

# OMUFA Performance Dashboards User Guide

## Navigation and Relevant Information

The [OMUFA Performance Dashboards](#) are organized into three categories: 1) OTC Monograph Order Request Submissions; 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. OMUFA Current Performance Dashboards for each category showing the two most recent years of performance for each goal
2. OMUFA Historical Performance Dashboards for each category showing the historical performance for each goal
3. OMUFA Goals Summary for each category showing the submission types, goal timelines, and performance goals for OMUFA I
4. FDA-TRACK Drugs Home Page
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## FDA-TRACK: Over-The-Counter Monograph Drug User Fee Program (OMUFA) Performance Dashboards

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Menu ^

	OTC Monograph Order Request Submissions	Procedural Notifications and Responses	Meeting Management
1.	• Current Performance	• Current Performance	• Current Performance
2.	• Historical Performance	• Historical Performance	• Historical Performance
3.	• Goals Summary	• Goals Summary	• Goals Summary

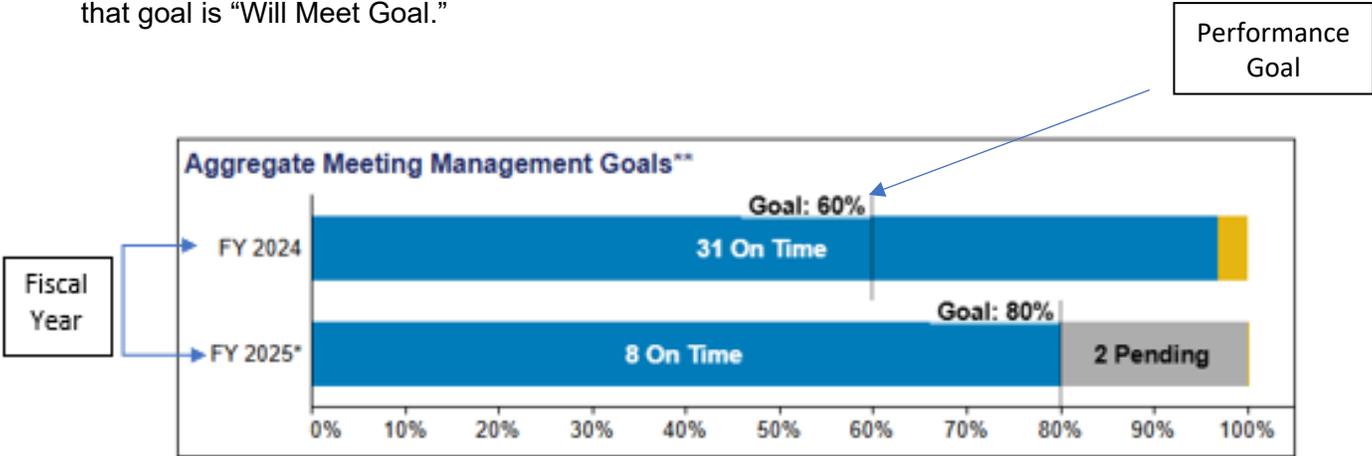
**Current Performance**

The Current Performance page of the OMUFA 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 OMUFA I. When more than one year of data is reported, the first [previous] year’s data is final, and the second [most recent] year’s data is preliminary with some actions still pending.

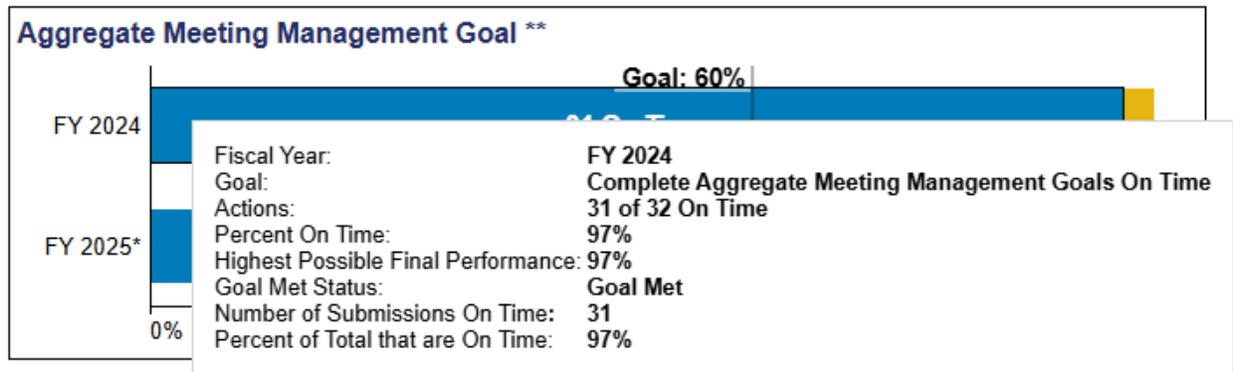
The Current Performance page displays a stacked bar chart for each year (two most recent) of performance:

- 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;
  - Yellow 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 bar/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 yellow 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, 32 submissions were filed in FY 2024. Of those submissions, 97% (31) met the performance goal, while 3% (1) did not. Since the yellow bar does not reach the performance goal line from the left, the status of that goal is “Goal Met.” In FY 2025, 10 submissions were filed; 80% (8) were on time, 20% (2) are pending, and there are none overdue. Since both the gray bar and blue bar reaches the performance goal line, the status of that goal is “Will Meet Goal.”



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 Final 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 OMFUA Performance Dashboards shows the past two to three years of data for each performance goal. Typically, the last five years of historical data and the most recent year's preliminary data are included, but due to this report being relatively new, only two to three years of data are currently available. The most recent year of data, which may include newly implemented goals, is preliminary with actions still pending, while prior years represent final data. The Submission Type Filter above the graphs allows for the selection of a submission type as seen in the example below.

# FDA-TRACK: Over-The-Counter Monograph Drug User Fee Program Historical Performance - Meeting Management

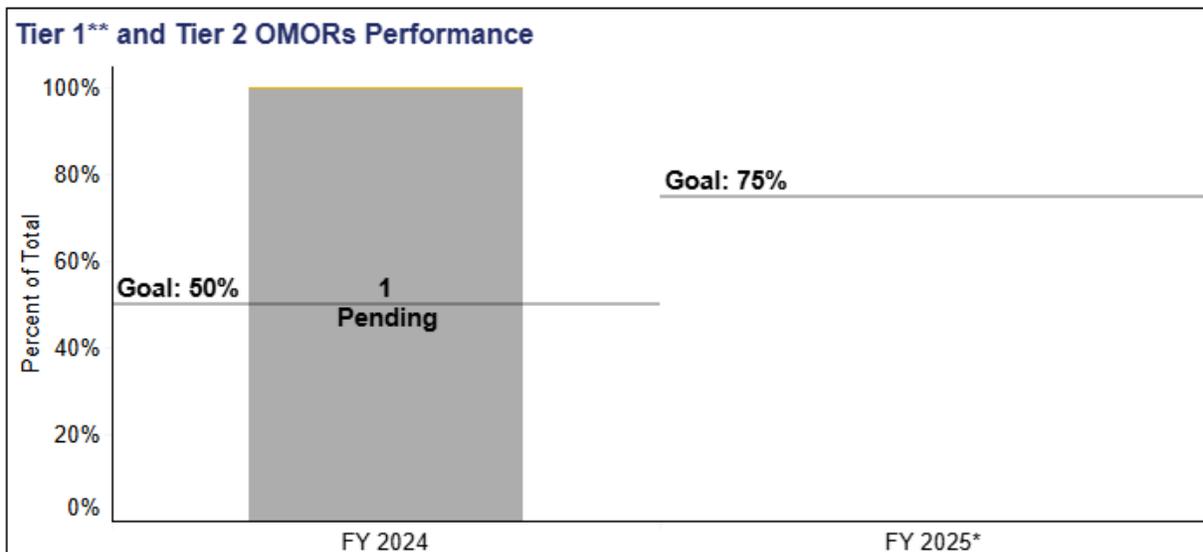
## Review Workload: FY 2024 to FY 2025

In the charts below, workload numbers from FY 2024 to FY 2025 are presented for the review goals which include: Tier 1 and Tier 2 OMORs, Tier 1 OMORs for Certain Safety Changes Only, and Tier 1 OMORs with GRASE Finalization.

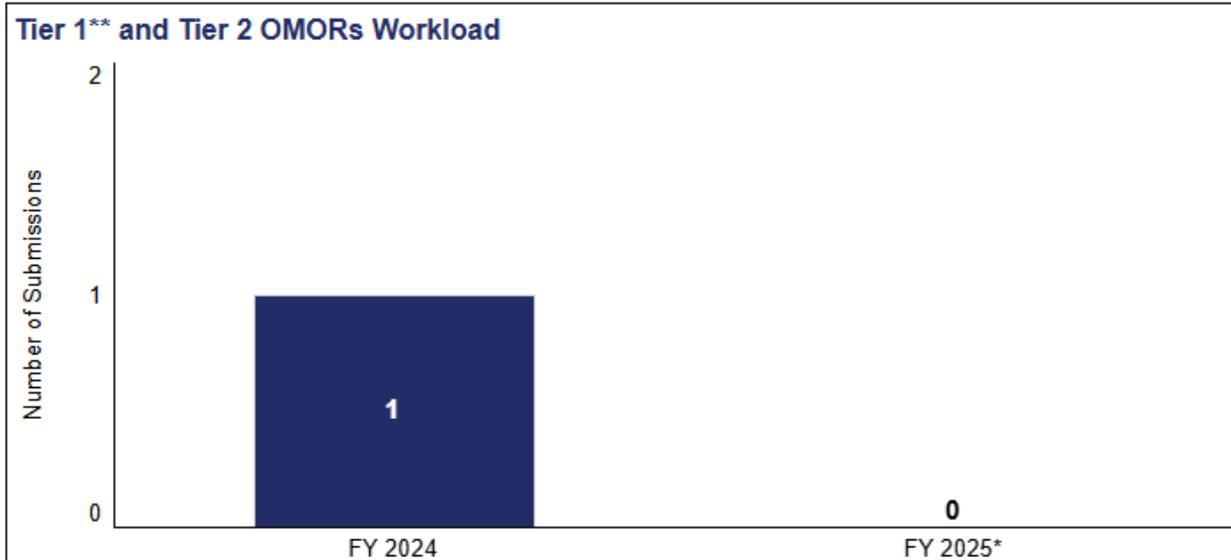
Review type definitions and other terms are found in Appendix A of the annual [OMFUA Performance Report](#).

**Submission Type:** Tier 1\*\* and Tier 2 OMORs

Review Status: ■ Overdue ■ Pending ■ On Time

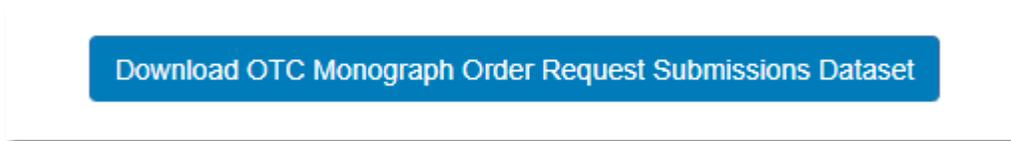


Workload data represents the number of submissions subject to the specific goals during the review process.



### ***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 OTC Monograph Order Request Submissions Dashboard.



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.

\*\* Excludes meeting request submissions that were denied because of nonpayment of OMUFA user fees or meeting requests that were withdrawn prior to the meetings granted/denied response goal date.