Performance Report to Congress

Over-the-Counter Monograph Drug User Fee Program

FY 2023

Executive Summary

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) was signed into law to aid response efforts for COVID-19. 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) reform and modernize the way over-the-counter (OTC) monograph drug products are regulated in the United States and (2) authorize 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 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

Beginning in March 2020, FDA experienced the unexpected onset of the COVID-19 public health emergency, the impact of which continued throughout FY 2023. During this emergency, the Agency appropriately shifted resources to prioritize its work focused on addressing the pandemic. Despite this, FDA managed to achieve the majority of its

FY 2023 OMUFA performance objectives that support its OTC monograph drug activities. Highlighted below are FDA's accomplishments in FY 2023:

- Posting of Deemed Final Administrative Orders Established by Section 505G of the FD&C Act
    - FDA posted the remaining final administrative orders deemed established upon the enactment of section 505G of the FD&C Act under the CARES Act on the OTC Monographs @ FDA web portal.[1] In FY 2023, FDA posted batches of these orders on a rolling basis, with a batch posted on October 10, 2022, and the final batch posted on May 2, 2023.
- Annual Forecast for Planned Monograph Activities[2]
    - FDA posted the third such annual forecast on September 29, 2023.
- IT Activities
    - FDA launched a public-facing IT web portal on October 1, 2022.
    - On Oct 3, 2022, FDA's enhancements to the CDER NextGen Portal were deployed to enable industry to make submissions related to over-the-counter monograph drugs, including meeting request submissions.
    - FDA established practices to meet the FY 2023 business needs for the IT platform related to electronic submission receipt, archiving, and reporting.
- Guidances for Industry
    - FDA issued the draft guidance for industry "Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program" on November 2, 2022.[3]
    - FDA issued the draft guidance for industry "Over-the-Counter Monograph Order Requests (OMORs): Format and Content" on April 12, 2023.[4]
    - FDA issued the draft guidance for industry "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section

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

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

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-over-counter-monograph-drug-user-fee-program.

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/over-counter-monograph-order-requests-format-and-content.

505G of the Federal Food, Drug, and Cosmetic Act" on June 23, 2023.[5]

- Cataloguing of Pre-OMUFA Paper Documents
    - FDA awarded a contract for the cataloguing of pre-OMUFA paper documents on February 3, 2023.
- Meeting Management Goals
    - FDA exceeded its initial meeting management goals for formal development meetings with industry in 2023.

[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-dispute-resolution-and-administrative-hearings-final-administrative-orders-under-section-505g.

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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.[6]

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.[7]

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:

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

[7] 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 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 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).[8]

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

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

adverse event associated with the use of the drug.[9]

The 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;
- Facilitates 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), provides 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.[10]

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[11] document (also known as the "OMUFA 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] See section 505G(b)(4) of the FD&C Act.

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

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

In 2021, FDA updated the OMUFA goal dates in the OMUFA Goals Document to reflect that FY 2021 is the first OMUFA program year.[12] This updating aligns with language in the OMUFA 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."[13] 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 Goals Document.[14]

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 current 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 expects to be able to implement 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 the preliminary performance results for the FY 2023 cohort of submissions that had actions completed or due for completion in FY 2023. Final performance for the FY 2023 cohort will be presented in the FY 2024 OMUFA Performance Report and will include actions for submissions still pending within the OMUFA goal date as of September 30, 2023. The following information refers to FDA's OMUFA-related performance results presented in this report:

- Performance goal results are reported for FY 2023.
- FDA annually reports OMUFA performance data for each *fiscal year receipt cohort* (defined as submissions filed from October 1 to September 30 of the

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

[13] See footnote 7.

[14] See footnote 7.

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.

- Preliminary aggregate meeting management performance results for FY 2023 submissions are shown as the percentage of submissions reviewed on time as of September 30, 2023, excluding submissions that are unacceptable for filing because of nonpayment of user fees or submissions withdrawn prior to the meetings granted/denied response goal date. Aggregate meeting management types with a current performance result of 50 percent or more reviewed by the goal date are shown as currently meeting the goal. The highest possible percent of reviews that may be completed on time (i.e., the highest possible performance results) if all non-overdue pending reviews are completed within the goal is also shown.

- FDA's performance for meeting management goals are reported in the aggregate and apply to all meeting types for the first 12 meetings only (after taking out exclusions as noted above) for FY 2023. 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).

- Unless otherwise noted, all information/statuses are as of September 30, 2023.

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

II. OMUFA Commitments

The OMUFA 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 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. The posting of these DFOs is an important first step for issuing FDA- or industry-initiated orders (e.g., in response to an OTC Monograph Order Request (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 29, 2023.[16] Planned actions mentioned in this most recently posted forecast include proposed orders addressing the following topics:

    - Risks associated with codeine-containing cough medicine;
    - Pediatric acetaminophen dosing;
    - Risks associated with propylhexedrine abuse and misuse;

[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/forecast.

- Nonsteroidal anti-inflammatory drugs and oligohydramnios;
- Oral healthcare in infants and children;
- Serious skin reactions associated with acetaminophen;
- Risks associated with the use of ipecac syrup as OTC poison treatment;
- Pediatric cough/cold dosing;
- Anticaries test methods; and
- Effectiveness of phenylephrine as an oral decongestant ingredient.

- 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 March 23, 2023.[17]

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

III. OMUFA Procedural and Processing Goals and Commitments

The OTC monograph reform process offers industry opportunities to engage in pre-submission meetings with FDA before requesting changes to OTC monographs. Sponsors and requestors (collectively referred to as meeting requesters) can meet with FDA to obtain advice on the studies and other information necessary to support OTC monograph order requests, to obtain advice on other matters relevant to OTC monograph drug regulation, or to obtain advice on OTC monograph drug development.[18] The OMUFA Goals Document designates these meetings as Type X, Type Y, and Type Z meetings.

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

In this report, only the first 12 meeting requests received in FY 2023 are reported in the aggregate, excluding any meeting request submissions that were unacceptable for filing because of nonpayment of user fees or meetings withdrawn prior to the meetings granted/denied response goal date.

A. Preliminary FY 2023 Procedural and Processing Performance Results

Table 1 details the preliminary performance results for FY 2023 submissions in achieving the goals related to meeting management outlined in the OMUFA 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.

- 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*

[18] 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.

possible final performance is the best potential final performance result, which accounts for actions pending within the OMUFA goal date.

Table 1. FY 2023 Preliminary Meeting Management Performance Results

Submission/Request Type	Progress	Aggregate Goal	FY 2023 Current Performance	Highest Possible Final Performance
Aggregate Meeting Management Goals (First 12 Meetings Only)*	28 of 32 complete	50%	96%	97%

* 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 2 details the preliminary progress results for FY 2023 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 2. FY 2023 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 7 complete	Respond within 14 days
Type Z Meeting Requests	5 of 5 complete	Respond within 21 days
Type X Meetings Scheduled	0 of 0 complete	Schedule within 30 days
Type Y Meetings Scheduled	3 of 4 complete	Schedule within 70 days
Type Z Meetings Scheduled	3 of 3 complete	Schedule within 75 days
Type X Written Response	0 of 0 complete	Respond within 30 days
Type Y Written Response	2 of 3 complete	Respond within 70 days
Type Z Written Response	0 of 1 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	3 of 3 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.

B. Preliminary FY 2023 Procedural and Processing Performance Details

The following detailed performance information for FY 2023 cohort submissions includes the number of 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 3.

Table 3. FY 2023 Aggregate Meeting Management

Type	Goal Threshold	Received*	Meeting Management Goals	On Time	Overdue	Pending Within Goal	Current Percent on Time	Highest Possible Percent on Time
Aggregate Meeting Management Goals (First 12 Meetings Only)*	50%	12	32	27	1	4	96%	97%

* 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 4 details the preliminary detailed results for FY 2023 submissions in achieving the goals related to meeting management that are reported in the aggregate above.

Table 4. FY 2023 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	7	6	0	1
Type Z Meeting Requests	Respond within 21 days	5	5	0	0
Type X Meetings Scheduled	Schedule within 30 days	0	0	0	0
Type Y Meetings Scheduled	Schedule within 70 days	4	3	0	1
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	3	2	0	1
Type Z Written Response	Respond within 75 days	1	0	0	1
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	3	2	1	0

Type	Action Goal	Received*	On Time	Overdue	Pending Within Goal
	meeting date				

* 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 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.

IV. Additional OMUFA Program Reporting

A. Hiring and Training of New Staff at FDA

The success of the OTC monograph reform program requires significant start-up resources, including hiring and training new staff. Recognizing this, FDA agreed, as part of the OMUFA performance goal, to hire and train staff to support the regulatory activities and the demands of the reformed OTC monograph system.

In FY 2023, 22 positions were allocated to the Center for Drug Evaluation and Research (CDER), and one position was allocated to the Office of the Commissioner (OC). As of September 29, 2023, OC has onboarded one employee, and CDER has onboarded 11 employees (with an additional nine candidates identified and two positions pending candidate identification). CDER plans to fill the remaining 11 vacant positions in FY 2024.

The 11 CDER hires constitute approximately 52 percent of the planned OMUFA hiring metrics for FY 2023. 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 5.

Table 5. 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	
2024	19		
2025	9		
Total		66‡	

* 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 30, 2023, there were a total of 66 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 Goals Document, FDA committed to conduct activities necessary to fulfill the OMUFA IT objectives and has met these objectives for FY 2023. Table 6 describes FDA's IT commitments and the progress in each area.

Table 6. OMUFA's IT Commitments and Their Progress

Activity	Due Date/Deadline	Status
Award the contract for the public-facing IT web portal	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 web portal 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 web portal	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 web portal	10/1/2022	Complete (A new public-facing IT web portal* was developed and is available to the public that includes new capabilities to modernize the OTC monograph review process and proposed order comment and search functionalities.)
Establish business requirements for the IT web portal	4/1/2023	Complete (The business requirements were finalized for initial platform deployment in September 2022.)
Establish a fully functioning IT web portal for FDA's OTC monograph review	4/1/2025	In Progress (Key internal technical milestones were met and are continuing as planned.)

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

V. Additional Activities to Promote Transparency and Enhance Communication

A. Activities in Fiscal Year 2023

In FY 2023, 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 three FDA Small Business and Industry Assistance Webinar Presentations open to industry and the general public:
        - OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2023 User Fees and Registration Webinar – May 16, 2023;
        - OTC Monograph Reform: OMOR Format and Content & Electronic Submissions – August 22, 2023; and
        - Electronic Drug Registration and Listing (eDRLS): Using CDER Direct Conference – September 28, 2023.
    - Delivered presentations on FDA's OTC monograph reform at an external conference:
- Sep 18-20, 2023: 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 OMUFA user fees.[19]

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

- Submitted a letter to Congress, on March 23, 2023, describing FDA's progress
- on evaluating and revising, as appropriate, the cough and cold monograph with respect to children under age 6.[20]
- Awarded a contract for the cataloguing of pre-OMUFA paper documents on February 3, 2023. The goal of this contract is the creation of a searchable electronic catalog for industry.
- As discussed in Section III.B., built new IT systems and expanded on existing systems and technology investments. These activities included implementation of the following:
    - The expansion of the CDER NextGen Portal to enable industry to request formal meetings and submit related meeting correspondence (e.g., meeting packages);
    - A workflow management system that allows CDER personnel to review industry submissions, manage review teams, and complete regulatory reviews;
    - A reporting/analysis system that captures key data for congressional and internal reporting; and
    - A new public-facing IT web portal (OTC Monographs @ FDA) for public viewing and commenting on OTC monograph orders.
- Continued to work on the expansion of the CDER NextGen Portal for other OTC monograph submissions, including OMORs.
- FDA posted the remaining DFOs on the OTC Monographs @ FDA web portal.[21] FDA posted batches of these DFOs on a rolling basis, with a batch posted on October 10, 2022, and the final batch posted on May 2, 2023.

B. OMUFA Guidance Development

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

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

FDA committed to increase its transparency in operations and to enhance its communication on critical information. In FY 2023, FDA published the following draft guidance documents for industry:

- "Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program" on November 2, 2022;[22]
- "Over-the-Counter Monograph Order Requests (OMORs): Format and Content" on April 12, 2023;[23] and
- "Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Federal Food, Drug, and Cosmetic Act" on June 23, 2023.[24]

[22] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-user-fees-under-over-counter-monograph-drug-user-fee-program

[23] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/over-counter-monograph-order-requests-format-and-content

[24] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-dispute-resolution-and-administrative-hearings-final-administrative-orders-under-section-505g

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.

- 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 generally recognized as safe and effective (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 process.

- OTC Monograph Drug - Under section 744L(5) of the FD&C Act, means a nonprescription drug without an approved NDA 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.

- Type X meetings either are the meetings that are necessary for an otherwise stalled monograph development program to proceed or are the 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 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 and 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 are any meetings that are not a Type X or Type Y meeting.

This report was prepared by FDA's Office of Planning, Evaluation, and Risk Management. For information on obtaining additional copies, please contact:

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