OTC Monograph reform benefits the healthcare system as a whole.

8 in 10 adults use them as a first response to minor ailments.

60% of medicines make up 60% of medicines – an estimated 100,000 products sold in the U.S.

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Developed in 1972, the system relied on an outdated, multi-layered rulemaking process that led to gridlock.

The FDA lacked the necessary funding and staff to keep up with OTC-related work.

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

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 next 5 years with increased funding, FDA’s capability to work on OTC monograph ingredients will more than triple.

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

Improving the mechanics of this critical regulatory structure will increase the efficiency and responsiveness necessary to protect the public health and ultimately provide Americans with more self-care choices.