Delivering on the Promise of Over-the-Counter Medicines

OTC Monograph User Fee Program (OMUFA) Reauthorization in 2025

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

The OTC Monograph System

There are approximately 100,000 safe and effective over-the-counter (OTC) drug products on the market giving consumers power to manage their self-care and to reduce the overall burden on other parts of the U.S. healthcare system. For more than 50 years, the U.S. Food and Drug Administration (FDA) has regulated OTC medicines under the OTC Monograph System. Established in 1972, the FDA developed this regulatory framework to review the safety and efficacy of OTC drugs.

The OTC Monograph system is how FDA regulates well-established drug ingredients and provides FDA's determination that these ingredients meet the legal, scientific standard of "General Recognition of Safety and Effectiveness" or "GRASE." Rather than requiring individual applications for each finished OTC product, OTC monographs are sets of rules and conditions for active ingredients in various categories that permit manufacturers to market OTC products without having to go through the new drug application (NDA) process required for newer OTC ingredients or prescription drugs.

Currently, there are 32 monographs for therapeutic categories such as analgesics, antacids, first aid, cough-cold, and many more.

The Story of OMUFA

The OTC Monograph System worked well for many decades, but over time, it became difficult for FDA to update product labels with new safety information based on new science and data. The resulting backlog also hindered the development of innovative products with established ingredients to meet growing consumer needs.

As part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act in 2020, Congress approved the OTC Monograph Drug User Fee Program, commonly referred to as "OMUFA." This legislation – which had bicameral/bipartisan support and broad support from stakeholders – both modernized the OTC Monograph System and provided the FDA with more resources, enabling the system to become more nimble, transparent, and conducive to innovation.

The user fee program requires reauthorization by Congress every five years.

As Congress begins work to reauthorize OMUFA in 2025, CHPA will be focusing on four key priorities:

1

Maintain the standard for "General Recognition of Safety and Effectiveness."

OMUFA should ensure the standard for safety and efficacy is unchanged and that it should primarily rely on published studies, potentially supplemented by unpublished research, data, and significant market experience.

2

Recognize that the process for determining the safety and efficacy of OTC medicines is distinct from the process for new drugs.

FDA's focus should be on assessing the safety and efficacy of active ingredients for conditions specified in the applicable monograph. This evaluation does not involve a review of inactive ingredients, which may vary among products authorized under a single monograph, as long as those inactive ingredients meet the applicable regulatory standards.

3

Make OMUFA meetings more productive.

Comprehensive advice and robust scientific dialogue during OMUFA meetings is essential. FDA should grant in-person meetings, provide opportunities for scientific dialogue, and offer comprehensive guidance based on legal principles with consideration of the full record, including any relevant OTC panel reviews.

4

Prioritize administrative orders and guidance for minor changes.

OMUFA requires FDA to establish a pathway for OTC makers to make minor changes in dosages without a formal FDA request, so long as they adhere to certain guardrails. By prioritizing this pathway, FDA would encourage more efficient development of important innovations in the OTC market — a significant hurdle in the previous monograph system — offering consumers easier access to improved and convenient dosage forms of safe and effective products.

About the Consumer Healthcare Products Association:

The Consumer Healthcare Products Association (CHPA) is the leading voice fighting to ensure that Americans have access to over-the-counter medications, dietary supplements, and consumer medical devices they can count on to be reliable, save money and time, and deliver new and better ways to get and stay healthy. CHPA's mission is to empower self-care by preserving and expanding choice and availability of consumer healthcare products.