FY 2021

PERFORMANCE REPORT TO CONGRESS

for the

OVER-THE-COUNTER MONOGRAPH DRUG USER FEE PROGRAM

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Commissioner's Report

I am pleased to present to Congress the first annual U.S. Food and Drug Administration (FDA or Agency) performance report to Congress for the Over-the-Counter Monograph Drug User Fee Program (OMUFA). On March 27, 2020, new provisions were added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136). These new FD&C Act provisions authorize FDA to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drug products and submitters of OTC monograph order requests. FDA refers to the OTC Monograph Drug User Fee Program as "OMUFA" throughout this document. Section 744N(a) of the FD&C Act, as added by the CARES Act, requires FDA to report annually on the performance of this user fee program. This report covers the period of October 1, 2020, through September 30, 2021, and presents FDA's accomplishments for the first year of OMUFA.

OMUFA supports FDA's important OTC monograph drug activities and ultimately helps provide safe, effective, and innovative OTC monograph drug product options for the general public. The OMUFA performance goals agreed to by FDA and industry reflect the Agency's commitment to optimizing the efficiency, quality, and predictability of the new process for regulating OTC monograph drugs enacted under the CARES Act.

FDA is committed to meeting all OMUFA performance goals. FDA will continue to strengthen efforts to improve its performance while maintaining a focus on ensuring that OTC monograph submissions are reviewed in an efficient and predictable time frame.

FDA looks forward to continued success and significant accomplishments in the OTC monograph drug process that OMUFA will support over the coming years.

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs

Acronyms

CARES Act – Coronavirus Aid, Relief, and Economic Security Act

CDER – Center for Drug Evaluation and Research

DFO – Deemed Final Order

FDA – U.S. 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

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 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 new 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. FDA anticipates that this user fee program will provide additional resources to help the Agency conduct important regulatory activities in a timely manner and will ultimately help 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. Although many performance goals are slated to be accomplished after fiscal year (FY) 2021, the Agency has already made progress in developing the infrastructure to achieve these future 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 2021. During this emergency, the Agency appropriately shifted resources to prioritize its work focused on addressing the pandemic. Despite this, FDA managed to achieve a considerable number of the FY 2021 OMUFA performance objectives in support of FDA's OTC monograph drug activities. Highlighted below are FDA's accomplishments since the passage of the CARES Act:

- Published a notice in the *Federal Register* (September 21, 2021; 86 FR 52474) announcing the availability of certain final administrative orders that were deemed established under the CARES Act (also known as deemed final orders or 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. This notice also announced (1) the process for making these DFOs available and (2) plans for modifying the Agency's regulations in accordance with the OTC monograph reform authority enacted under the CARES Act.

- Started posting DFOs on FDA's new web portal called OTC Monographs@FDA.[1]

- Posted the first annual forecast for planned monograph activities.

- Issued a Request for Proposals to secure information technology (IT) services in support of mandated technical requirements.

- Awarded a contract to provide IT services.

[1] www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.

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Table of Contents

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Introduction/Overview of OTC Monograph Reform & OMUFA

Two hundred and forty million Americans use over-the-counter (OTC) drugs every year. OTC drugs are available to consumers without a prescription and can be safely and effectively used without the supervision of a healthcare provider. OTC 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 OTC 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.

OTC drugs are brought to market either under the OTC monograph process, also known as the "OTC Drug Review," or under the new drug application (NDA) process. Of the more than 100,000 marketed OTC drugs, most are marketed through the OTC Drug Review process.[2]

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 NDA and FDA pre-market approval). 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.[3]

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:

- Burdensome, multistep rulemakings to establish or amend monographs;
- Lack of adequate resources to devote to the rulemaking process;
- Delays in finalizing 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.

[2] See www.fda.gov/news-events/fda-voices/exciting-new-chapter-otc-drug-history-otc-monograph-reform-cares-act.
[3] Id.

OTC Monograph Reform 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).[4]

The new process also provides an expedited procedure for FDA to initiate an safety-related administrative order when FDA determines either that

- a 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.[5]

OTC monograph reform accomplishes the following:

- Improves the process by replacing rulemaking with administrative orders;
- Improves the efficiency, timeliness, and predictability of FDA's OTC monograph drug activities;
- Facilitates innovation;
- Establishes a process to rapidly address safety issues;
- Finalizes pending monographs; and
- Through the Over-the-Counter Monograph Drug User Fee Program (OMUFA), provides FDA with 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.[6]

Over-the-Counter Monograph Drug User Fee Program

The CARES Act also amended the FD&C Act to authorize 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

[4] *OMORs* are requests for an administrative order that adds, removes, or changes GRASE conditions for an OTC drug monograph. See www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor.
[5] See section 505G(b)(4) of the FD&C Act.
[6] www.fda.gov/drugs/over-counter-otc-drug-monograph-process.

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[7] 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, beginning after congressional enactment of OTC monograph reform (which occurred under the CARES Act).

In 2021, FDA updated the OMUFA goal dates in the OMUFA Goals Document to reflect that FY 2021 is the first OMUFA program year.[8] 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*." 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.

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 is expected to be consumed by current external mandates, safety activities, OTC monograph reform implementation, and infrastructure development activities. By Year 3, FDA expects review resources will grow to the point where limited OMUFA performance goals can begin 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.

[7] www.fda.gov/media/106407/download.
[8] See www.fda.gov/media/146283/download.

Information Presented in This Report

This report presents OMUFA performance commitment information and tracks FDA's performance from the passage of the CARES Act through the first full fiscal year of OMUFA.

The following information refers to the FDA performance results presented in this report.

- Performance goal results are reported from passage of the CARES Act (March 27, 2020) through the end of the first full fiscal year of OMUFA (i.e., through September 30, 2021).
- Unless otherwise noted, all information/statuses are as of September 30, 2021.
- Definitions of key terms used throughout this report can be found in Appendix A.

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" or "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.[9] On September 20, 2021, FDA began to make available these DFOs in batches on a rolling basis and will continue until all such DFOs are available in the repository on FDA's new web portal called OTC Monographs@FDA.[10] Additional batches were posted on September 24, 2021, and October 1, 2021.

- 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 publicly posted on October 1, 2021.[11] Planned actions include proposed orders addressing:

    - Acetaminophen safety labeling for serious skin reactions
    - Non-steroidal anti-inflammatory drugs updated pregnancy labeling
    - Risks associated with codeine-containing cough medicine
    - Pediatric acetaminophen dosing
    - Propylhexedrine safety warning for misuse/abuse
    - Updates to anticaries test methods

[9] The DFOs may be amended, revoked, or otherwise modified via the administrative order process.
[10] www.accessdata.fda.gov/scripts/cder/omuf/index.cfm. Note that posting the DFOs correlates to the OMUFA performance goal regarding Tentative Final Monograph Category I finalization activities, given that under the CARES Act amendments, the finalization of such Tentative Final Monographs was addressed by the authority establishing DFOs.
[11] www.fda.gov/media/152546/download.

Additional OMUFA Program Reporting

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 to hire and train staff, as part of the OMUFA performance goals, to support the regulatory activities and the demands of the reformed OTC monograph system.

In FY 2021, 27 of the target 30 positions were allocated to the Center for Drug Evaluation and Research (CDER). As of September 30, 2021, CDER had placed 13 employees in roles as part of the OMUFA hiring initiative. The other three target positions were allocated elsewhere within the Agency but have not been filled. The COVID-19 public health emergency has presented many challenges to FDA, including in the the Agency's recruiting, hiring, and onboarding of new staff. Delays in publishing the *Federal Register* notice announcing FY 2021 OMUFA fees and the subsequent delayed collections of OMUFA fees also delayed the ability to onboard hires until the funding became available. The 13 CDER hires constitute 43 percent of the planned OMUFA hiring metrics for FY 2021. These employees received orientation and training that included a focus on OTC monograph drug activities and the OMUFA user fee program.

FDA will target the onboarding of staff in each of the fiscal years as follows:

Fiscal Year	Hiring/Onboarding Target	Actual
2021	30	13
2022	24	
2023	23	
2024	19	
2025	9	

Information Technology Platforms and Enhanced Technology

The OTC monograph reform requires important information technology (IT) improvements to enhance the efficiency of OTC monograph drug activities and to facilitate user fee collections and tracking. 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 conducting activities necessary to fulfill the OMUFA IT objectives. The following table describes FDA's IT commitments and the progress in each area.

Activity	Due Date/Deadline	Status
Award the contract for the public-facing IT dashboard	10/1/2021	Complete (Awarded contract for the public-facing platform 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 (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 dashboard 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	In progress
Establish business requirements for the IT platform	4/1/2023	In progress
Establish a fully functioning IT platform for FDA's OTC monograph review	4/1/2025	In progress

Additional Activities to Promote Transparency and Enhance Communications

Activities Since Passage of the CARES Act

FDA has made significant progress on communications regarding OTC monograph reform implementation activities. Key activities and accomplishments include 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, which were open to industry/general public, including the following:

        - Webinar #1 – May 29, 2020 (Office of Nonprescription Drugs) – Monograph Reform is Here! What to Expect and How to Prepare
        - Webinar #2 – January 27, 2021 (Office of Nonprescription Drugs) – OTC Monograph Reform in the CARES Act: Safety Orders
        - Webinar #3 – June 3, 2021 (Division of User Fee Management) – OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2021 User Fees

    - Initiated the User Fee FDA InBrief/Listserve e-mail/stakeholder outreach
    - Delivered presentations on FDA's OTC monograph reform at various external conferences
    - Posted questions and answers on two different landing pages of FDA's website: one for overall monograph reform and one for OMUFA user fees
    - Released an FDA Voices Blog on monograph reform

- Updated the dates for the Goals Document

- Built new IT systems and expanded on existing systems and technology investments

    - Created a new interim public-facing web portal called OTC Monographs@FDA, which provides a resource for the public to view proposed, final, and interim final orders for OTC monographs. OTC Monographs@FDA also facilitates the submission of comments and data from the public on the proposed and interim final administrative orders.

- Published a proposed order to revise the deemed final order for sunscreens.

Overall, FDA continues to work toward improving its performance in meeting or exceeding expectations in the implementation and completion of the performance goals established under OMUFA.

Meeting Management

The OTC monograph reform offers industry opportunities to engage in pre-submission meetings with FDA before requesting changes to OTC monographs. Requestors can meet with FDA before OMOR submissions and during OMOR reviews. OMUFA designates these meetings as "Type X," "Type Y," and "Type Z" meetings. The meeting classifications and descriptions are as follows:

- "Type X meetings" either are those 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.

- "Type Y meetings" are intended to facilitate (1) milestone discussions during the lifecycle of the OTC monograph development program and (2) the OTC monographs conditions of use. Examples of these meetings include meetings to discuss the overall data requirements to support a GRASE determination and pre-OMOR submission meetings to discuss the adequacy of the proposed submission.

- "Type Z meetings" are any meetings that are not a Type X or Type Y meeting.

Performance goals regarding meeting management will become effective on October 1, 2022.

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Appendices

Appendix A: Definition of Key Terms

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

B. 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 a respective DFO, as of the date of enactment of the CARES Act.

C. 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.

D. 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) .

E. 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.

F. 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."

G. Over-the-Counter (OTC) Drug - a nonprescription drug product marketed for use by the consumer without the intervention of a healthcare professional. Under section 505G 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). OTC drugs are developed under the OTC monograph process or through the NDA process.

H. 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.

I. 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.

J. 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.

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This report was prepared by FDA's Office of Planning in collaboration with the Center for Drug Evaluation and Research. For information on obtaining additional copies, contact:

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