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September 13, 2017

Honorable Michael C. Burgess
Chairman, Subcommittee on Health
House Committee on
Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Honorable Gene Green
Ranking Member, Subcommittee on Health
House Committee on
Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: Modernizing FDA's Regulation of Over-the-Counter Drugs

Dear Chairman Burgess and Ranking Member Green:

As the House Energy and Commerce Committee begins considering legislation to reauthorize the Prescription Drug User Fee Act (PDUFA), we urge you to streamline 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 are a kind of "rule book" for allowing new OTC drug products to be marketed without prior FDA approval. The rule book contains 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 are also intended to inspire consumer confidence that these products are safe and effective.

Unfortunately, the laborious administrative process for updating OTC drug monographs is leading to obsolete testing for safety, identity, strength, quality, and purity.

For example, consumers assume the antigingivitis/antiplaque products they are purchasing have met the latest safety and effectiveness standards. However, the OTC monograph for anticaries drug products (products that aid in the prevention of dental cavities) has not been updated since 1995.[2] This means the safety and effectiveness of these products is being based on decades-old science when newer and better testing methods are available.

Consumers deserve to know that the oral health drug products they are buying comport with best available quality and safety standards. Streamlining the FDA's monograph development process would be an important step in that direction.

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. Megan Mortimer at 202-898-2402 or mortimerm@ada.org.

Sincerely,

/s/

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

/s/

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

GLR:KTO:rjb

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[1] 21 CFR Part 330.

[2] 21 CFR Part 355.