



APhA

2215 Constitution Avenue, NW • Washington, DC 20037-2985

July 31, 2018

RE: Regulatory Framework for Nonprescription Medications

Dear Commissioner Gottlieb:

The American Pharmacists Association (“APhA”) applauds the Food and Drug Administration (FDA) for revitalizing efforts to expand patient access to nonprescription medications. However, we are concerned the role of pharmacists and other health care professionals was not addressed in recently released guidance. As you may be aware, APhA worked with FDA to help develop and advance the framework commonly referred to as the Nonprescription Drug Safe Use Regulatory Expansion (NSURE). APhA continues to offer our expertise and urges FDA to better address the role of healthcare practitioners in its efforts to expand access to nonprescription medications.

APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Across all settings, patients rely on pharmacists to learn about safe medication use.

APhA reiterates our support for revising the drug classification paradigm to allow greater access to certain medications under conditions of safe use while maintaining patients’ relationships with their pharmacists and other health care providers. As FDA considers innovative approaches to expand patient access to a wider array of nonprescription medications, these approaches should not be the exclusive ways for consumers to gain access. Based on upon experience and data collected from an APhA-conducted demonstration project, technology alone often cannot replace the benefits of a health care professional, like a pharmacist. APhA believes pharmacists’ services and expertise need to be included among the approaches drug sponsors consider when identifying additional conditions necessary for safe and effective use for a nonprescription drug product.

As FDA works to increase patient access to safe and affordable medications, including those available without a prescription, APhA urges FDA to work with our organization and pharmacists, the medication experts on the patient’s health care team and the health care provider on the front lines of patients and their struggle against high drug prices. Should you have any questions or wish to gain insights from pharmacists, please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

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Executive Vice President and CEO

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs