Modern Regulation

After more than four decades, we now have a modern over-the-counter (OTC) Monograph system, the regulatory framework for OTC medicines, to unlock gridlock, spur innovation, and better serve consumers.

OTC Monograph reform benefits the healthcare system as a whole.

ENHANCE FDA EFFICIENCY AND CAPACITY

- Provide FDA with significantly more funding and staff to support OTC-related work
- Build a critical IT infrastructure to speed reviews and access to information

IMPROVE RESPONSIVENESS

- Enable FDA to quickly address labeling and safety issues
- Accelerate decisions considerably, while maintaining high standards

BOOST INNOVATION

- Create a pathway for innovation
- Support marketplace innovations, such as new uses for ingredients, dosage forms, and common-sense ingredient combinations

The concept of the OTC Monograph system remains sound but the way it operated broke down.

Developed in 1972, the system relied on an outdated, multi-layered rulemaking process that led to gridlock.

OTC monographs were backlogged and product labels could take years to update.

Congress, FDA, public health stakeholders, and industry came together with bi-partisan support to fix what was broken and create a modern regulatory system.

OVER-THE-COUNTER MEDICINES

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

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