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## User Fees and the Future of the OTC Monograph System

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1. [Webinar – Overview of the FDA's Expanded Access Process](#) – July 12<sup>th</sup> at 1 PM EST
2. [REdI Pharmaceutical Quality Symposium](#) – July 20/21 – Silver Spring, MD.
3. Webinar - New Requirement for Electronic Submission of Drug Master Files : Question and Answer session." - *Coming Soon*
4. Introducing [CDER SBIA's new LinkedIn Showcase page](#) – Follow us!

Reform is in the air for over-the-counter (OTC) drug products. FDA's recent [public meeting on OTC Monograph User Fees](#) provided the opportunity to obtain input from industry and other stakeholders on the potential development of a user fee program for nonprescription (or OTC) monograph drugs. A user fee program could provide additional funding to support timely FDA review of the ingredients included in these products and to modernize the OTC review process.

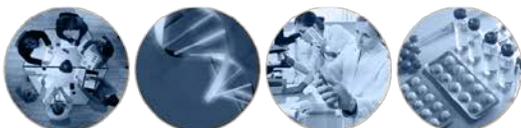
Because OTC drugs typically are easily accessible, require no prescription and are used for purposes of self-care, it is crucial that there is sufficient regulatory oversight. Since consumers often self-diagnose and self-treat with OTC drugs, these products have a very high rate of exposure to the American public, including children and the elderly. There are hundreds of thousands of OTC monograph drugs on the U.S. market today, and this number is growing.

Unfortunately, the current OTC monograph drug regulatory system is outdated and needs reform to help to ensure that drugs marketed under this system are effective and safe. A statutory user fee program would provide resources to alleviate the existing problems and make the OTC review process more efficient, but such implementation would require input and collaboration from all stakeholders. User fees would be expected to support proposed monograph reform efforts, in which discussions and negotiations are still ongoing.

In the public meeting, we heard from FDA staff - including CDER Director Dr. Janet Woodcock - consumer and healthcare professional organizations, industry associations, and members of the scientific community. Most of the speakers conveyed that a statutory OTC monograph user fee program may provide FDA with resources to encourage innovation and implement new measures to better protect the safety of public health. However, FDA also heard concerns that a user fee program could affect the availability of OTC products and the costs to consumers and small business.

**Our current system for OTC regulation:** Although OTCs are sometimes reviewed through submission of a product-specific new drug application (NDA), most marketed OTC products are regulated through a system of ingredient-based monographs that was implemented in the 1970s. The OTC monograph process is ingredient-based rather than product-based, and each ingredient-specific monograph must be finalized through a multi-step public rulemaking process that has proven to be labor-intensive and unwieldy, often resulting in each rulemaking requiring a long period of time for completion. Each monograph describes the conditions of use (for example, dosing) under which active ingredients are generally recognized as safe and effective for inclusion in an OTC drug. The monograph allows industry to market a drug product that contains a monograph ingredient without an approved NDA as long as the manufacturer complies with all applicable regulations.

There exist approximately 88 simultaneous rulemakings in 26 broad therapeutic areas, and approximately 800 active ingredients for over 1,400 different therapeutic uses. The OTC monograph drug review process remains one of the largest and most complex regulatory programs ever undertaken at FDA.



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**So what is wrong with the current system?** FDA has been able to make determinations about the general safety and efficacy of the active ingredients in thousands of OTC monograph drug products, providing consumers with access to drug products on which they depend. The current system also alleviates burden on the health care system by allowing self-care. However, the system is administratively taxing and has many downfalls, all of which reflect that FDA is critically under-resourced in this area.

- Oversight of OTC monographs and review of monograph drug products are supported by \$8.2 million of resources, reflecting approximately 30 full-time employees (FTEs) across the Center and 18 FTEs within CDER's Division of Non-Prescription Drug Products. For context, it takes approximately 18 FTEs to review one NDA.
- Though the monograph system began in the 1970s and many monographs were finalized, multiple OTC monographs have not yet reached finalization. As a result, there are OTC drug products on the market under proposed monographs and for which the FDA has not made a final determination on safety and effectiveness. At the current funding level, it would take multiple decades to review and finalize all of the monographs that are currently in this non-final status.
- With its current resources, it is difficult for FDA to modernize the OTC review process to keep up with evolving science and the fast pace of the pharmaceutical and consumer healthcare products industry. In contrast, the prescription new drug review process, which is supported by user fee programs, better encourages innovation.
- Many of the FDA's monograph review resources must be diverted to address urgent safety issues in nonprescription products. This means that definitive action on the general safety and effectiveness of non-final monograph drugs and innovation review can occur only as resources permit, and new safety information may not be rapidly incorporated into product regulation.

**How can an OTC Monograph User Fee Program fix these problems?** User fee programs have greatly modernized regulatory practices relevant to prescription, generic, and biosimilar drug products, providing vital resources that have enabled more timely and efficient evaluation of product safety and efficacy. User fees can be a source of stable and predictable funding, and can create incentives and benefits for stakeholders. Additional resources could enable FDA to provide more opportunities for communication regarding issues of innovation related to OTC products. The Agency currently has user fee programs that include those within CDER for new drugs (PDUFA), generic drugs (GDUFA), and therapeutic biologics (BsUFA). Through PDUFA, FDA receives resources and commits to various goals, including specific time frames for reviewing applications. Current user fee programs impose fees on products, facilities or establishments, and/or applications. An approach negotiated for OTC monograph-regulated products could resemble these programs or come up with different bases altogether.

To quote Dr. Woodcock, "it is possible that there would be a win-win-win - for the public, for the Agency, for the industry - in having a user fee program." The public and stakeholders would benefit from timely and efficient monograph review, response to safety issues, and communication. FDA could have the resources to review new testing methods and innovations. The Agency understands the need to consider possible consequences of OTC monograph user fees on manufacturers' costs and how these might be passed on to consumers. Many speakers at the public meeting urged that the implementation of OTC monograph user fees should be transparent and measurable. In their view, the focus of an OTC monograph user fee program should include the timeliness of review but also extend to innovation and the meaningful dimensions of modernization. Some meeting participants saw a need to account for less developed, smaller companies that may not be able to pay fees and to consider a tiered fee structure linked to the complexity of review required. Other stakeholders stated that a user fee program should not replace appropriated dollars to attend to currently non-finalized monographs. Many also asked that progress toward a user fee program be shared with the public. Collectively, we must understand how additional resources could better OTC regulation in meaningful ways, with a balanced and fair program that serves the self-care needs of patients and consumers.

Just as user fees have transformed FDA's review of the safety and efficacy of new prescription drugs, along with the timeliness and efficiency of their review, an appropriate user fee program could improve the OTC monograph system. Moving forward, FDA is considering the comments and concerns expressed in response to the public meeting. Information about the meeting is available on the [FDA website](#), including a webcast, transcripts, presentations, [Frequently Asked Questions](#), and [FDA Voice Blog](#).

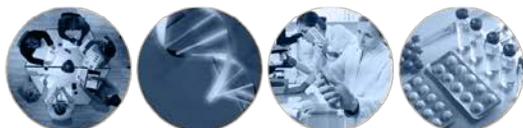
Until Next Time,

*Renu Lal, Pharm.D.*

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