Reforms to the OTC Monograph System:
A more responsive, innovative approach to regulating OTC medicines

OTC Monograph (OMUFA) reform
The Consumer Healthcare Products Association (CHPA) strongly supports the Over-the-Counter (OTC) Monograph system as a balanced framework for regulating OTC medicines containing ingredients with a proven history of safe use. We believe that policy reforms could make the system even more flexible, responsive, and accommodating to innovation. We support reform efforts by Congress to modernize the framework, so that FDA and industry are able to update products with safe, effective ingredients in the market today, so that FDA has the resources to approve safety labeling changes and innovation in the OTC market, and to finalize unfinished monographs.

OTC medicines and the Monograph system in context
OTC medicines are regulated under one of two systems. The new drug application (NDA) system requires a submission to the FDA, with review and approval prior to marketing. A minority of OTC medicines are marketed under this system, primarily medicines that were formerly limited to prescription. Meanwhile, most of the medicines in our homes are regulated under the OTC Monograph system. This includes nearly 300 active ingredients and over a hundred thousand products, ranging from antacids to diaper rash creams, from analgesics to cough/cold products.

The Monograph system has saved time and other resources for FDA since there is no need to re-review each individual product with established ingredients, already proven safe. For the makers of these medicines, it also saves time, resources, and provides for more efficient market access – stimulating competition, thus providing Americans with a wide array of affordable choices and access.

The Problem
In the 40-plus years since the OTC Monograph system was first created, the process is not yet complete and movement on unfinished items has ground to a halt. Further, there is no system in place to innovate in a timely manner, benefitting consumers and the marketplace. Change is needed to have a system that allows for advances in science, new information concerning safety of an ingredient, and completing unfinished monographs.

Today, monographs require notice and comment rulemaking. When an agency is setting requirements across a broad spectrum of the regulated community, notice and comment rulemaking makes sense. But when FDA is making scientific and medical determinations about a specific ingredient, such as a label warning, or a new dosage form, rulemaking is slow and cumbersome. These delays to label warnings can have serious implications to consumers.

Moving Forward – OMUFA
CHPA has worked with FDA and with Members of Congress to craft an update to the Monograph process by which FDA could make scientific determinations for these ingredients through an administrative order process with protections for dispute resolution and issue escalation. This would let FDA follow an approach that is closer to NDA procedures, but would continue to not require an individual product approval for every product with the same active ingredient.
Description of OTC Monograph (OMUFA) Legislation
OMUFA would add a new section to the federal Food, Drug, and Cosmetic Act (FDCA) to:
- include by reference existing OTC Review Final Monographs and deem final Tentative Final Monographs (TFM) by statute;
- move away from the cumbersome current monograph finalization process to an administrative order procedure. Such a procedure will have additional processes in place to ensure recourse should issues arise;
- create a mechanism for faster safety label changes;
- create new pathways and incentives to bring innovative monograph products to consumers;
- ensure the new drug approval pathway and other nonprescription drugs otherwise lawfully marketed are not affected; and
- authorize user fees so FDA has predictable resources to act on these reforms

Benefits of reforms to the Monograph system
The benefits of Monograph system reform include:
- Increased consumer protections, including more rapid action in the event of safety issues;
- Increased consumer confidence, due to stronger support of the system by FDA; and
- Increased consumer choice, facilitated by a system that enables innovation.

FDA, the regulated community, and the public all have an interest in the agency having the ability to make scientific decisions about established ingredients efficiently, and without having to resort to product-by-product determinations for medicines that are already in the market. An administrative order process with appropriate protections is a smarter means to this end.

*CHPA, founded in 1881, is a member-based association representing the leading U.S. manufacturers and distributors of nonprescription, OTC medicines and dietary supplements. For more information, please contact Marc Schloss at 202.429.3533 (mschloss@chpa.org) or visit chpa.org.*