

Review Article

ENHANCING OTC MONOGRAPH DRUG REGULATION THROUGH USER FEE PROGRAM

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ABSTRACT

Food and Drug Administration (FDA) has introduced a distinctive regulatory program known as Over-the-Counter Monograph Drug User Fee Program (OMUFA) to improve the efficacy and security of over-the-counter (OTC) medications made available to consumers. The program, which represents a pivotal shift in the regulatory landscape, aims to address the challenges associated with the oversight of OTC monograph drugs. The OMUFA's primary objective is to expedite the review and approval process of OTC monograph drugs while maintaining stringent safety standards. By imposing user fees on manufacturers and sponsors seeking to bring new OTC products to market or seeking updates for existing ones, the program is designed to support the FDA's ability to allocate additional resources for timely reviews and assessments. This work delves into the key components and mechanics of the OMUFA, such as the user fee structure, types of submissions covered, and the corresponding performance goals established for the FDA. While acknowledging the benefits of the OMUFA, this work also discusses potential challenges and concerns raised by industry stakeholders and consumer advocacy groups. This critical regulatory initiative has the potential to facilitate further research and discussions on optimizing drug safety and access within the OTC market through required modifications and initiatives.

Keywords: FDA, OMUFA, OTC medications, User fees, Efficacy, Safety standards

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INTRODUCTION

OTC Medications are an essential part of healthcare, providing readily accessible remedies for common ailments without the need for a prescription. OMUFA was established by the FDA of the United States to guarantee the efficacy, quality, and safety of these medications [1].

The FDA's regulatory actions for OTC monograph pharmaceuticals are supported by the OMUFA program, which was approved by US Congress and is funded in part by industry fees. The FDA and industry reached a "Commitment Letter" agreement that served as the basis for Congress's authorization of the OMUFA Program [2]. As part of this agreement, the FDA committed to upholding performance standards, including the deadlines for reviewing submissions. The Federal Food, Drug, and Cosmetic Act (FD and C) Act's section 744L (6) lists the OTC monograph pharmaceutical activities that OMUFA payments will aid in funding and cover a variety of activities related to OTC monograph drugs as well as facility inspections for such goods [1]. We will also discuss common challenges that manufacturers face and offer recommendations for a successful OMUFA registration. By referring to this, stakeholders can form a clear understanding of the OMUFA registration process and how it can unlock numerous benefits for OTC drug manufacturers [3].

Methods and search criteria

The research carefully considers the activities of the Food and Drug Administration (FDA) in examining the regulatory frameworks controlling OTC drugs in the United States of America (USA). This paper utilizes guidelines (FDA) and existing literature on the subject published after 2005 to create a representation of OMUFA. Keywords used to search relevant literature and guidelines are "OTC Drugs", "OTC Monograph", "FDA User Fees", "FD and C OTC Regulations", "OMUFA".

DISCUSSION

OTC monograph drugs are non-prescription medications that follow specific pre-established guidelines provided by the FDA. These guidelines cover a wide range of therapeutic categories, including

pain relief, cough and cold remedies, antacids, and sunscreens. Unlike prescription drugs, which undergo a rigorous approval process, OTC monograph drugs are considered safe and effective based on their active ingredients and dosages [4].

The need for the OTC monograph drug user fee program

Over the years, the OTC market has expanded significantly, with an increasing number of products hitting the shelves. To keep up with the ever-growing volume of OTC drugs and to ensure their safety and efficacy, the FDA recognized the need for additional resources. As a result, the OMUFA was created [5].

Objectives of OMUFA

The primary objectives of OMUFA are as follows:

- **Enhancing safety:** With an influx of new ingredients and formulations in the OTC market, it is crucial to continuously assess the safety of these drugs. OMUFA provides the FDA with the necessary resources to conduct comprehensive safety reviews and address potential risks promptly [6]
- **Streamlining regulatory process:** Before the implementation of OMUFA, the process of updating OTC monographs was often slow and cumbersome. The program aims to expedite this process, allowing for quicker adjustments to monographs when new information becomes available [7]
- **Facilitating innovation:** OMUFA encourages innovation in the OTC market. Manufacturers who invest in research and development of new ingredients or formulations can now obtain quicker approval for their products, benefiting consumers with more effective and diverse treatment options [8].

The impact on consumers

OMUFA has several significant implications for consumers:

- **Safer products:** The program ensures that OTC drugs available in the market undergo rigorous safety assessments, reducing the likelihood of adverse effects and health risks [9]

- **Increased access to effective treatments:** Faster updates to OTC monographs mean that consumers can access improved and newly developed medications more swiftly [9]

- **Greater transparency:** The FDA's increased vigilance and regular safety reviews foster trust and confidence in the OTC market, assuring consumers that the products they use meet stringent safety and efficacy standards [10]

The impact on manufacturers

OMUFA affects OTC drug manufacturers in the following ways:

- **Regulatory compliance:** Manufacturers are required to pay user fees to the FDA, which contribute to the resources needed for safety assessments and regulatory processes [11]

- **Incentive for innovation:** The program rewards manufacturers investing in research and development, as they can benefit from faster approval times for new OTC products [12]

- **Efficiency and expediency:** The streamlined regulatory process enables manufacturers to respond quickly to changing market demands and consumer needs [12]

Common OMUFA terminologies

- **OTC monograph drugs:** A non-prescription drug without a valid new drug application is referred to as an OTC monograph drug as per the guidelines of FD and C Act section 505G (21 U. S. C. 355h) (FD and C Act section 744L (5)) [13]

- **OTC monograph drug facilities:** An organization, foreign or local, that manufactures or processes the finished dosage form of an OTC monograph drug while also fulfilling all other requirements is referred to as an OTC monograph drug facility (MDF) [14]

- **OTC contract manufacturing organization:** An OTC monograph drug facility is a contract manufacturing organization (CMO) if the proprietor, any associates of the proprietor, or the establishment does not market the OTC monograph drug produced at the facility directly to consumers, merchants, or wholesalers in the United States, in accordance with the FD and C Act's section 744L (2) [15]

Overview of the OMUFA user fee and its significance

As part of the registration process, manufacturers are required to provide a user fee to OMUFA. This fee is essential for funding the agency's activities and ensuring the efficient processing of registrations. The OMUFA user fee varies depending on the size of the manufacturer and the number of products being registered [16]. It is important to note that the user fee is non-refundable, even if the registration is not approved. Therefore, it is crucial for manufacturers to carefully evaluate their products and ensure they meet *al. l* the necessary requirements before initiating the registration process [17].

The user fee plays a significant role in the registration process as it helps OMUFA allocate resources and prioritize applications. Manufacturers who pay the user fee are given priority in the processing queue, leading to faster registration approval times. Additionally, the user fee helps maintain the integrity of the registration process by discouraging frivolous or incomplete applications. By charging a user fee, OMUFA ensures that only serious and committed manufacturers proceed with the registration, contributing to a more efficient and effective regulatory system [17].

OMUFA user fees

There are two types of OMUFA User Fees: Facility fees and OTC Monograph Order Request (OMOR) Fee [18]:

OMUFA facility fee

For qualified facilities that manufacture or prepare an OTC monograph drug's finished dosage form; assessments and payments are required annually. Depending on the facility's registration status (i.e., MDF or CMO) in the FDA's Electronic Drug Registration and Listing System (eDRLS), different facility user fee rates apply [19]. Assessment of OMUFA Facility Fees-A facility fee is due for the fiscal

year from anybody who owned an OTC monograph facility on December 31 of the fiscal year or at any time during the prior twelve months, including facilities held by contract manufacturing organizations. A reduction in OMUFA facility expenses based on the size or income of an organization is not expressly permitted by the FD and C Act. If a facility was classified in eDRLS as an OTC monograph facility at any time between January 1 and December 31, 2022, it will be assessed an FY 2023 fee [20].

Facilities that are subject to OMUFA fees

- Manufacture OTC medications for humans made in accordance with a valid drug application.

- Manufacture human OTC medicines that are n't made in accordance with a monograph or an approved drug application.

- Have amended their eDRLS registration to reflect the change and have stopped all OTC monograph drug-related activities prior to December 31 of the fiscal year that immediately precedes the relevant fiscal year.

Only manufacture active pharmaceutical ingredients (API) for use in a subsequent step in the production or processing of the final dosage form of a pharmacological product covered by an OTC monograph [21].

Facilities that are not subject to OMUFA fees

Facilities engaged in the following activities are exempt from the facility fee:

- Only manufacture or process the completed dosage form for the purpose of producing materials for clinical research testing

- Facilities whose sole manufacturing or processing activities consist of applying containers combining multiple products, exterior packaging such as to create multipacks, when the final packaging for each monograph drug product contained in the over packaging has already been completed before the over packaging is applied to the package [22]

OMOR

The term OMOR refers to a request for an administrative order made under section 505G(b)(5) of the FD and C Act, as defined by section 744L (7) of the FD and C Act, about an OTC monograph drug. For an OTC drug monograph, an OMOR request is used to add, remove, or change a condition that is generally recognized as safe and effective [23].

Types of OMORs

Tier 1 OMOR

Any OMOR that has n't been identified as a Tier 2 OMOR [24].

Additions like these serve as examples: An addition of a substance to a monograph including one or more compounds that have already been given the Generally Recognized as Safe and effective (GRASE) label.

Adding a monograph's addition of a new indication after already having one or more GRASE substances and that also pertain to one or more of those GRASE ingredients [25].

Tier 2 OMOR

OMORs could take part in the following: Rearranging the information already present within the drug fact label (DFL). Adding details to the DFL's "Other Information" section (with some restrictions). A modest dosage form adjustment necessitated a change to the Section of the DFL titled "Directions for Use." Standardization of a given finished ingredient's concentration or dose inside a specifically completed monograph. Align the naming of ingredients with a group that creates standards. A term that can be used interchangeably was added [26].

OMOR fees

OMOR Fees are as follows: Except for OMORs that require specific safety-related adjustments. Due on the day the OMOR is submitted.

Not accounted for in the facility fees based OMUFA target income estimation [27].

There are two OMOR fee tiers: Tier 1 OMOR Fee and Tier 2 OMOR Fee [27].

OMOR fee exemptions

If the OMOR wants to make specific safety adjustments to a medicine covered by an OTC monograph, no cost will be charged. If the FDA determines that OMOR plans to amend, no fee will be assessed to modify an OTC monograph medicine's drug facts labeling in a way that will strengthen or add to a warning, caution, or contraindication. A declaration describing the dangers of abuse or misuse. A dosage or administration recommendation meant to improve the safety of using the OTC monograph medication covered under Section 744M(a)(2)(C) of the FD and C Act [26].

Fiscal Year 2023 fee schedule

Fee Rates for Facilities

MDF-\$26,153

CMO-\$17,435

Fee Schedule for OMOR

Tier 1-\$517,381

Tier 2-\$103,476(28)

Failure to pay fees

Failure to pay user fees accrued in accordance with the FD and C Act's section 744M could result in sanctions for the organization and/or their affiliates based on the type of cost. Additionally, if the fee isn't paid within 30 d after the invoice's issuance, it will be viewed as owing money to the US government. The government may then take legal action to collect the fee if it is not paid. Before declining to accept an OMOR application due to unpaid fees, the FDA is not compelled to notify requestors [28, 29].

Requesters are in the right position to keep an eye on their business partners to see if they are upholding their OMUFA fee responsibilities. Before filing an OMOR, the requestor must make sure that all of them have complied with its user fee responsibilities and those of its affiliates [30].

Facility fees

There are many repercussions if the facility fee is not paid:

- If a facility's yearly fee is not paid by the deadline stipulated in FD and C Act § 744M(e)(1)(A), in accordance with section 502(ff) according to the FD and C Act, the facility will be added to a list of facilities that are behind on payments, and all OTC monograph drug products created there or using a component made there will be declared misbranded
- Any OMOR submitted to the FDA by a person subject to a facility charge is deemed incomplete if they fail to pay the facility fee, and the FDA will not accept their OMOR for filing until all amounts due have been settled. A company ought to get in touch with the User Fee Management Division at the FDA website if it believes a facility's inclusion on the list of facilities in arrears is inaccurate and includes supporting documentation [31]
- When submitting an OMOR, if the proper payment is not made or the submitter is currently in arrears, the OMOR will be deemed incomplete and won't be allowed until all costs have been paid for filing. Requests for Monograph OTC medication meetings made by people who are behind on their OMOR fees will be declined or cancelled [32]

OMUFA registration process

The OMUFA registration process involves a few crucial steps as depicted in fig. 1.

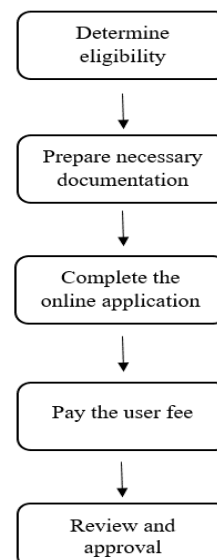


Fig. 1: OMUFA registration process

Steps Of OMUFA registration process

- **Determine eligibility:** Before initiating the registration process, manufacturers must determine if their products meet the eligibility criteria set by OMUFA. This includes ensuring that the products are classified as OTC drugs and have an active FDA monograph or are eligible for an OTC monograph
- **Prepare necessary documentation:** Manufacturers must gather all the required documentation for the registration process. This includes product formulation details, labeling information, safety data, manufacturing process details, and any additional information requested by OMUFA
- **Complete the online application:** Once the necessary documentation is prepared, manufacturers can proceed with the online application. This involves creating an account on the OMUFA website, providing product and company information, and uploading the required documents.
- **User fee to be paid:** As part of the registration process, manufacturers must pay the OMUFA user fee. The fee can be paid online through the OMUFA website using a secure payment gateway
- **Review and approval:** After submitting the application and paying the user fee, the registration is reviewed by OMUFA. The agency may request additional information or clarification during the review process. Once the review is complete and all requirements are met, the registration is approved, and the manufacturer receives a registration number [18]

Tips for successful OMUFA registration

- **Start early:** OMUFA registration can be a time-consuming process, so it is advisable to start early and allow ample time for gathering documentation, completing the application, and addressing any potential issues that may arise.
- **Seek professional assistance:** If the requestor is unfamiliar with the OMUFA registration process or finds it overwhelming, consider seeking professional assistance. There are consulting firms and experts who specialize in OMUFA registration and can provide guidance through the process, ensuring a smooth and successful registration.
- **Stay informed:** Requestors must stay updated with the latest regulatory requirements and guidelines issued by OMUFA. This can be done by regularly checking of FDA website, subscribing to newsletters, and attending industry conferences or webinars to stay informed about any changes or updates that may impact the registration of OTC products

- **Maintain accurate records:** It is crucial to maintain accurate records of all the documentation submitted during the registration process. This includes product formulation details, safety data, labeling information, and any correspondence with OmuFA. These records will be valuable in case of any future audits or inquiries
- **Prompt addressable concerns:** If OmuFA raises any concerns or requests additional information during the review process, requestors should address those promptly and provide the requested information in a timely manner. This will help expedite the review process and increase the likelihood of a successful registration [33]

Common challenges in OmuFA registration

- **Complex regulatory requirements:** The regulatory requirements for OmuFA registration can be complex and overwhelming for manufacturers. To overcome this challenge, a thorough review of the OmuFA guidelines and seeking professional assistance can help. Consulting companies that specialize in OmuFA registration can offer insightful advice to make sure all standards are met.
- **Lack of documentation:** Gathering all the necessary documentation for OmuFA registration can be a time-consuming task. To address this challenge, it is recommended to start early and to create a checklist of all the required documents. Maintaining organized records and ensuring that all documentation is complete and up to date is also important [34]
- **Communication with OmuFA:** Manufacturers may face challenges in effectively communicating with OmuFA during the registration process. It is important to maintain open lines of communication and promptly respond to any requests or inquiries from the agency. It is advisable to designate a dedicated point of contact within the organization to handle all communication with OmuFA
- **Navigating the online application:** The online application process for OmuFA registration may be unfamiliar to manufacturers. It is important to be familiarized with the application interface and ensure that all required fields are completed accurately. If any technical difficulty is encountered, it is advisable to reach out to OmuFA for assistance [35]

Benefits of OmuFA registration

OmuFA registration offers a wide range of benefits for OTC drug manufacturers.

- It provides manufacturers with legal authorization to market their products in the US. This registration guarantees that the OTC medications fulfil the required criteria for quality and are secure for use by the general population.
- OmuFA registration allows manufacturers to gain credibility and build trust with consumers and healthcare professionals. Registered manufacturers are seen as trustworthy and reliable sources of OTC drugs, which can significantly boost their sales and market presence
- OmuFA registration provides manufacturers access to valuable resources and information. Registered manufacturers receive updates on the latest regulatory requirements, guidelines, and industry trends. This information is crucial for manufacturers to stay compliant and adapt to the evolving regulatory landscape. OmuFA also offers assistance and support to registered manufacturers, helping them navigate any challenges they may face during the registration process or beyond [36]

Penalties for non-compliance with OmuFA registration

Non-compliance with OmuFA registration can have severe consequences for OTC drug manufacturers. The penalties for non-compliance can range from warning letters and fines to product recalls and even legal action. It is essential for manufacturers to understand and fulfill all the requirements of OmuFA registration to avoid these penalties and protect their business reputation. Below are the most common penalties:

- One of the most common penalties for non-compliance is the issuance of warning letters. These letters are sent to manufacturers who fail to register their OTC drugs or who violate any of the regulatory requirements. Warning letters serve as a formal notice of non-compliance and provide manufacturers with an opportunity to rectify the issue. Failure to address the concerns raised in the warning letter can lead to further penalties, including fines and product recalls [37]
- In serious cases of non-compliance, legal action may be taken against manufacturers. This can result in hefty fines, damage to the manufacturer's reputation, and potential closure of the business. It is crucial for manufacturers to take OmuFA registration seriously and ensure full compliance with all the regulatory requirements to avoid these severe penalties [38]

Refunds, fees disputes, and appeal process

- **Requests for refunds and disputes involving fees:** One can submit a formal request to the FDA asking for the recovery of any costs they feel were paid inadvertently or challenging the FDA's user fee assessment in other ways. The FD and C Act provides more details regarding the legal foundations for a return in Section 744M(a)(3). Requests for refunds or challenges to the FDA's user fee assessment must be submitted no later than 180 calendar days from the date the fee was paid. It should be noted that if an official request is not made in writing within 180 calendar days of the day the fee was paid, no refund of fees will be granted. A written request and Form FDA 3913 that is fully filled out is submitted to Division of User Fee Management via FDA website portal [39]
- **Reconsideration request:** If FDA rejects an organization's request for a refund or a charge reduction wholly or in part, the organization may ask FDA to review its decision. A request for reconsideration must be submitted within 30 calendar days of the FDA's decision to reject a refund or fee reduction request fully or partially. FDA suggests that requests for reconsideration include any additional information that is relevant to the entity's position as well as a justification for why the business believes the FDA's decision was wrong. The Agency will provide a statement in response after taking the reconsideration request into account and making its decision [40]. Emails requesting reconsideration must include the following information and be sent to CDERCollections@fda.hhs.gov 550: Division of User Fee Management, Division Director, The Centre for Drug Evaluation and Research (CDER), 555 [41]. CDER, 555 is a division of the USFDA responsible for regulating prescription and OTC drugs, including their approval, safety, and labelling [42].

Appeal request

The entity may decide to file an appeal if a request is turned down after being given another chance. Within 30 calendar days following the FDA's choice to uphold, an appeal must be made if it rejects a request for a refund or a reduction in user fees [43]. The appeal must contain all of the following details:

- Initial request
- The initial request's refusal
- The request for reconsideration
- The refusal of the request for reconsideration
- A justification for why the organization thinks the earlier judgments were incorrect [44]

All appeal requests must be directed to the Director of CDER's Office of Management and the CDER Formal Dispute Resolution Project Manager at CDERCollections@fda.hhs.gov [45]. The contact information is available on the CDER Formal Dispute Resolution webpage. An alternative is for an organization to mail the FDA the request using a carrier of their choice [46].

CONCLUSION

The OmuFA introduced a user fee system to improve the efficiency and regulation of over-the-counter (OTC) monograph medications. Its goals included expediting FDA assessments, reducing monograph

backlogs, and increasing the availability of safe OTC products in the market. The initiative successfully streamlined the approval process for OTC drugs, fostering innovation and facilitating faster access to essential medications. The program potentially empowered the FDA to enhance oversight, ensuring OTC monographs adhere to quality and safety standards. Improved communication between the FDA and industry may have boosted transparency. To accurately assess OMUFA's impact, real-time data is crucial. Manufacturers benefit from OMUFA registration, gaining legal authorization, credibility, and access to resources for market entry. Staying informed and addressing concerns ensures a smooth registration process, offering opportunities for OTC manufacturers in the competitive market.

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AUTHORS CONTRIBUTIONS

CA played a comprehensive role by conceptualizing and designing the study and was involved in literature search, data acquisition and analysis, statistical analysis, manuscript preparation, editing, and review. SM supported in study design and was actively involved in content preparation, data synthesis, manuscript preparation, editing, and review of the same. AM contributed to manuscript preparation, editing, and review. MP helped in the study conceptualization and review of the manuscript.

CONFLICTS OF INTERESTS

The authors declare no conflict of interest.

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