Performance Report to Congress

Over-the-Counter Monograph Drug User Fee Program

FY 2024

Executive Summary

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) was signed into law. In addition to aiding the COVID-19 response efforts, the CARES Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include statutory provisions that (1) reformed and modernized the way over-the-counter (OTC) monograph drug products are regulated in the United States and (2) authorized the U.S. Food and Drug Administration (FDA or Agency) to assess and collect user fees from qualifying manufacturers of OTC monograph drug products and submitters of OTC monograph order requests.

The availability of OTC monograph drug products provides significant value to the U.S. healthcare system. Prior to the CARES Act, the OTC monograph process consisted of a three-phase rulemaking process that presented challenges to FDA's ability to act quickly on safety issues and beneficial innovations. The CARES Act amended the FD&C Act to replace that rulemaking process with a streamlined administrative order process for establishing, revising, and amending OTC monographs. This new administrative order process is intended to improve the efficiency, timeliness, and predictability of the OTC monograph review process. FDA expects the administrative order process will not only facilitate OTC monograph drug innovations that promote consumer choice but also help FDA address safety issues more rapidly to enable better protection of public health.

As noted above, the CARES Act amendments to the FD&C Act provided FDA the authority to assess and collect user fees from the OTC monograph drug industry, which are dedicated to OTC monograph drug activities. This user fee program provides additional resources to help the Agency conduct important regulatory activities in a timely manner and ultimately helps provide the public with access to safe, effective, and innovative OTC monograph drug products.

Section 744N(a) of the FD&C Act, as added by the CARES Act, requires FDA to report annually on its progress in achieving the goals identified in the Over-the-Counter Monograph Drug User Fee Program (OMUFA) performance goals and procedures document. The Agency continues to make excellent progress in meeting the OMUFA performance goals and OTC monograph reform objectives.

Achievements Since Passage of the CARES Act

FDA achieved the majority of its fiscal year (FY) 2024 OMUFA goals that support its OTC monograph drug activities. Highlighted below are FDA's accomplishments in FY 2024:

- Administrative Orders

- FDA published a proposed administrative order "Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use" on June 14, 2024.[1]

- Annual Forecast for Planned Monograph Activities[2]
  - FDA posted the fourth such annual forecast on September 30, 2024.

- IT Activities
  - FDA established practices to meet the FY 2023 business needs for the IT platform related to electronic submission receipt, review, and reporting.
  - On October 1, 2023, FDA's enhancements to the CDER NextGen Portal were implemented to enable industry to make submissions related to over-the-counter monograph drugs, including Over-the-Counter Monograph Order Requests (OMORs). FDA also enhanced CDER Nexus to allow for the review of the OMOR submission, OMOR Filing Review, and OMOR Discipline Review tasks.
  - On September 20, 2024, the CDER Nexus platform was enhanced to incorporate the ability to submit an OMOR to FDA and to facilitate FDA's OMOR review process and issuing of a proposed, interim final, or final administrative order.

- Guidances for Industry
  - FDA issued the final guidance for industry "Providing Over-the-Counter Monograph Submissions in Electronic Format" on July 24, 2024.[3]

- Cataloguing of Pre-OMUFA Paper Documents
  - FDA continued to make progress on the cataloguing of pre-OMUFA paper documents.

- Meeting Management Goals
  - FDA exceeded the 50 percent aggregate performance level for meeting. management goals for formal development meetings with industry in FY

[1] Available at https://dps.fda.gov/omuf/ordersearch/order_otc000035.

[2] Available at https://dps.fda.gov/omuf/forecast.

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-over-counter-monograph-submissions-electronic-format.

2023.

- FDA is currently exceeding the 60 percent aggregate performance level for meeting management goals in FY 2024. With some submissions still within the OMUFA goal date, FDA has the potential to meet or exceed the 60 percent aggregate meeting management goal for FY 2024.

- Review Goals
  - FDA received its first OMOR submission in FY 2024. FDA has the potential to meet or exceed the 50 percent performance level for Tier 1 and 2 OMORs (excluding Tier 1 OMORs for Certain Safety Changes) for FY 2024.

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Acronym List

CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDER	Center for Drug Evaluation and Research
DFO	Deemed Final Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FY	Fiscal Year (October 1 to September 30)
GRASE	Generally Recognized as Safe and Effective
IT	Information Technology
OMOR	Over-the-Counter Monograph Order Request
OMUFA	Over-the-Counter Monograph Drug User Fee Program
OTC	Over-the-Counter

I. Introduction

Two hundred and forty million Americans use nonprescription drugs every year. Nonprescription drugs are available to consumers without a prescription and can be safely and effectively used without the supervision of a healthcare provider. Nonprescription drugs have long provided an efficient, low-cost way for Americans to manage every-day health needs, and these drugs play an increasingly vital role in our healthcare system. The vast array of nonprescription drugs includes cough and cold medicines, fever reducers, sunscreens, pain relievers, antacids, and more. These drugs can be purchased in many online and retail outlets, including pharmacies, grocery stores, and convenience stores.

Nonprescription drugs are brought to market either under the over-the-counter (OTC) monograph process (also referred to as the "OTC Drug Review") or under the application process (new drug application (NDA) or abbreviated new drug application (ANDA)). Of the more than 100,000 marketed nonprescription drugs, most are marketed through the OTC monograph process.[4]

A. The OTC Drug Review Program

In 1972, the U.S. Food and Drug Administration (FDA or Agency) established the OTC Drug Review, which established conditions under which OTC drugs without an approved application were generally recognized as safe and effective (GRASE) and not misbranded (and, upon meeting other applicable requirements, could be marketed without an approved NDA or ANDA). These GRASE conditions are described in OTC drug monographs for each OTC therapeutic drug class. Simply stated, an OTC monograph is a "rule book" of conditions for each therapeutic category that describes the active ingredients, uses (indications), doses, route of administration, labeling, and testing for an OTC drug to be considered GRASE.[5]

Despite FDA's successes in providing consumers with access to a wide variety of safe and effective OTC monograph drug products, challenges with the nearly 50-year-old OTC Drug Review process became apparent prior to the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) on March 27, 2020. (The CARES Act is described in greater detail in the next section below.) The biggest challenges of the OTC Drug Review prior to the CARES Act included the following:

[4] See https://www.fda.gov/news-events/fda-voices/exciting-new-chapter-otc-drug-history-otc-monograph-reform-cares-act.

[5] Id.

- Burdensome, multistep rulemakings to establish or amend OTC monographs;
- Lack of adequate resources to devote to the rulemaking process;
- Delays in finalizing OTC monographs;
- Limited, burdensome process for innovation (e.g., new combinations of ingredients or new dosage forms);
- Delays in responding to safety issues; and
- Challenges in keeping pace with evolving science and changing market conditions.

B. OTC Monograph Reform Enacted Under the CARES Act

The CARES Act was enacted to aid response efforts for COVID-19. In addition, the CARES Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include statutory provisions that reform and modernize the way OTC monograph drug products are regulated in the United States. These new FD&C Act provisions replaced the old rulemaking process with a streamlined administrative order process for establishing, revising, and amending the monographs for OTC drug products. In particular, these provisions authorize FDA to issue administrative orders that add, remove, or change GRASE conditions for an OTC drug monograph. Either industry or FDA can initiate the administrative order process. A request by industry to initiate the administrative order process is called an OTC Monograph Order Request (OMOR).[6]

This process also provides an expedited procedure for FDA to initiate a safety-related administrative order when FDA determines either that:

- The drug poses an imminent hazard to public health or
- A change in the labeling of a drug, class of drugs, or combination of drugs is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with the use of the drug.[7]

[6] See http://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor.

[7] See section 505G(b)(4) of the FD&C Act.

OTC monograph reform has accomplished the following:

- Improved the process by replacing rulemaking with administrative orders;
- Improved the efficiency, timeliness, and predictability of FDA's OTC monograph drug activities;
- Facilitated innovation;
- Established a process to rapidly address safety issues;
- Finalized pre-CARES pending monographs; and
- Through authority for the Over-the-Counter Monograph Drug User Fee Program (OMUFA), provided FDA with the ability to collect user fees to support OTC monograph drug activities.

More information on the history of the OTC drug monograph process is available on FDA's website.[8]

C. OTC Monograph Drug User Fee Program

The FD&C Act authorizes the Agency to assess and collect user fees from the regulated industry, for fiscal years (FYs) 2021 through 2025, to support OTC monograph drug activities. These fees provide FDA with additional resources that allow the Agency to conduct these important regulatory activities in a timely manner, ultimately helping provide the public with access to safe, effective, and innovative OTC monograph drug products. The Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2018-2022 document (also known as the "OMUFA I Goals Document") was drafted by FDA and industry to specify mutually agreed-upon timelines and performance goals for implementation of certain OTC monograph drug activities supported with OMUFA fees, beginning after congressional enactment of OTC monograph reform (which occurred under the CARES Act).[9]

In 2021, FDA updated the OMUFA goal dates in the OMUFA I Goals Document to reflect that FY 2021 was the first OMUFA program year.[10] This update aligns with

[8] See http://www.fda.gov/drugs/over-counter-otc-drug-monograph-process.

[9] See http://www.fda.gov/media/106407/download.

[10] See http://www.fda.gov/media/146283/download.

language in the OMUFA I Goals Document stating that although it was drafted under the assumption that FY 2018 would be the first program year, "If the program has a different effective date, goal dates… will need to be adjusted accordingly."[11] The updated goal dates should be referred to in place of the *Summary of Dates of Specified Activities under OMUFA* table on pages 34-37 of the OMUFA I Goals Document.[12]

Many OMUFA performance goals are slated to be accomplished in fiscal years after FY 2021. During the first 3 years following passage of the CARES Act, essentially all of FDA's effective OTC monograph-related review capacity was consumed by external mandates, safety activities, OTC monograph reform implementation, and infrastructure development activities. By Year 3, FDA's review resources grew to the point where limited OMUFA performance goals began for meetings. In Years 4 and 5, FDA is implementing timelines and limited performance goals for OMOR submissions and will continue progressive performance goals for meeting management, guidance development, and other activities. However, even by Year 5, FDA's effective monograph review capacity is not expected to be at the steady state required to handle the eventual anticipated full workload of OTC monograph drug activities because recently hired staff will not yet be fully trained, and FDA's review capacity will continue to grow beyond Year 5 as newly onboarded staff continue to complete training in this complex review area.

D. Information Presented in This Report

This report presents FDA performance in achieving two different types of OMUFA goals: (1) the review of OMORs and issuing related final orders pertaining to requested changes to the OTC monographs and (2) meeting management and other procedural goals related to the OMOR review process.

OMUFA performance information related to achieving these two types of goals includes reviews of submissions pending from the previous fiscal year and related actions as well as reviews of submissions received and actions taken during the current fiscal year. This report presents the final performance results for the FY 2023 cohort of submissions based on actions completed in FY 2023 and FY 2024. In addition, this report includes the preliminary performance results for the FY 2024 cohort of submissions that had actions completed or due for completion in FY 2024. Final performance for procedural and processing goals for the FY 2024 cohort will be presented in the FY 2025 OMUFA

[11] See https://www.fda.gov/media/106407/download.

[12] See footnote 11.

Performance Report. Final performance, for review goals, for the FY 2024 cohort will be presented in the FY 2025 and FY 2026 OMUFA Performance Report (due to some of these goals having a longer review time) and will include actions for submissions still pending within the OMUFA goal date as of September 30, 2024. The following information refers to FDA's OMUFA-related performance results presented in this report:

- Performance goal results are reported for FY 2023 and FY 2024.

- FDA files OMORs that are sufficiently complete and formatted to permit a substantive review.[13] Generally, under the OMUFA I Goals Document, the Agency intends to make a filing determination within 60 calendar days after receipt of the OMOR. The OMUFA clock begins upon FDA's receipt of the OMOR.

- FDA annually reports OMUFA performance data for each *fiscal year receipt cohort* (defined as submissions received from October 1 to September 30 of the following year). In each fiscal year, FDA receives submissions that will have associated goals due in the following fiscal year. For these submissions, FDA's performance data will be reported in subsequent fiscal years, either after the Agency takes an action or when the goal becomes overdue, whichever comes first.

- Submission types (e.g., Tier 1 OMORs) with longer applicable goal timeframes (e.g., 17.5 months to issuance of a final order) tend to have a smaller percentage of goals completed within the reporting period, and these submission types' preliminary performance data are a less reliable indicator of their final performance results.

Final aggregate meeting management performance results for FY 2023 submissions are shown as the percentage of submissions reviewed on time. Aggregate meeting management types with 50 percent or more submissions reviewed by the goal date are shown as having met the goal.

Preliminary performance results for FY 2024 submissions are shown as the percentage of on time goals. Submission types with a current performance result of 50 percent or more for Tier 1 OMORs, Tier 2 OMORs, and Dispute Resolution and 60 percent or

[13] Filing decisions also involve, as applicable, the requirements for OMORs proposing a new monograph active ingredient.

more for Tier 1 OMORs for Certain Safety Changes Only[14] and aggregate meeting management types fulfilling the goal date are shown as currently meeting the goal. The highest possible percent of goals that may be completed on time (i.e., the highest possible performance results) if all non-overdue pending actions are completed within the goal is also shown.

- FDA's performance for meeting management goals is reported in the aggregate and applies to all meeting types for the first 12 meetings only for FY 2023 and for all meetings for FY 2024. These goals include the following: Meeting Request Response (X, Y, Z), Meeting Scheduling (X, Y, Z), Written Response (X, Y, Z), Meeting Preliminary Response (Y only), and Meeting Minutes (X, Y, Z).

- OMOR submissions include submissions that have been filed or are in pending filing status. Data do not include submissions that are unacceptable for filing because of nonpayment of user fees, have been withdrawn before filing, or have been refused to file.

- Meeting requests exclude requests that are denied because of nonpayment of OMUFA user fees or meeting requests withdrawn prior to the meeting's granted/denied response goal date.

- Unless otherwise noted, all information/statuses are as of September 30, 2024.

- Definitions of key terms used throughout this report can be found in Appendix A accompanying this report.

[14] These are OMORs that seek to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—(i) a contraindication, warning, or precaution; (ii) a statement about risk associated with misuse or abuse; or (iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

II. OMUFA Commitments

The OMUFA I Goals Document outlines specific performance goals and program enhancements for the OTC monograph review process and related OTC monograph drug activities. These performance goals are critical for facilitating FDA's success in implementing OTC monograph reform. FDA and industry designed these enhancements to optimize the efficiency of the new OTC monograph review process. Additionally, FDA conducted activities that are not specified in, but further the goals outlined in, the OMUFA I Goals Document. The information reported below details the work FDA has performed.

The CARES Act amendments to the FD&C Act established (or "deemed") certain final administrative orders, also known as "deemed final orders" (DFOs). These DFOs provide the OTC monograph conditions that are in effect for each therapeutic category addressed by a respective DFO, as of the date of enactment of the CARES Act.[15] On September 20, 2021, FDA began to make available these DFOs in batches on a rolling basis. In FY 2023, on October 10, 2022, FDA posted one such batch, and on May 2, 2023, FDA completed the posting of all 33 remaining DFOs on a new web portal called OTC Monographs @ FDA.[16] The posting of these DFOs is an important first step for issuing FDA- or industry-initiated orders (e.g., in response to an OMOR).

- The Annual Forecast is a nonbinding list, issued each year, of monograph activities that FDA intends to address over the upcoming 3 years. This forecast was most recently publicly posted on September 30, 2024.[17] One item, a proposed safety order regarding serious skin reactions associated with acetaminophen, was removed from the forecast because FDA has already issued a proposed order addressing this issue. Planned actions mentioned in this most recently posted forecast of September 2024 include:
    - FDA-initiated proposed orders addressing the following topics:
        - Risks associated with codeine-containing cough medicine;
        - Pediatric acetaminophen dosing;

[15] The DFOs may be amended, revoked, or otherwise modified via the administrative order process under section 505G of the FD&C Act.

[16] Available at https://dps.fda.gov/omuf/.

[17] Available at https://dps.fda.gov/omuf/forecast.

        - Risks associated with propylhexedrine abuse and misuse;
        - Nonsteroidal anti-inflammatory drugs and oligohydramnios;
        - Oral healthcare in infants and children;
        - Risks associated with the use of ipecac syrup as OTC poison treatment;
        - Pediatric cough/cold dosing; and
        - Effectiveness of phenylephrine as an oral decongestant ingredient.
    - Request for data on anticaries test methods to help inform future monograph activities.

- The congressionally required Pediatrics Cough/Cold Letter, describing the FDA's progress in evaluating and revising, as appropriate, the cough and cold monograph with respect to children under age 6, was sent to Congress on January 31, 2024.[18]

[18] As required by section 3855(a) of the CARES Act.

III. OMUFA Review Goals

The OTC monograph reform process enacted under section 505G of the FD&C Act offers industry opportunities to submit OMORs proposing changes to the OTC monographs, including for OTC monograph drug innovations, safety changes to monograph drug labeling, and other monograph condition of use changes, and for finalizations of certain GRASE determinations pending prior to monograph reform.

In the OMUFA I Goals Document, FDA committed to timelines for reviewing OMOR submissions and for issuing a final order, beginning in FY 2024 for Tier 1 and Tier 2 OMORs.[19]

A. Preliminary FY 2024 Review Performance Results

Table 1 details the preliminary performance results for FY 2024 OMOR submissions in achieving the goals related to issuing a final order as outlined in the OMUFA I Goals Document. These results include the number of OMORs with final orders issued *on time* (i.e., acted on by the OMUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). Current performance and highest possible final performance results are presented.

- The *progress* (i.e., the number of review activities completed, pending, or overdue) and the total number of OMOR submissions received for each submission type are shown in the second column. *Current performance* includes the number of final orders issued *on time* (i.e., acted on by the OMUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). *Highest possible final performance* is the best potential final performance result, which accounts for actions pending within the OMUFA goal date.

[19] The OMUFA I Goals Document designates these OMOR submission types as Innovation OMORs and Specified Safety Change OMORs with timelines beginning in FY 2024 and GRASE Finalization OMORs and Resubmitted Original OMORs with timelines beginning in FY 2025.

Table 1. FY 2024 Preliminary Review Goal Performance Results.

Submission Type*	Progress	Goal: Issue Final Order 50 Percent Within†	FY 2024 Current Performance	Highest Possible Final Performance
Tier 1 OMORs‡	0 of 1 complete	17.5 months of receipt date	--	100%
Tier 2 OMORs	0 of 0 complete	15.5 months of receipt date		

* Industry-requested changes only.
† Final Order Goal Date may be extended due to comment review extension or Major Amendment. Please refer to Appendix A: Definitions of Key Terms for details.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.

Submission Type*	Progress	Goal: Issue Final Order 60 Percent Within†	FY 2024 Current Performance	Highest Possible Final Performance
Tier 1 OMORs for Certain Safety Changes Only	0 of 0 complete	11.5 months of receipt date	NA	NA

* Industry-requested changes only.
† Final Order Goal Date may be extended due to comment review extension or Major Amendment. Please refer to Appendix A: Definitions of Key Terms for details.

B. Preliminary FY 2024 Review Goal Performance Details

Tables 2 and 3 provide preliminary detailed performance information for FY 2024 OMOR submissions including the number of submissions *received* and final orders issued *on time* (i.e., acted on by the OMUFA goal date) and *overdue* (i.e., acted on past the goal date or pending past the goal date). The number of OMOR submissions not yet acted on but still pending within the OMUFA goal date (*pending within goal*) is also provided, along with the highest possible percent of final orders that may be completed on time (*highest possible percent on time*).

Table 2. FY 2024 Tier 1 and Tier 2 OMORs.

Submission Type*	Goal: Issue Final Order 50 Percent Within†	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Tier 1 OMORs‡	17.5 months of receipt date	1	0	0	1	--	100%
Tier 2 OMORs	15.5 months of receipt date	0	0	0	0		

* Industry-requested changes only.
† Final Order Goal Date may be extended due to comment review extension or Major Amendment. Please refer to Appendix A: Definitions of Key Terms for details.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.

Table 3. FY 2024 Tier 1 OMORs for Certain Safety Changes Only.

Submission Type*	Goal: Issue Final Order 60 Percent Within†	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Tier 1 OMORs for Certain Safety Changes Only	11.5 months of receipt date	0	0	0	0	NA	NA

* Industry-requested changes only.
† Final Order Goal Date may be extended due to comment review extension or Major Amendment. Please refer to Appendix A: Definitions of Key Terms for details.

IV. OMUFA Procedural and Processing Goals

The OTC monograph reform process enacted under section 505G of the FD&C Act offers industry opportunities to engage in pre-submission meetings with FDA before requesting changes to OTC monographs through submission of an OMOR. Sponsors and requestors (collectively referred to as "meeting requestors") can meet with FDA to discuss studies and other information necessary to support OMORs, to obtain advice on other matters relevant to OTC monograph drug regulation, or to obtain advice on OTC monograph drug development.[20] The OMUFA I Goals Document designates these meetings as Type X, Type Y, and Type Z meetings.

FDA committed to timelines for responding to meeting requests, scheduling meetings or sending written responses, sending preliminary responses before meetings (Type Y ONLY), and sending meeting minutes, beginning in FY 2023 for the first 12 meeting requests received, and for all meeting requests received in subsequent years. Additionally, beginning in FY 2024, FDA committed to timelines for responding to dispute resolution requests.

In this report, meeting requests are reported in the aggregate, excluding any meeting request submissions that were denied because of nonpayment of OMUFA user fees or meeting requests withdrawn prior to the meetings granted/denied response goal date.

A. Final FY 2023 Procedural and Processing Performance Results

Table 4 details the final performance results for FY 2023 submissions in achieving the goals related to meeting management outlined in the OMUFA I Goals Document. The final performance results for submission types that met or exceeded the goal are shown in bold text. FY 2023 performance results are presented only in the aggregate. FDA exceeded the performance level for aggregate meeting management goals in FY 2023.

[20] See section 505G(h) of the FD&C Act; see also the draft guidance "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs," published on February 1, 2022, available at https://www.fda.gov/media/155864/download.

Table 4. FY 2023 Final Aggregate Meeting Management Performance Results.

Submission/Request Type	Aggregate Goal	Total	FY 2023 Performance
Aggregate Meeting Management Goals (First 12 Meetings Only)*	50%	30 of 31 on time	97%

* This number 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.

Table 5 details the final progress results for FY 2023 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 5. FY 2023 Final Meeting Management Results.

Submission/Request Type	Total*	Action Goal
Type X Meeting Requests	0 of 0 on time	Respond within 14 days
Type Y Meeting Requests	6 of 6 on time	Respond within 14 days
Type Z Meeting Requests	6 of 6 on time	Respond within 21 days
Type X Meetings Scheduled	0 of 0 on time	Schedule within 30 days
Type Y Meetings Scheduled	3 of 3 on time	Schedule within 70 days
Type Z Meetings Scheduled	3 of 3 on time	Schedule within 75 days
Type X Written Response	0 of 0 on time	Respond within 30 days
Type Y Written Response	2 of 2 on time	Respond within 70 days
Type Z Written Response	2 of 2 on time	Respond within 75 days
Preliminary Response for Type Y Meetings	3 of 3 on time	Issue no later than 5 days prior to meeting date
Type X Meeting Minutes	0 of 0 on time	Issue within 30 days after meeting date
Type Y Meeting Minutes	3 of 3 on time	Issue within 30 days after meeting date
Type Z Meeting Minutes	2 of 3 on time	Issue within 30 days after meeting date

* This number 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.

B. Final FY 2023 Procedural and Processing Details

Table 6 details the final performance data for FY 2023 submissions in achieving the goals related to meeting management. These data include the number of meeting request submissions reviewed *on time* (i.e., acted on by the OMUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). The performance data presented here have been updated from the preliminary performance information reported in the FY 2023 OMUFA Performance Report.

Table 6. FY 2023 Aggregate Meeting Management.

Type	Goal Threshold	Meeting Requests Received*	Meeting Management Goals	On Time	Overdue	Percent on Time
Aggregate Meeting Management Goals (First 12 Meetings Only)*	50%	12	31	30	1	97%

* This number 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.

Table 7 details the final progress results for FY 2023 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 7. FY 2023 Meeting Management.

Type	Action Goal	Received*	On Time	Overdue
Type X Meeting Requests	Respond within 14 days	0	0	0
Type Y Meeting Requests	Respond within 14 days	6	6	0
Type Z Meeting Requests	Respond within 21 days	6	6	0
Type X Meetings Scheduled	Schedule within 30 days	0	0	0
Type Y Meetings Scheduled	Schedule within 70 days	3	3	0

Type	Action Goal	Received*	On Time	Overdue
Type Z Meetings Scheduled	Schedule within 75 days	3	3	0
Type X Written Response	Respond within 30 days	0	0	0
Type Y Written Response	Respond within 70 days	2	2	0
Type Z Written Response	Respond within 75 days	2	2	0
Preliminary Response for Type Y Meetings	Issue no later than 5 days prior to meeting date	3	3	0
Type X Meeting Minutes	Issue within 30 days after meeting date	0	0	0
Type Y Meeting Minutes	Issue within 30 days after meeting date	3	3	0
Type Z Meeting Minutes	Issue within 30 days after meeting date	3	2	1

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled. This number 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.

C. Preliminary FY 2024 Procedural and Processing Performance Results

Tables 8 and 9 detail the preliminary performance results for FY 2024 submissions in achieving the goals related to meeting management and dispute resolution as outlined in the OMUFA I Goals Document. These results include the number of submissions reviewed *on time* (i.e., acted on by the OMUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). *Current performance* and *highest possible final performance* results are presented only in the aggregate for meeting management.

- The *progress* (i.e., the number of review activities completed or pending overdue) and the total number of submissions received for each submission type are shown in the second column. *Current performance* includes the number of submissions reviewed *on time* (i.e., acted on by the OMUFA goal date) or *overdue* (i.e., acted on past the goal date or pending past the goal date). *Highest possible final performance* is the best potential final performance result, which

accounts for actions pending within the OMUFA goal date.

Table 8. FY 2024 Preliminary Aggregate Meeting Management Performance Results.

Submission/Request Type	Progress	Aggregate Goal	FY 2024 Current Performance	Highest Possible Final Performance
Aggregate Meeting Management Goals*	30 of 32 complete	60%	97%	97%

* This number 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.

Table 9. FY 2024 Preliminary Dispute Resolution Performance Results.

Submission/Request Type	Progress	Goal: 50 Percent	FY 2024 Current Performance	Highest Possible Final Performance
Dispute Resolutions	0 of 0 complete	Respond within 30 days	NA	NA

Table 10 details the preliminary progress results for FY 2024 meeting request submissions in achieving the goals related to meeting management that are reported in the aggregate in Table 8 above.

Table 10. FY 2024 Preliminary Meeting Management Progress Results.

Submission/Request Type	Progress*	Action Goal
Type X Meeting Requests	0 of 0 complete	Respond within 14 days
Type Y Meeting Requests	6 of 6 complete	Respond within 14 days
Type Z Meeting Requests	7 of 7 complete	Respond within 21 days
Type X Meetings Scheduled	0 of 0 complete	Schedule within 30 days
Type Y Meetings Scheduled	3 of 3 complete	Schedule within 70 days
Type Z Meetings Scheduled	3 of 3 complete	Schedule within 75 days

Submission/Request Type	Progress*	Action Goal
Type X Written Response	0 of 0 complete	Respond within 30 days
Type Y Written Response	1 of 2 complete	Respond within 70 days
Type Z Written Response	3 of 3 complete	Respond within 75 days
Preliminary Response for Type Y Meetings	3 of 3 complete	Issue no later than 5 days prior to meeting date
Type X Meeting Minutes	0 of 0 complete	Issue within 30 days after meeting date
Type Y Meeting Minutes	3 of 3 complete	Issue within 30 days after meeting date
Type Z Meeting Minutes	1 of 2 complete	Issue within 30 days after meeting date

* This number excludes meeting submissions that were unacceptable for filing because of nonpayment of user fees or meetings that were withdrawn prior to the meetings granted/denied response goal date.

D. Preliminary FY 2024 Procedural and Processing Performance Details

The following detailed performance information for FY 2024 cohort submissions includes the number of meeting submissions *received*, reviewed *on time* (i.e., acted on by the OMUFA goal date), and *overdue* (i.e., acted on past the goal date or pending past the goal date). The number of submissions not yet acted on but still pending within the OMUFA goal date (*pending within goal*) is also provided, along with the highest possible percent of reviews that may be completed on time (*highest possible percent on time*).

Aggregate meeting management performance information is presented in Table 11.

Table 11. FY 2024 Aggregate Meeting Management.

Type	Goal Threshold	Meeting Requests Received*	Meeting Management Goals	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Aggregate Meeting Management Goals*	60%	13	32	29	1	2	97%	97%

* This number 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.

Table 12 details the preliminary detailed results for FY 2024 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 12. FY 2024 Meeting Management.

Type	Action Goal	Received*	On Time	Overdue	Pending Within Goal
Type X Meeting Requests	Respond within 14 days	0	0	0	0
Type Y Meeting Requests	Respond within 14 days	6	6	0	0
Type Z Meeting Requests	Respond within 21 days	7	7	0	0
Type X Meetings Scheduled	Schedule within 30 days	0	0	0	0
Type Y Meetings Scheduled	Schedule within 70 days	3	2	1	0
Type Z Meetings Scheduled	Schedule within 75 days	3	3	0	0
Type X Written Response	Respond within 30 days	0	0	0	0
Type Y Written Response	Respond within 70 days	2	1	0	1

Type	Action Goal	Received*	On Time	Overdue	Pending Within Goal
Type Z Written Response	Respond within 75 days	3	3	0	0
Preliminary Response for Type Y Meetings	Issue no later than 5 days prior to meeting date	3	3	0	0
Type X Meeting Minutes	Issue within 30 days after meeting date	0	0	0	0
Type Y Meeting Minutes	Issue within 30 days after meeting date	3	3	0	0
Type Z Meeting Minutes	Issue within 30 days after meeting date	2	1	0	1

* Not all meeting requests are granted; therefore, the number of meetings scheduled may differ from the number of meeting requests received. Not all scheduled meetings are held; therefore, the number of meeting minutes may differ from the number of meetings scheduled. This number 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.

Table 13 details the preliminary detailed results for FY 2024 submissions in achieving the goals related to dispute resolution.

Table 13. FY 2024 Dispute Resolution.

Type	Goal: 50 Percent	Requests Received*	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Dispute Resolution	Respond within 30 days	0	0	0	0	NA	NA

V. Additional OMUFA Program Reporting

A. Hiring and Training of New Staff at FDA

The success of the OTC monograph reform program enacted under section 505G of the FD&C Act required significant start-up resources, including hiring and training new staff. Recognizing this, FDA agreed, as part of OMUFA performance goals, to hire and train staff to support the regulatory activities and the demands of the reformed OTC monograph system.

In FY 2024, 19 positions were allocated to the Center for Drug Evaluation and Research (CDER). As of September 29, 2024, CDER has onboarded eight employees (with an additional two candidates who have received Final Offers and are set to enter on duty in FY 2025 and two positions with candidates identified who are awaiting Final Offers). CDER plans to fill the remaining seven vacant positions in FY 2025.

The eight CDER hires constitute approximately 42 percent of the planned OMUFA hiring metrics for FY 2024. These new hires received orientation and training that focused on OTC monograph drug activities and the OMUFA user fee program.

FDA will target the onboarding of new staff in the future fiscal years, as shown in Table 14.

Table 14. OMUFA Hiring Targets vs Actual Hires.

Fiscal Year	Hiring/Onboarding Target	Hiring Actuals within Allocation for FY	Hiring Following the Previous FY
2021	30	13*	17
2022	24	19†	5
2023	23	12	11
2024	19	8‡	--
2025	9	--	--
Total	105	85§	

* The remaining 17 FY 2021 positions were hired in FY 2022.
† The remaining five FY 2022 positions and the 12 FY 2023 positions were hired in FY 2023.
‡ As of September 29, 2024, the remaining 11 FY 2023 positions and eight of FY 2024 were hired.
§ As of September 29, 2024, there were a total of 85 hired full-time equivalents.

B. Information Technology Platforms and Enhanced Technology

The OTC monograph reform program requires important information technology (IT) improvements to enhance the efficiency of OTC monograph drug activities. FDA continues to devote resources to IT improvements that integrate OTC monograph information across relevant Agency systems. In the OMUFA I Goals Document, FDA committed to conduct activities necessary to fulfill the OMUFA IT objectives and has met these objectives for FY 2024. Table 15 describes FDA's IT commitments and the progress in each area.

Table 15. OMUFA's IT Commitments and Their Progress.

Activity	Due Date/Deadline	Status
Award the contract for the public-facing IT dashboard	10/1/2021	Complete (A contract was awarded for the public-facing web portal project on 9/29/21.)
Issue a Request for Proposals for an IT platform for receiving electronic submissions, archiving monograph review work, and generating reports	2/1/2022	Complete (A Request for Proposals was issued in August 2021.)
Award the initial contracts for the IT platform	4/1/2022	Complete (Contracts for the public-facing IT web portal and electronic submission receipt, archiving, and reporting were awarded on 9/29/21 and 9/27/21, respectively.)
Implement the public-facing IT dashboard	10/1/2022	Complete (A new public-facing IT web portal* was developed and is available to the public that includes new capabilities to help facilitate transparency of the OTC monograph process and enhance proposed order comment and search functionalities.)

Establish business requirements for the IT platform	4/1/2023	Complete (The business requirements were finalized for initial platform deployment in September 2022.)
IT platform fully functional	4/1/2025	On schedule to have full functionality prior to target date. Additional improvements will continue throughout the system lifecycle.

* Available at https://dps.fda.gov/omuf.

VI. Additional Activities to Promote Transparency and Enhance Communication

A. Activities in Fiscal Year 2024

In FY 2024, FDA made significant progress on communications regarding OTC monograph reform implementation activities. Key activities and accomplishments included the following:

- Engaged in sustained efforts to recruit and hire new talent for the OTC monograph reform program.
- Facilitated significant industry and public outreach on OTC monograph reform, including:
  - Hosted one FDA Small Business and Industry Assistance Webinar Presentations open to industry and the general public:
    - June 18, 2024: OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2024 User Fees and Registration.[21]
  - Delivered presentations on FDA's OTC monograph reform at external conferences:
    - Oct 24 - 25, 2023: Personal Care Products Council Science Symposium
    - Sep 17 - 18, 2024: Consumer Healthcare Products Association Regulatory, Scientific & Quality Conference
- Updated and posted frequently asked questions on two different landing pages of FDA's website: OTC Monographs @ FDA and Over-The-Counter Monograph Drug User Fee Program (OMUFA).[22]
- Submitted a letter to Congress, on January 31, 2024, describing FDA's progress on evaluating and revising, as appropriate, the cough and cold monograph with

[21] Available at https://www.fda.gov/drugs/news-events-human-drugs/otc-monograph-drug-user-fee-program-omufa-understanding-fy-2024-user-fees-and-registration-06182024.

[22] Available at https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa and https://dps.fda.gov/omuf.

respect to children under age 6.[23]

- Continued to work on the expansion of the CDER NextGen Portal for other OTC monograph submissions, including OMORs.

B. OMUFA-supported Guidance Development

FDA committed to increase its transparency in operations and to enhance its communication on critical information. In FY 2024, FDA published the following guidance for industry:

- FDA issued the final guidance for industry "Providing Over-the-Counter Monograph Submissions in Electronic Format" on July 24, 2024.[24]

[23] As required by section 3855(a) of the CARES Act.

[24] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-over-counter-monograph-submissions-electronic-format.

Appendix A: Definition of Key Terms

- Administrative Order - An order under section 505G of the FD&C Act that adds, removes, or changes GRASE conditions for an OTC drug monograph.

- Deemed Final Order (DFO) - Certain final administrative orders that were deemed established under the CARES Act amendments to the FD&C Act. These DFOs provide the OTC monograph conditions that are in effect for each therapeutic category addressed by the respective DFO, as of the date of enactment of the CARES Act.

- Federal Food, Drug, and Cosmetic Act (FD&C Act) - The federal statute giving FDA the authority to regulate foods, drugs, medical devices, cosmetics, and tobacco products.

- Tier 1 OMOR is any OMOR not determined to be a Tier 2 OMOR (as described in section 744L(8) of the FD&C Act). Note: For reporting purposes, Tier 1 OMORs for Certain Safety Changes Only are reported separately from all other Tier 1 OMORs.

- Tier 1 OMOR for Certain Safety Changes Only, as described in section 744M(a)(2)(C) of the FD&C Act, is any OMOR that seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

- Tier 2 OMOR, as described in section 744L(9) of the FD&C Act, is any OMOR that requests:

    1) Reordering of existing information in the drug facts label of an OTC monograph drug;

    2) The addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

    3) Modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made

pursuant to section 505G(c)(3)(A);

4) The standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

5) A change to ingredient nomenclature to align with nomenclature of a standards-setting organization;

6) Addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations); or

7) Other any other OMOR which, based on program implementation experience or other factors found appropriate by FDA, FDA characterizes as a Tier 2 OMOR (including recharacterizing an OMOR from Tier 1 to Tier 2), pursuant to a proposed order issued pursuant to section 505G of the FD&C Act.

- OTC Monograph - Simply stated, an OTC monograph is a "rule book" of conditions for each therapeutic category that describes the active ingredients, uses (indications), doses, route of administration, labeling, and testing for an OTC monograph drug to be considered GRASE.

- OTC Monograph Order Request (or OMOR) - Defined in section 744L(7) of the FD&C Act and refers to a request for FDA to issue an administrative order under section 505G of the FD&C Act.

- Labeling - According to 21 CFR 1.3(a), "Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce."

- Nonprescription Drug - A nonprescription drug product marketed for use by the consumer without the intervention of a healthcare professional. Under section 505G(q) of the FD&C Act, a *nonprescription drug* is a drug not subject to the requirements of section 503(b)(1) of the FD&C Act (relating to prescription drugs). Nonprescription drugs are legally marketed under the OTC monograph process or through the NDA or ANDA process.

- OTC Monograph Drug - Under section 744L(5) of the FD&C Act, means a nonprescription drug without an approved application that is governed by the provisions of section 505G of the FD&C Act.

- OTC Monograph Drug Activities - Under section 744L(6) of the FD&C Act, means activities of the FDA associated with OTC monograph drugs and the inspection of facilities associated with such products, including various activities specified under this provision.

- OTC Monograph Drug Facility - Under section 744L(10) of the FD&C Act, is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug.

- Final Order Goal Date Extensions:

    - Comment Review Extension

        - As described in the OMUFA I Goals Document, comments received during the public comment period on proposed orders that are numerous or substantive will have the effect of extending the final order goal date:

        - For final orders derived from Tier 1 OMORs: 5-month extension

            - For final orders derived from Tier 1 OMORs for Certain Safety Changes Only: 3-month extension

        - For final orders derived from Tier 2 OMORs: 3-month extension

    - Major Amendments

        - Major Amendments can extend the final order goal date. The final order goal date can be extended by 3 months if:

            - Original Requestor submitted a Major Amendment prior to issuance of the proposed order

        - Original Requestor submitted a Major Amendment after the end of the comment period and prior to issuance of a final order

        - A Major Amendment, as described in the OMUFA I Goals Document, may include, for example, a major clinical safety or efficacy study that was not previously submitted to the current OMOR; or a major reanalysis of a study or studies previously submitted to the current OMOR.

- Type X meetings, as described in the OMUFA I Goals Document, are either (1)

meetings that are necessary for an otherwise stalled monograph development program to proceed or (2) meetings that are necessary to address an important safety issue related to an OTC monograph drug that is marketed or being developed.

- Type Y meetings, as described in the OMUFA I Goals Document, are intended for milestone discussions during the course of a meeting requester's OTC monograph order development program. Type Y meetings are as follows:

    - Meetings to discuss the overall data recommended to support either (1) a positive GRASE determination for an OTC monograph drug containing a particular active ingredient or subject to some other condition of use after FDA has stated its intent to make the final GRASE determination or (2) an OMOR submission when a meeting requester has an interest in initiating an OMOR, or

    - Pre-OMOR submission meetings (for when a sponsor is nearing completion of its development program for an OMOR) to provide an opportunity for the sponsor to present a summary of the data supporting the OMOR, discuss the proposed format for the OMOR, and obtain FDA feedback on both the adequacy of the proposal for the OMOR submission and the appropriate categorization of an OMOR.

- Type Z meetings, as described in the OMUFA I Goals Document, are any meetings that are not a Type X or Type Y meeting.

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