Report to Congress

Over-the-Counter Monograph Drug User Fee Program Performance Report

FY 2022

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. Although many performance goals are slated to be accomplished after fiscal year (FY) 2022, 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 2022. 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 2022 OMUFA performance objectives in support of FDA's OTC monograph drug activities. Highlighted below are FDA's accomplishments in FY 2022:

- Posted 23 final administrative orders deemed established by the CARES Act (deemed final orders (DFOs)) on OTCMonographs@FDA.[1] FDA posted these DFOs on a rolling basis beginning September 20, 2021, with additional batches of DFOs posted on October 1, 2021, November 23, 2021, December 16, 2021, and April 4, 2022.

- Annual Forecast for Planned Monograph Activities (Annual Forecast)
    - Posted the first Annual Forecast on October 1, 2021[2]
    - Posted the second Annual Forecast on September 30, 2022[3]

- IT Activities
    - Awarded contract for public facing IT dashboard on September 29, 2021
    - Published request for proposals for IT platform for electronic submission receipt, archiving, and reporting on August 5, 2021
    - Awarded contract for IT platform for electronic submission receipt, archiving, and reporting on September 27, 2021
    - Established business requirements for IT platform for electronic submission receipt, archiving, and reporting
    - Fully developed, tested, and readied for an early FY 2023 launch of a public facing IT dashboard

- Guidances[4]
    - Published a draft guidance for industry "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs" on February 1, 2022[5]
    - Published a draft guidance for industry "Providing Over-the-Counter Monograph Submissions in Electronic Format" on September 27, 2022[6]

[1] Available at https://dps.fda.gov/omuf.
[2] Available at https://www.fda.gov/media/152546/download.
[3] Available at https://www.fda.gov/media/161835/download.
[4] When final, these guidances will represent the FDA's current thinking on this topic.
[5] This guidance also contains information related to consolidated proceedings to facilitate efficient participation by multiple requestors or sponsors. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-food-and-drug-administration-and-sponsors-or-requestors-over-counter.
[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-over-counter-monograph-submissions-electronic-format.

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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/Overview of OTC Monograph Reform & OMUFA

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 Drug Review," also known as the OTC monograph process, 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.[7]

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.[8]

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 OTC monographs;
- Lack of adequate resources to devote to the rulemaking process;

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

- 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 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).[9]

The new process also provides an expedited procedure for FDA to initiate a 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.[10]

OTC monograph reform 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

[9] *OMORs* are requests for an administrative order that adds, removes, or changes GRASE conditions for an OTC drug monograph. See http://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#omor.

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

- 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.[11]

C. Over-the-Counter 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[12] 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).

In 2021, FDA updated the OMUFA goal dates in the OMUFA Goals Document to reflect that FY 2021 is the first OMUFA program year.[13] 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

[11] http://www.fda.gov/drugs/over-counter-otc-drug-monograph-process.
[12] http://www.fda.gov/media/106407/download.
[13] See http://www.fda.gov/media/146283/download.

to complete training in this complex review area.

D. Information Presented in This Report

This report presents OMUFA performance commitment information and tracks FDA's performance for FY2022.

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

- Performance goal results are reported for FY2022
- Unless otherwise noted, all information/statuses are as of September 30, 2022
- Definitions of key terms used throughout this report can be found in Appendix A

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" 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.[14] 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 OTCMonographs@FDA.[15] FDA continued to release the DFOs in batches in FY 2022. Additional batches were posted on October 1, 2021, November 23, 2021, December 16, 2021, and April 4, 2022.

- 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 last publicly posted on September 30, 2022.[16] 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
    - Oral health care drug products containing benzocaine and/or phenol
    - Pediatric cough/cold drug product dosing
    - Risks associated with use of ipecac syrup as an OTC poison treatment

[14] The DFOs may be amended, revoked, or otherwise modified via the administrative order process under section 505G of the FD&C Act.
[15] http://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.
[16] https://www.fda.gov/media/161835/download.

- 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 15, 2022.[17]

[17] As required by CARES Act (P.L. 116-136) Section 3855(a).

III. 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 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 2022, 23 of the targeted 24 positions were allocated to the Center for Drug Evaluation and Research (CDER). As of September 30, 2022, CDER had placed 19 employees in roles as part of the OMUFA hiring initiative. In addition to the 19 employees on board there were two additional candidates set to enter on duty in early FY 2023. The hiring process for the two-remaining vacant CDER positions had to be restarted due to candidate declinations. In addition to the 23 CDER positions, one targeted position was allocated elsewhere within the Agency but has not been filled. All 17 remaining FY 2021 positions were also filled in FY 2022.

The 19 hires constitute 79 percent of the planned OMUFA hiring metrics for FY 2022. 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:

Table I. OMUFA Hiring Targets vs Actual Hires

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

*The remaining 17 FY 2021 positions were hired in FY 2022 in addition to the 19 FY 2022 hires.

B. 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. 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 and has met these objectives for FY 2022. The following table describes FDA's IT commitments and the progress in each area.

Table II. OMUFA IT Commitments and their Progress

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	Complete (A new public facing IT dashboard[18] has been 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 platform	4/1/2023	Complete (Business requirements finalized for initial platform deployment in September 2022)
Establish a fully functioning IT platform for FDA's OTC monograph review	4/1/2025	In progress

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

IV. Additional Activities to Promote Transparency and Enhance Communication

A. Activities in Fiscal Year 2022

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 – December 15, 2021: Deemed Final Orders (Office of Nonprescription Drugs)[19]

        - Webinar – December 15, 2021: OTC Sunscreen Drugs (Office of Nonprescription Drugs)[20]

        - Webinar – March 29, 2022: Overview of Draft Guidance for Industry: Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs (Office of Nonprescription Drugs)[21]

    - Delivered presentations on FDA's OTC monograph reform at various external conferences

    - Posted and updated questions and answers on two different landing pages of FDA's website: one for overall monograph reform[22] and one for OMUFA user fees[23]

[19] Available at: https://www.fda.gov/drugs/news-events-human-drugs/otc-monograph-reform-deemed-final-orders-12152021-12152021.
[20] Available at: https://www.fda.gov/drugs/news-events-human-drugs/otc-monograph-reform-otc-sunscreen-drugs-12152021-12152021.
[21] See: https://www.fda.gov/drugs/news-events-human-drugs/otc-monograph-reform-overview-draft-guidance-formal-meetings-03292022.
[22] Available at: https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa.
[23] Available at: https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa.

- Held implementation meetings with industry on December 13, 2021,[24] April 19, 2022,[25] and September 1, 2022,[26] and posted minutes from those meetings on FDA's website.

- Submitted letter to Congress describing FDA's progress on evaluating and revising, as appropriate, the cough and cold monograph with respect to children under age 6 (March 15, 2022).[27]

- As discussed in Section III.B., built new IT systems and expanded on existing systems and technology investments. This includes implementation of:

  - The expansion of the CDER NextGen Portal (i.e., IT platform) 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

  - A new public-facing IT dashboard (OTCMonographs@FDA) for public viewing and commenting on OTC monograph orders

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

- Posted DFOs for the following therapeutic categories as shown in Table III:

Table III. Posted DFOs for Therapeutic Categories

OTC Monograph ID	OTC Monograph Title
M002	Antiflatulent Products for OTC Human Use[28]
M005	Topical Antifungal Drug Products for Over-the-Counter Human Use[29]

[24] https://www.fda.gov/media/155202/download.
[25] https://www.fda.gov/media/158249/download.
[26] https://www.fda.gov/media/162300/download.
[27] As required by CARES Act (P.L. 116-136) Section 3855(a).
[28] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M002-AntiflatulentProductsforOTCHumanUse_09202021.pdf.
[29] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M005-Topical%20Antifungal%20drug%20products%20for%20OTC%20Human%20Use%2012.16.2021.pdf.

OTC Monograph ID	OTC Monograph Title
M006	Topical Acne Drug Products for Over-the-Counter Human Use[30]
M008	Antidiarrheal Drug Products for Over-the-Counter Human Use[31]
M009	Antiemetic Drug Products for Over-the-Counter Human Use[32]
M010	Nighttime Sleep Aid Drug Products for OTC Human Use[33]
M014	Topical Otic Drug Products for OTC Human Use[34]
M015	Anorectal Drug Products for Over-the-Counter Human Use[35]
M016	Skin Protectant Drug Products for Over-the-Counter Human Use[36]
M018	Ophthalmic Drug Products for Over-the-Counter Human Use[37]
M019	Antiperspirant Drug Products for Over-the-Counter Human Use[38]
M020	Sunscreen Drug Products for Over-the-Counter Human Use[39]
M024	Anthelmintic Drug Products for Over-the-Counter Human Use[40]
M025	Cholecystokinetic Drug Products for Over-the-Counter Human Use[41]
M026	Deodorant Drug Products for Internal Use for Over-the-Counter Human Use[42]
M027	Orally Administered Menstrual Drug Products for Over-the-Counter Human Use[43]

[30] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M006-Topical%20Acne%20drug%20products%20for%20OTC%20Human%20Use%2011.23.2021.pdf.
[31] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M008-Antidiarrheal%20Drug%20Products%20for%20OTC%20Human%20Use%2004.04.22.pdf.
[32] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M009-Antiemetic%20Drug%20Products%20for%20OTC%20Human%20Use%2011.23.2021.pdf.
[33] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M010-NighttimeSleepAidDrugProductsforOTCHumanUse_09202021.pdf.
[34] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M014-TopicalOticDrugProductsforOTCHumanUse09202021.pdf.
[35] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M015-Anorectal%20Drug%20Products%20for%20OTC%20Human%20Use%20Posted%20Corrected%2002_23_22.pdf.
[36]https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M016SkinProtectantDrugProductsforOTCHumanUse09242021.pdf.
[37] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M018-Ophthalmic%20Drug%20Products%20for%20OTC%20Human%20Use%2004.04.22.pdf.
[38] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M019-Antiperspirant%20Drug%20Products%20for%20OTC%20Human%20Use%2011.23.2021.pdf.
[39] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M020-SunscreenDrugProductsforOTCHumanUse09242021.pdf.
[40] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M024-Anthelmintic%20Drug%20Products%20for%20OTC%20Human%20Use%2012.16.2021.pdf.
[41] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M025-Cholecystokinetic%20Drug%20Products%20for%20OTC%20Human%20Use%2012.16.2021.pdf.
[42] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M026-Deodorant%20Drug%20Products%20for%20OTC%20Human%20Use%2011.23.2021.pdf.
[43] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M027-Orally%20Administered%20Menstural%20Drug%20Products%20for%20OTC%20Human%20Use%2012.16.2021.pdf.

OTC Monograph ID	OTC Monograph Title
M028	Wart Remover Drug Products for Over-the-Counter Human Use[44]
M029	Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use[45]
M030	Corn and Callus Remover Drug Products for OTC Human Use[46]
M031	Pediculicide Drug Products for Over-the-Counter Human Use[47]
M032	Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis for Over-the-Counter Human Use[48]

B. OMUFA Guidance Development

FDA committed to increasing transparency in operations and enhancing communication on critical information. In FY 2022, FDA published the following draft guidance documents for industry:[49]

- Draft guidance for industry: Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs (02/01/2022) (Formal Meetings draft guidance).[50] This guidance also specifies procedures to facilitate efficient participation by multiple sponsors or requestors and/or organizations nominated by them to represent their interests. The information serves to fulfill the first portion of the commitment to publish a draft guidance for industry on consolidated proceedings. The second portion of the consolidated proceedings guidance will be included in the draft guidance on dispute resolution with a goal date of February 3, 2023 (OMUFA Year 3).

- Draft guidance for industry: Providing Over-the-Counter Monograph Submissions in Electronic Format (09/27/2022).[51]

[44] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M028-WartRemoverDrugProductsforOTCHumanUse10012021.pdf.
[45] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M029-IngrownToenailReliefDrugProductsforOTCHumanUse10012021.pdf.
[46] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M030-CornandCallusRemoverDrugProductsforOTCHumanUse09202021.pdf.
[47] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTCMonograph_M031-PediculicideDrugProductsforOTCHumanUse10012021.pdf.
[48] https://www.accessdata.fda.gov/drugsatfda_docs/omuf/OTC%20Monograph_M032-Drug%20Products%20for%20the%20Control%20of%20Dandruff%20Seborrheic%20Dermatitis%20and%20Psoriasis%2012.16.2021.pdf.
[49] When final, these guidances will represent the FDA's current thinking on this topic.
[50] https://www.fda.gov/media/155864/download.
[51] https://www.fda.gov/media/161822/download.

C. Meeting Management

The OTC monograph reform 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 submissions, to obtain advice on other matters relevant to OTC monograph drug regulation, or to obtain advice on OTC monograph drug development.[52] The OMUFA Goals Document designates these meetings as Type X, Type Y, and Type Z meetings. The meeting classifications and descriptions as discussed in the Formal Meetings draft guidance 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 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:

  (1) Overall data recommendations meetings to discuss the overall data recommended to support the following 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, and

  (2) Pre-OMOR submission meeting when a sponsor is nearing completion of its development program for an OMOR, for the sponsor to present a summary of the data supporting the OMOR and discuss the proposed format for the OMOR, obtain FDA feedback on 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.

Performance goals regarding meeting management will become effective in FY 2023.

[52] 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* (02/01/2022), at https://www.fda.gov/media/155864/download.

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 the 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. 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). 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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