Performance Report to Congress

Over-the-Counter Monograph Drug User Fee Program

FY 2025

U.S. FOOD & DRUG ADMINISTRATION

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

This report summarizes FDA's performance results in meeting OMUFA goals and commitments for Fiscal Year (FY) 2024 and FY 2025. Specifically, this report updates performance data for submissions received in FY 2024 (initially reported in the FY 2024 OMUFA performance report) and presents preliminary data on FDA's progress in meeting FY 2025 goals.

FDA achieved the majority of its FY 2024 and FY 2025 OMUFA goals that support its OTC monograph drug activities. Highlighted below are FDA's accomplishments in meeting these goals and commitments:

- Administrative Orders
  - FDA posted proposed administrative order Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs[1] on June 5, 2025
  - FDA posted proposed administrative order Over-the-Counter Monograph Condition B001: Single-Unit or Unit-Dose Containers for Over-the-Counter Monograph Drugs in Orally Disintegrating Tablet and Film Dosage Forms[2] on June 5, 2025
  - FDA posted proposed administrative order Amending Over-the-Counter Monograph M012: Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use[3] on November 8, 2024

- Annual Forecast for Planned Monograph Activities[4]
  - FDA posted the fifth such annual forecast on September 2, 2025.

- IT Activities
  - In January 2025, FDA enhanced the CDER Nexus workflow management platform with improved signature and clearance capabilities to streamline administrative order processing and workflow efficiency.
  - In May 2025, FDA implemented platform integration enhancements to the CDER Nexus workflow management platform, enabling comprehensive submission processing and cross-platform data exchange capabilities.
  - In August 2025, FDA completed migration of the CDEROne reporting and

[1] See https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=OrderDetail&orderid=OTC000038

[2] See https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=OrderDetail&orderid=OTC000037

[3] See https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=OrderDetail&orderid=OTC000036

[4] Available at https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=forecast

analytics system to modernize legacy infrastructure and integrate enhanced data management capabilities with improved system performance.

  - In September 2025, FDA deployed Formal Dispute Resolution workflows and FDA-initiated order processing capabilities, including integrated notification systems for industry stakeholders.

  - By September 2025, FDA had successfully delivered a fully functional IT system within the OMUFA I timeline, providing comprehensive digital transformation and modernized capabilities for workflow management, electronic submission processing, regulatory review operations, and data analytics.

- Guidances for Industry

  - FDA issued the draft guidance for industry *Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs: Draft Guidance for Industry*[5] on June 4, 2025.

- Cataloguing of Pre-OMUFA Paper Documents

  - A searchable electronic catalogue of all identified pre-OMUFA paper documents was posted on February 13, 2025.[6]

- Meeting Management Goals

  - FDA exceeded the 60 percent aggregate performance level for meeting management goals for formal development meetings with industry in FY 2024.

  - FDA is currently exceeding the 80 percent aggregate performance level for meeting management goals in FY 2025. With some submissions still within the OMUFA goal date, FDA has the potential to meet or exceed the 80 percent aggregate meeting management goal for FY 2025.

- Review Goals[7]

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[5] See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-complying-over-counter-monograph-procedure-minor-changes-c001-minor-changes-solid

[6] See https://www.accessdata.fda.gov/drugsatfda_docs/omuf/General/catalog-of-pre-omufa-documents.xlsx

[7] FDA did not receive any applicable OMOR submissions in FY 2025.

- 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.[8]

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.[9]

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:

[8] See https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs.

[9] 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

In part, 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).[10]

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.[11]

OTC monograph reform has accomplished the following:

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

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

- 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.[12]

C. OTC Monograph Drug User Fee Program

OMUFA I authorized 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.[13] 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).[14]

In 2021, FDA updated the OMUFA goal dates in the OMUFA I Goals Document to

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

[13] OMUFA was reauthorized for fiscal years 2026 through 2030 under the Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (PL 119-37). For purposes of this fiscal year 2025 OMUFA Performance Report, we refer to the OMUFA statutory authority under sections 744L, 744M, and 744N of the FD&C Act as in effect on September 30, 2025.

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

reflect that FY 2021 was the first OMUFA program year.[15] This update aligns with 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."[16] 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.[17]

OMUFA performance goals were designed to evolve over time, as the program matures. 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 has been implementing timelines and limited performance goals for OMOR submissions and will continue progressive performance goals for meeting management, guidance development, and other activities.

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 issuance of 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 2024 cohort of submissions based on actions completed in FY 2024 and FY 2025. Final performance for some review goals for the FY 2024 cohort may need to be presented in the 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, 2025. In addition, this report includes the preliminary performance results for the FY 2025 cohort of submissions that had actions completed or due for completion in FY 2025. Final performance for procedural and processing goals for the FY 2025 cohort will be presented in the FY 2026 OMUFA Performance Report. Final

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

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

[17] Ibid.

performance for review goals for the FY 2025 cohort will be presented in the FY 2026 OMUFA Performance Report and, if needed, the FY 2027 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, 2025. The following information refers to FDA's OMUFA-related performance results presented in this report:

- Performance goal results are reported for FY 2024 and FY 2025.
- FDA files OMORs that are sufficiently complete and formatted to permit a substantive review.[18] 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 performance results for FY 2024 submissions are shown as the percentage of submissions reviewed on time. Submission types with 60 percent or more submissions reviewed by the goal date are shown as having met the goal[19].
- Preliminary performance results for FY 2025 submissions are shown as the percentage of on time goals. Submission types with a current performance result of 75 percent or more for Tier 1 OMORs, Tier 2 OMORs, Dispute Resolutions; 80

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

[19] There is one review performance goal and one processing and procedural performance goal with a performance threshold at 50 percent. Therefore, a performance result at these rates or higher will be shown as meeting the goal.

percent or more for Tier 1 OMORs for Certain Safety Changes Only[20] and aggregate meeting management types; and 50 percent or more for Tier 1 OMORs with GRASE Finalization 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 FY 2024 and FY 2025. 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, 2025.

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

[20] 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 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 2, 2025.[21] One item, a proposed order regarding the effectiveness of phenylephrine as an oral decongestant ingredient was removed from the forecast because FDA has already issued a proposed order[22] addressing this issue.[23] Planned actions mentioned in this most recently posted forecast of September 2025 include:
  - FDA-initiated proposed orders addressing the following topics:
    - Risks associated with codeine-containing cough medicine;
    - Pediatric acetaminophen dosing;
    - 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;

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

[22] See: https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after

[23] See: https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm?event=OrderDetail&orderid=OTC000036

- Request for data on anticaries test methods to help inform future monograph activities.

The statutorily required annua 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 15, 2025.[24]

[24] 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.[25] Table 1 reflects these performance goal timelines.

Table 1. OMUFA I Review Performance Goals for FYs 2024 to 2025

Submission Type*	Goal: Issue Final Order Within†	FY 2024	FY 2025
Tier 1 OMORs‡	17.5 months of receipt date	50%	75%
Tier 2 OMORs	15.5 months of receipt date		
Tier 1 OMORs for Certain Safety Changes Only	11.5 months of receipt date	60%	80%
Tier 1 OMORs with GRASE Finalization	17.5 months of receipt date	--	50%

* 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.

A. Updated FY 2024 Review Performance Results

Table 2 details the updated 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

[25] 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 with timelines beginning in FY 2025. While the OMUFA I Goals Document includes reference to "Resubmitted Original OMORs", the subsequently enacted authority for OMORs under section 505G of the FD&C Act includes no provision for such a submission type, and therefore, they are not included in this report.

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 fourth 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.

Table 2. FY 2024 Updated Review Goal Performance Results.

Submission Type*	Performance Goal	Goal: Issue Final Order Within†	Progress	FY 2024 Current Performance§	Highest Possible Final Performance§
Tier 1 OMORs‡	50%	17.5 months of receipt date	0 of 1 complete	--¶	100%
Tier 2 OMORs	50%	15.5 months of receipt date	0 of 0 complete		
Tier 1 OMORs for Certain Safety Changes Only	60%	11.5 months of receipt date	0 of 0 complete	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.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.
§ For submission types marked "NA", performance goals do not apply because no submissions were received.
¶ Current Performance cannot be calculated as all submissions are currently pending within goal.

B. Updated FY 2024 Review Goal Performance Details

Table 3 provides updated 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 3. FY 2024 Tier 1 and Tier 2 OMORs.

Submission Type*	Performance Goal	Goal: Issue Final Order Within†	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time§	Highest Possible Percent on Time§
Tier 1 OMORs‡	50%	17.5 months of receipt date	1	0	0	1¶	--#	100%
Tier 2 OMORs	50%	15.5 months of receipt date	0	0	0	0		
Tier 1 OMORs for Certain Safety Changes Only	60%	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.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.
§ For submission types marked "NA", performance goals do not apply because no submissions were received.
¶ Final performance for this pending submission will be reported in a later performance report when the final submission has received an action.
# Current Percent on Time cannot be calculated as all submissions are currently pending within goal.

C. Preliminary FY 2025 Review Goal Performance Results

Table 4 contains the preliminary performance results for the FY 2025 OMOR submissions and their progress toward achieving the goals related to issuing a final order as outlined in the OMUFA I Goals Document. Current performance and highest possible final performance results are presented.

Table 4. FY 2025 Preliminary Review Goal Performance Results.

Submission Type*	Performance Goal	Goal: Issue Final Order Within†	Progress	FY 2025 Current Performance§	Highest Possible Final Performance§
Tier 1 OMORs‡	75%	17.5 months of receipt date	0 of 0 complete	NA	NA
Tier 2 OMORs	75%	15.5 months of receipt date	0 of 0 complete		
Tier 1 OMORs for Certain Safety Changes Only	80%	11.5 months of receipt date	0 of 0 complete	NA	NA
Tier 1 OMOR with GRASE Finalization	50%	17.5 months of receipt date	0 of 0 complete	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.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.
§ For submission types marked "NA", performance goals do not apply because no submissions were received.

D. Preliminary FY 2025 Review Goal Performance Details

Table 5 provides preliminary detailed performance information for FY 2025 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 5. FY 2025 Preliminary Review Goal Performance Results.

Submission Type*	Performance Goal	Goal: Issue Final Within†	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time§	Highest Possible Percent on Time§
Tier 1 OMORs‡	75%	17.5 months of receipt date	0	0	0	0	NA	NA
Tier 2 OMORs	75%	15.5 months of receipt date	0	0	0	0		
Tier 1 OMORs for Certain Safety Changes Only	80%	11.5 months of receipt date	0	0	0	0	NA	NA
Tier 1 with GRASE Finalization OMOR	50%	17.5 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.
‡ Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.
§For submission types marked "NA", performance goals do not apply because no submissions were received.

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 presubmission meetings with FDA before requesting changes to OTC monographs through submission of an OMOR. Sponsors and requestors (collectively referred to as "meeting requesters") 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.[26] 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. Table 6 reflects these procedural and processing performance goal targets.

Table 6. OMUFA I Meeting Management and Procedural Response Performance Goals

Submission/Request Type	Goal:	FY 2023	FY 2024	FY 2025
Meeting Management				
Aggregate Meeting Management Goals	Varies*	50%†	60%	80%
Procedural Responses				
Dispute Resolutions	Respond within 30 days	--	50%	75%

*See table 8 below for details on goal timelines for each individual meeting management metric that comprises the aggregate meeting management performance goal.
†Applies to the first 12 meeting requests received only.

[26] 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.

A. Final FY 2024 Procedural and Processing Performance Results

Table 7 details the final performance results for FY 2024 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 2024 performance results are presented only in the aggregate. FDA exceeded the performance level for aggregate meeting management goals in FY 2024.

Table 7. FY 2024 Final Aggregate Meeting Management Performance Results.

Submission/Request Type	Aggregate Goal	Total	FY 2024 Performance
Aggregate Meeting Management Goals*	60%	31 of 32 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 8 details the final progress results for FY 2024 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 8. FY 2024 Final Meeting Management Results.

Submission/Request Type	Total*	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	7 of 7 on time	Respond within 21 days
Type X Meetings Scheduled	0 of 0 on time	Schedule within 30 days
Type Y Meetings Scheduled	2 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	3 of 3 on time	Respond within 75 days

Submission/Request Type	Total*	Goal
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 2 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.

Table 9 details the final detailed results for FY 2024 submissions in achieving the goals related to dispute resolution.

Table 9. FY 2024 Final Dispute Resolutions.

Submission/Request Type	Performance Goal	Goal	Total	FY 2024 Performance*
Dispute Resolutions	50%	Respond within 30 days	0 of 0 complete	NA

*For submission types marked "NA", performance goals do not apply because no submissions were received.

B. Final FY 2024 Procedural and Processing Details

Table 10 details the final performance data for FY 2024 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 2024 OMUFA Performance Report.

Table 10. FY 2024 Aggregate Meeting Management.

Submission/ Request Type	Performance Goal	Meeting Requests Received*	Meeting Management Goals	On Time	Overdue	Percent on Time
Aggregate Meeting Management Goals*	60%	13	32	31	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 11 details the final progress results for FY 2024 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 11. FY 2024 Meeting Management.

Submission/Request Type	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	7	7	0
Type X Meetings Scheduled	Schedule within 30 days	0	0	0
Type Y Meetings Scheduled	Schedule within 70 days	3	2	1
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	3	3	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	2	2	0

* 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 12 details the final progress results for FY 2024 submissions in achieving the goals related to dispute resolutions.

Table 12. FY 2024 Dispute Resolutions.

Submission/Request Type	Performance Goal	Goal	Received	On Time	Overdue	Percent on Time*
Dispute Resolutions	50%	Respond within 30 days	0	0	0	NA

* For submission types marked "NA", performance goals do not apply because no submissions were received.

C. Preliminary FY 2025 Procedural and Processing Performance Results

Tables 13 and 14 detail the preliminary performance results for FY 2025 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 13. FY 2025 Preliminary Aggregate Meeting Management Performance Results.

Submission/Request Type	Aggregate Goal	Progress	FY 2025 Current Performance	Highest Possible Final Performance
Aggregate Meeting Management Goals*	80%	8 of 10 complete	100%	100%

* 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 14. FY 2025 Preliminary Meeting Management Progress Results.

Submission/Request Type	Progress*	Goal
Type X Meeting Requests	0 of 0 complete	Respond within 14 days
Type Y Meeting Requests	1 of 1 complete	Respond within 14 days
Type Z Meeting Requests	3 of 3 complete	Respond within 21 days
Type X Meetings Scheduled	0 of 0 complete	Schedule within 30 days
Type Y Meetings Scheduled	1 of 1 complete	Schedule within 70 days
Type Z Meetings Scheduled	1 of 1 complete	Schedule within 75 days
Type X Written Response	0 of 0 complete	Respond within 30 days
Type Y Written Response	0 of 0 complete	Respond within 70 days
Type Z Written Response	1 of 1 complete	Respond within 75 days
Preliminary Response for Type Y Meetings	0 of 1 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	0 of 1 complete	Issue within 30 days after meeting date
Type Z Meeting Minutes	1 of 1 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.

Table 15 details the preliminary performance results for FY 2025 submissions in achieving the goals related to dispute resolutions.

Table 15. FY 2025 Preliminary Dispute Resolutions Performance Results.

Submission/Request Type	Performance Goal	Goal	Progress	FY 2025 Current Performance*	Highest Possible Final Performance*
Dispute Resolutions	75%	Respond within 30 days	0 of 0 complete	NA	NA

*For submission types marked "NA", performance goals do not apply because no submissions were received.

D. Preliminary FY 2025 Procedural and Processing Performance Details

The following detailed performance information for FY 2025 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*).

The FY 2025 OMUFA meeting management goals are measured, in the aggregate, against an 80 percent metric. Aggregate meeting management performance information is presented in Table 16.

Table 16. FY 2025 Aggregate Meeting Management.

Submission/ Request Type	Performance Goal	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*	80%	4	10	8	0	2	100%	100%

* 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 17 details the preliminary detailed results for FY 2025 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 17. FY 2025 Meeting Management.

Submission/Request Type	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	1	1	0	0
Type Z Meeting Requests	Respond within 21 days	3	3	0	0
Type X Meetings Scheduled	Schedule within 30 days	0	0	0	0
Type Y Meetings Scheduled	Schedule within 70 days	1	1	0	0
Type Z Meetings Scheduled	Schedule within 75 days	1	1	0	0
Type X Written Response	Respond within 30 days	0	0	0	0
Type Y Written Response	Respond within 70 days	0	0	0	0
Type Z Written Response	Respond within 75 days	1	1	0	0
Preliminary Response for Type Y Meetings	Issue no later than 5 days prior to meeting date	1	0	0	1
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	1	0	0	1
Type Z Meeting Minutes	Issue within 30 days after meeting date	1	1	0	0

* 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 18 details the preliminary results for FY 2025 submissions achieving the goals related to dispute resolutions.

Table 18. FY 2025 Dispute Resolutions.

Submission/Request Type	Performance Goal	Goal	Received	On Time	Overdue	Pending Within Goal	Current Percent on Time*	Highest Possible Percent on Time*
Dispute Resolutions	75%	Respond within 30 days	0	0	0	0	NA	NA

*For submission types marked “NA”, performance goals do not apply because no submissions were received.

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 2025, 9 positions were allocated to the Center for Drug Evaluation and Research (CDER). As of September 29, 2025, CDER has onboarded one employee.

The new hire received orientation and training that focused on OTC monograph drug activities and the OMUFA user fee program.

FDA onboard of new staff as shown in Table 19.

Table 19. 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‡	6
2025	9	1§	--
Total	105	80¶	

* 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, 2025, one FY25 position was hired. In 2025, the FDA underwent significant organizational restructuring and HR reductions due to a hiring freeze and HHS Reduction in Force (RIF).
¶ As of September 29, 2025, there were a total of 80 hired full time equivalents

B. Information Technology Platforms and Enhanced Technology

The OTC monograph reform program necessitates important information technology (IT) improvements to enhance the efficiency of FDA's 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 all objectives on or ahead of schedule. Table 20 describes FDA's successfully achieved IT commitments.

Table 20. 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	Complete (Full functionality was achieved prior to the target date. Additional enhancements 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 2025

In FY 2025, FDA made significant progress on communications regarding OTC monograph reform implementation activities. Key activities and accomplishments included the following:

- Facilitated significant industry and public outreach on OTC monograph reform, including:
  - Hosted one FDA Small Business and Industry Assistance Webinar Presentation open to industry and the general public titled: OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2025 User Fees and Registration.[27]
  - Delivered presentations on FDA's OTC monograph reform at external conferences:
    - September 9-10, 2025: Presented at Consumer Healthcare Products Association Regulatory, Scientific, and 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).[28]
- Submitted a letter to Congress, on January 15, 2025, describing FDA's progress on evaluating and revising, as appropriate, the cough and cold monograph with respect to children under age 6.[29]
- Continued to work on the expansion of the CDER NextGen Portal for other OTC monograph submissions, including OMORs.

[27] https://www.fda.gov/drugs/news-events-human-drugs/otc-monograph-drug-user-fee-program-omufa-understanding-fy-2025-user-fees-and-registration-05202025

[28] 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.

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

B. OMUFA-supported Guidance Development

FDA committed to increase its transparency in operations and to enhance its communication on critical information. In FY 2025, FDA published the following draft guidance for industry:

- FDA issued the draft guidance for industry *Recommendations for Complying With Over-the-Counter Monograph Procedure for Minor Changes C001: Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs: Draft Guidance for Industry* on June 5, 2025[30].

[30] See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-complying-over-counter-monograph-procedure-minor-changes-c001-minor-changes-solid

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 section 505G of the FD&C Act upon its enactment. 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 section 505G.

- 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[31], is any OMOR that requests:

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

[31] The statutory definition of Tier 2 OMOR was expanded as part of the OMUFA reauthorization for fiscal years 2026 through 2030, as enacted under the Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (PL 119-37). For purposes of this FY 2025 OMUFA Performance report, we are referring to section 744L(9) of the FD&C Act as in effect on September 30, 2025.

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 Extensions
        - 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. Note: Does not include any Tier 1 OMORs for Certain Safety Changes Only as those are reported separately.
            - 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.

This report was prepared by Performance Management Staff in collaboration with FDA's Center for Drug Evaluation and Research. For information on obtaining additional copies, please contact:

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