

July 17, 2017

Honorable Mitch McConnell
Majority Leader
United States Senate
S-230 The Capitol
Washington, DC 20510

Honorable Charles E. Schumer
Minority Leader
United States Senate
S-221 The Capitol
Washington, DC 20510

Re: Over-the-Counter Drug Monograph Reform

Dear Majority Leader McConnell and Minority Leader Schumer:

As the Senate begins considering legislation to reauthorize user fees for the Food and Drug Administration (FDA) to review new drug product applications, we urge you to enact policy that will modernize FDA's 40 year-old system for developing over-the-counter (OTC) drug monographs. The current system involves a three-phase public rulemaking process that can take years (and sometimes decades) to resolve.¹

Drug monographs specify the conditions and procedures that, if followed, would allow new OTC drug products to be marketed without prior FDA approval (e.g., anticaries drug products, first aid antibiotics, sunscreens, etc.). They stipulate the allowable formulation(s) and concentration(s) of active ingredients. They also include predetermined requirements for laboratory testing, package sizing, labeling (e.g., warning statements, directions for use, etc.), and more.

Drug monographs free the FDA from having to review every new OTC drug product the agency would ordinarily consider safe and effective and correctly branded. They also inspire confidence that these products will still meet generally accepted standards of safety and quality.

Unfortunately, the laborious administrative process for updating OTC monographs is leading to obsolete testing for safety, quality, and efficacy. Under the current regulatory scheme, FDA must go through a three-phase public rulemaking process to revise an OTC monograph. The process can take years (and sometimes decades) to resolve.

For example, the OTC monograph for anticaries drug products (products that aid in the prevention of dental cavities) has not been updated since 1995.² Newer and better tests are available to evaluate the safety, identity, strength, quality, and purity of these products (e.g., one minute fluoride release test in fresh and aged samples). The FDA monograph, however, requires that these products still be evaluated using decades old tests that are outdated and no longer necessary (e.g., caries reduction studies in animals).

Streamlining the FDA's monograph development process would make it faster and easier to replace outdated product testing requirements with more modern scientific tests and methodologies. It would also build confidence that new OTC drug products have met the latest and best available scientific standards for safety, identity, strength, quality, and purity.

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Again, we urge you to enact policy that will modernize FDA's 40 year-old system for developing over-the-counter drug monographs. We would be happy to work with you on this effort. If you have any questions, please contact Mr. Chris Tampio at 202-789-5178 or tampioc@ada.org.

Sincerely,

/s/

Gary L. Roberts, D.D.S.
President

GLR:KTO:rjb

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

¹ 21 CFR Part 330.

² 21 CFR Part 355.