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January 12, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Re: Over-the-Counter Drug Monograph Reform

Dear Chairman Walden and Ranking Member Pallone:

As the Energy and Commerce Committee continues 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, effective, and correctly branded. They also inspire confidence that these products will still meet generally accepted standards of safety and quality.

Currently, the regulatory scheme requires the FDA to go through a three-phase public rulemaking process to resolve an OTC monograph, taking years (and sometimes decades) to reach a resolution. Unfortunately, the laborious administrative process for updating OTC monographs is leading to obsolete testing for safety, quality, and efficacy.

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 The FDA monograph, however, requires that these products still be evaluated using decades old tests that are outdated and no longer necessary (e.g., caries reduction studies in animals).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.

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 Ms. Natalie Hales at 202-898-2404 or halesn@ada.org.

Sincerely,

Joseph P. Crowley, D.D.S.
President

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

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[1] 21 CFR Part 330.

[2] 21 CFR Part 355.