For over 45 years, the Food and Drug Administration (FDA) has regulated the majority of over-the-counter (OTC) medicines under what’s called the OTC Monograph system. Established as a regulatory framework, the FDA developed this system to review the safety and efficacy of OTC ingredients, doses, formulations, and labeling used in medicines available to consumers without a prescription.

A Look Back
The original concept of the OTC Monograph system remains sound, but the way it operated broke down. It was outdated, cumbersome, and in desperate need of modernization. Lacking funding and staffing, when the FDA needed to make updates to existing monographs based on new science, the multi-layered rulemaking process could take years – resulting in difficulties updating product labels with new safety information and a back-log of monographs.

A Collaborative Approach
Recognizing the dire need for reform, FDA, Congress, public health stakeholders, and industry came together to drive historic change. As a champion and vocal advocate for OTC Monograph reform, the Consumer Healthcare Products Association (CHPA) strongly supported the bipartisan legislation – the Over-the-Counter Monograph Safety, Innovation, and Reform Act – that overhauled the system and will affect Americans for generations to come.

OTC medicines make up 60% of all medicines (Rx and OTC) – an estimated 100,000 products sold in the U.S.

OTC medicines are available 24/7 and provide millions of Americans with safe, effective, and affordable therapies to treat, manage, and prevent many common ailments and conditions.

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A Modern Regulatory System

The modernized OTC Monograph system provides the FDA with more resources and makes the OTC Monograph system more nimble, more transparent, more certain, and more conducive to innovation.

▶ Resources
• Increases funding and staffing, tripling the FDA’s capacity to work on OTC Monograph ingredients
• Enables the building of a critical IT infrastructure

▶ Nimble
• Removes barriers by creating an efficient review process within the FDA, while maintaining current high standards
• Allows FDA to more quickly address emerging safety and labeling issues

▶ Transparency
• Establishes an up-to-date, centralized, public database of information and labeling requirements

▶ Certainty
• Allows FDA to standardize procedures, processes, and requirements
• Sets actual timelines and performance goals for FDA on reviews and decisions

▶ Innovation
• Boosts innovation by creating a regulatory pathway
• Provides incentives to advance OTC options and broaden consumer choice
• Accommodates marketplace innovations, such as new uses for ingredients, dosage forms, and common-sense ingredient combinations

The OTC Monograph system has finally moved into the 21st century. It incorporates advances in science and incentivizes innovation to meet modern consumers’ needs – while making sure these medicines continue to be safe for consumers.

For more information, visit www.chpa.org.