

# PDUFA Performance Dashboards User Guide

## ***Navigation and Relevant Information***

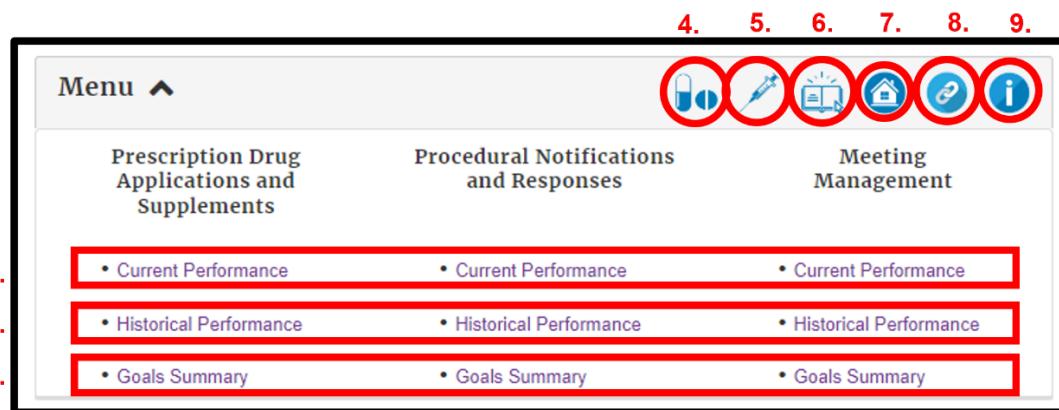
The [PDUFA Performance Dashboards](#) are organized into three categories: 1) Prescription Drug Applications and Supplements; 2) Procedural Notifications and Responses; and 3) Meeting Management. Each category includes a Current and Historical Performance Dashboard with a navigation menu and icons at the top of each dashboard. The menu and icons include information to:

1. PDUFA Current Performance Dashboards for each category showing the two most recent years of performance for each goal
2. PDUFA Historical Performance Dashboards for each category showing the historical performance for each goal
3. PDUFA Goals Summary for each category showing the submission types, goal timelines and performance goals for PDUFA VII
4. FDA-TRACK Drugs Home Page
5. FDA-TRACK Biologics Home Page
6. PDUFA Performance Dashboards User Guide
7. FDA-TRACK Home Page
8. Relevant Links about PDUFA
9. General background about PDUFA

## **FDA-TRACK: Prescription Drug User Fee Act (PDUFA) Performance**

[Subscribe to Email Updates](#) [!\[\]\(d66ff64371a51729ac8c1cdaa685ba6f\_img.jpg\) Share](#) [!\[\]\(0f31ebba7abcd47777e178db26f29705\_img.jpg\) Post](#) [!\[\]\(63ea948177b1bcc486b2b76d20d5fb69\_img.jpg\) LinkedIn](#) [!\[\]\(886f7dced1265a6d438eca0881817b40\_img.jpg\) Email](#) [!\[\]\(bb381b56be27580041e232a6cbb04464\_img.jpg\) Print](#)

[Subscribe to FDA-TRACK Updates](#)



4. 5. 6. 7. 8. 9.

1. • Current Performance • Current Performance • Current Performance

2. • Historical Performance • Historical Performance • Historical Performance

3. • Goals Summary • Goals Summary • Goals Summary

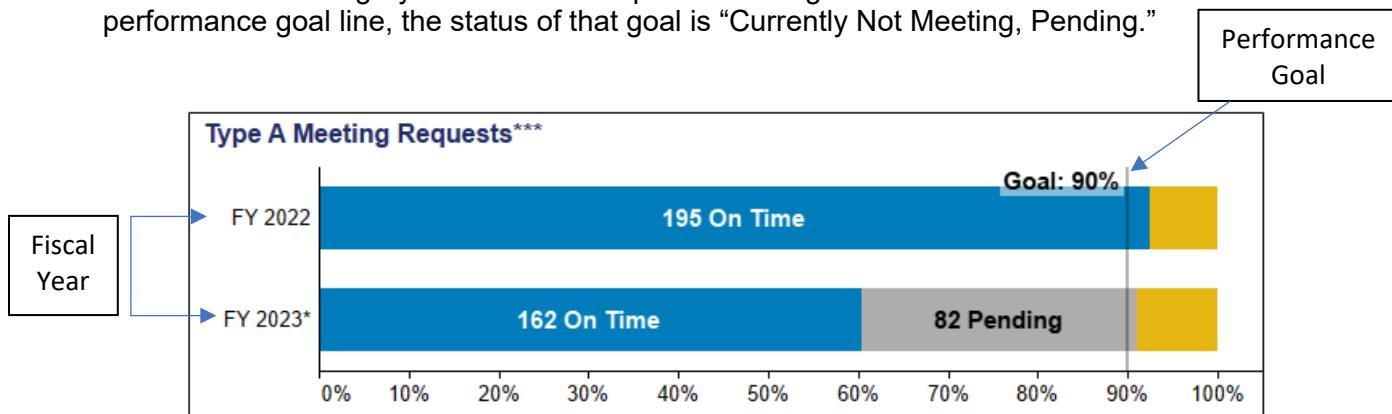
## Current Performance

The Current Performance page of the PDUFA Performance Dashboards shows the two most recent years of performance for each established goal and the most recent year of performance for newly implemented goals established under PDUFA VII. When more than one year of data is reported, the first year's data is final, and the second year's data is preliminary with some actions still pending.

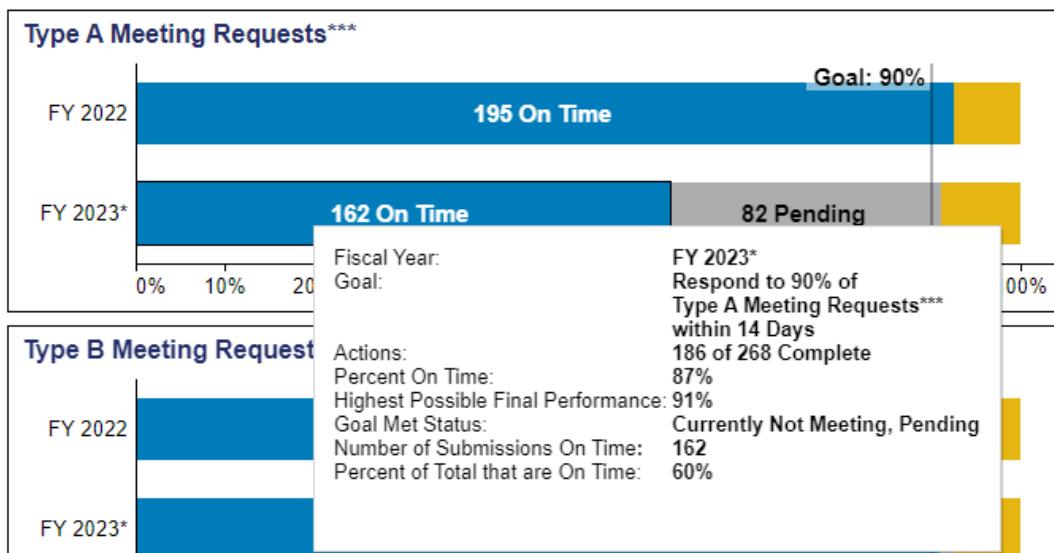
The Current Performance page displays a stacked bar chart for each year of performance:

- 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 visualization software. If you hover the cursor 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 from the left, the goal status is “Goal Met”, or “Will Meet Goal.”
  - If the gray bar crosses the performance goal line and the Percent On Time meets or exceeds the performance goal, the goal status is “Currently Meeting, Pending.” If the gray bar crosses the performance goal line and the Percent On Time is below the goal, the goal status is “Currently Not Meeting, Pending.”
  - If the orange bar reaches the performance goal line from the right, the goal status is “Goal Not Met” or “Will Not Meet Goal.”

In the example below, 211 submissions were filed in FY 2022. Of those submissions, 92% (195) met the performance goal, while 8% (16) did not. Since the orange bar does not reach the performance goal line from the left, the status of that goal is “Goal Met.” In FY 2023, 268 submissions were filed; 60% (162) were on time, 31% (82) were still pending, and 9% (24) were overdue. Since the gray bar reaches the performance goal line but the blue bar is below the performance goal line, the status of that goal is “Currently Not 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.
- Goal: The performance goal, type of action, and review time of the goal.
- Actions:
  - For final data, the number of actions that were on time out of the total.
  - 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,” “Currently Not Meeting, Pending,” “Will Not Meet Goal,” “Goal Not Met,” or “N/A” if no submissions were filed for a goal.
- 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%).
- Additional Notes: Any additional pertinent information about how a specific performance goal is measured.

## Historical Performance

The Historical Performance page of the PDUFA Performance Dashboards shows the past six years of data for each performance goal. The past five years of data are final and the past year of data, which may include newly implemented goals, is preliminary with actions still pending. The Submission Type Filter above the graphs allows for the selection of a submission type as seen in the example below.

# FDA-TRACK: PDUFA Historical Performance - Prescription Drug Applications and Supplements

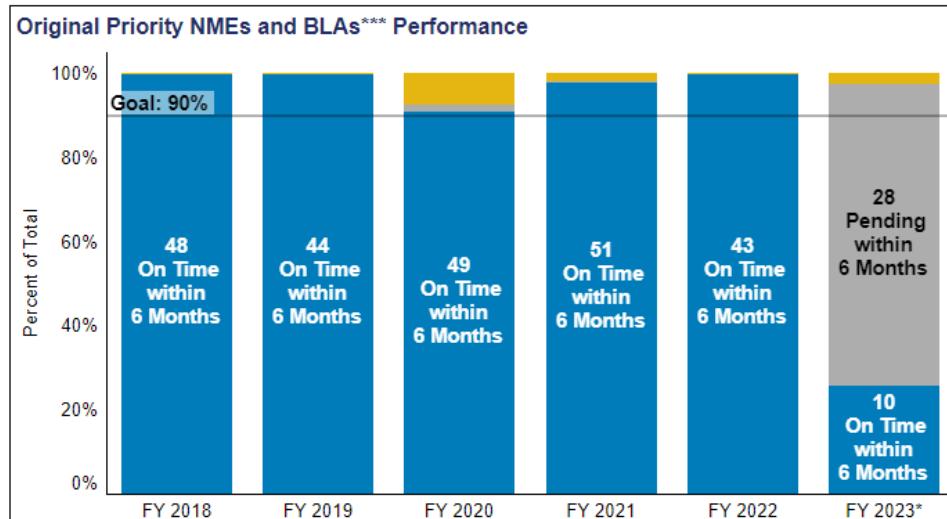
## Review Workload: FY 2018 to FY 2023

In the charts below, preliminary workload numbers from FY 2023 are compared to the previous 5-year averages, where applicable, for the review goals which include: BLAs, NDAs, resubmissions, efficacy supplements, and manufacturing supplements. FDA saw an increase between FY 2022 and FY 2023 in the annual workload number of Original Priority Non-NME NDAs, Original Standard Non-NME NDAs, and NDA and BLA Manufacturing Supplements Requiring Prior Approval and Not Requiring Prior Approval.

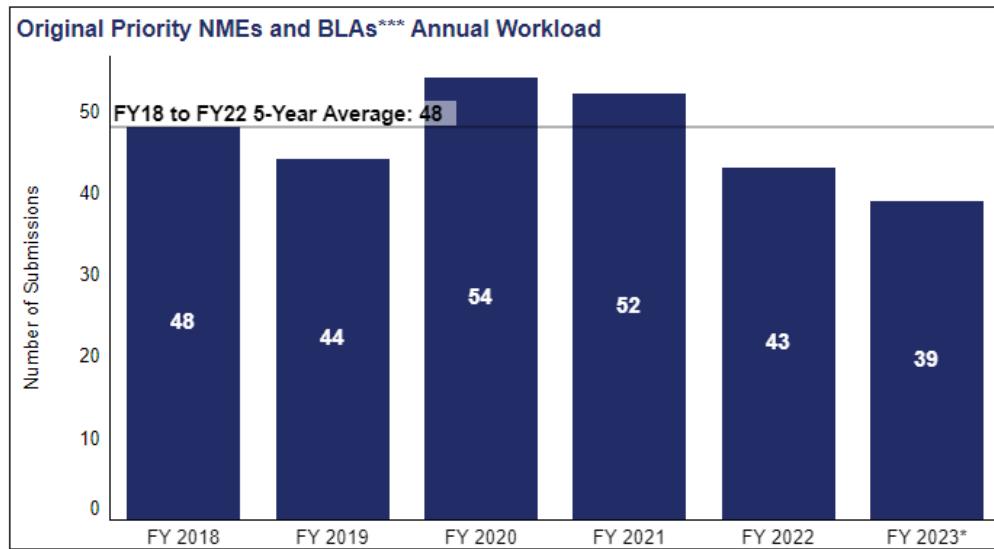
Submission type definitions and other terms are found in Appendix E of the annual PDUFA Performance Report. The data presented in these charts represent receipts by FDA of the submission types.

Submission Type: Original Priority NMEs and BLAs\*\*\*

Review Status: Overdue Pending On Time



Workload data represents the number of submissions subject to the specific goals during the drug review process. The “average” line through the graph represents the average number of submissions over the five-year period of final performance data, excluding the preliminary data.



### Datasets and Footnotes

The data in each dashboard can be downloaded by selecting the dataset button below each dashboard, as shown below for the Current Performance for the Prescription Drug Applications and Supplements Dashboard.

[Download Prescription Drug Applications and Supplements Dataset](#)

Footnotes are provided below each dashboard showing relevant information, for example, noting whether there were changes in the performance goals, or whether data is preliminary.

---

Footnotes:

\* Performance is currently preliminary due to pending submissions.

\*\* New Performance Goal for PDUFA VII (see [Changes for this Goal](#), pages 20-27).

\*\*\* The most recent FY workload and performance data includes meetings where the type cannot be initially determined.