: The Fiscal Year of the receipt of the submission subject to the goal.
- AGDUFA Reauthorization: Which reauthorization of AGDUFA the performance goal falls under.
- Goal: The performance goal and type of action.
- Actions:
    - For final data, the number of actions out of the total that were on time
    - For preliminary data, the number of actions that are completed, regardless of whether they were on time or overdue, out of all potential actions
- Percent on Time: The percent of actions that met the goal
- Highest Possible Performance: The highest performance that can be achieved if all "Pending" within goal submissions are acted upon within goal.
- Goal Met Status: The statuses are "Goal Met," "Will Meet Goal," "Currently Meeting, Pending," "Will Not Meet Goal," or "Goal Not Met"
- Number of Submissions: For a specified status, the number of submissions included in that status
- Percent of Total: For a specified status, the percentage portion of submissions in relation to the total (100%).

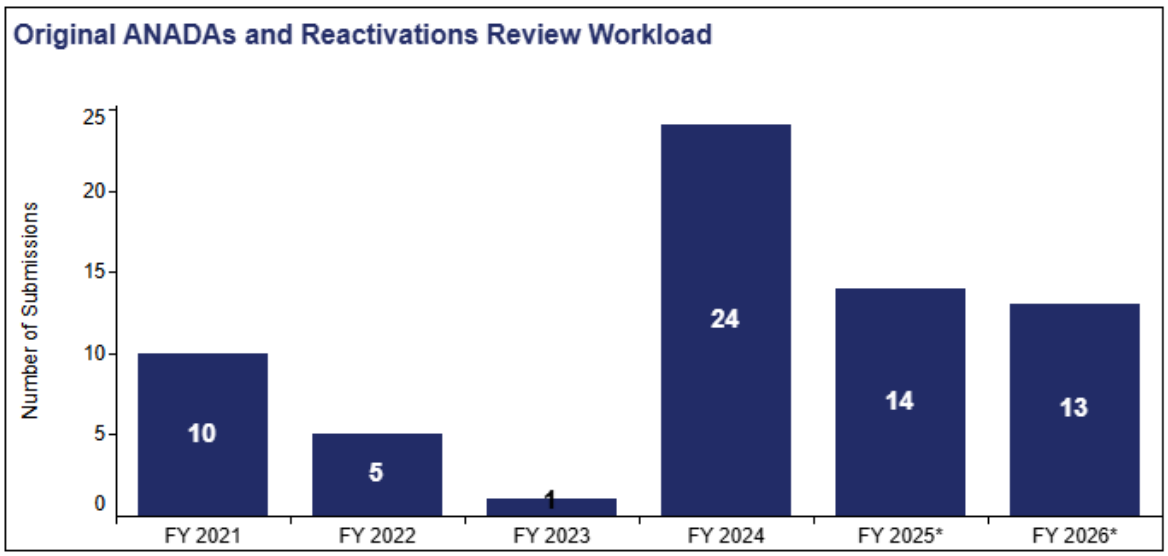
AGDUFA Historical Performance

The Historical Performance page of the AGDUFA Performance Dashboard shows the past six years of data with the current fiscal year representing performance year-to-date for each performance goal. The first four years of data are final and the past two years of data, which may include newly implemented goals, is preliminary with actions still pending.

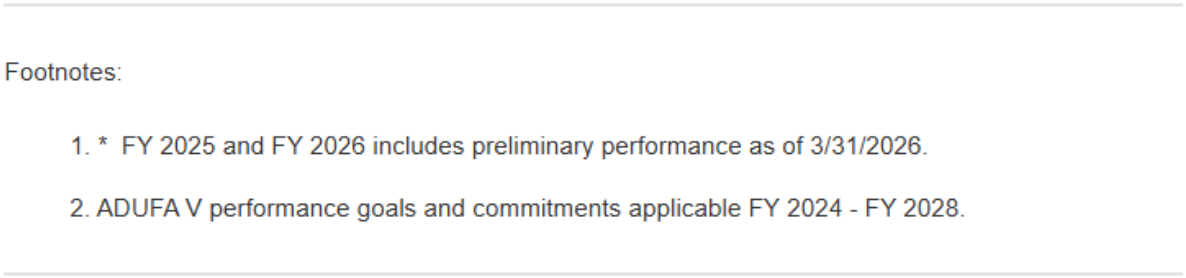
A drop-down list is provided at the top of the page that allows selection of an animal drug submission type for a given performance area as shown in the example below.



Workload data represents the number of submissions subject to the specific goals during the drug review process.



Datasets and Footnotes

Dashboard data can be downloaded by selecting the *Download Dataset* button under each dashboard, as shown below.

Footnotes are provided under each dashboard showing relevant information, for example, noting whether data is preliminary.