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

September 17, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Innovative Approaches for Nonprescription Drug Products; Draft Guidance for Industry; Availability (Docket No. FDA-2018-D-2281)

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to submit comments in response to the Food and Drug Administration (FDA) Draft Guidance, "Innovative Approaches for Nonprescription Drug Products" (hereinafter, "Draft Guidance"). 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.

APhA supports FDA's efforts to increase patients' access to safe and affordable medications, however, we are disappointed the roles of pharmacists and other health care professionals are not considered in the approaches contained in the Draft Guidance. Across all settings, patients rely on pharmacists to learn about safe medication use. Consequently, APhA believes pharmacists' services and expertise need to be included among the approaches applicants consider when identifying additional conditions necessary for safe and effective use of a nonprescription drug product when the labeling alone is not sufficient.

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. In the Draft Guidance, FDA identifies two innovative approaches it may consider when determining safety and effectiveness for a nonprescription drug product for which the drug facts label (DFL) alone is not sufficient to ensure safety and effectiveness. APhA offers the following key considerations and recommendations for FDA as it finalizes the Draft Guidance and develops regulation that provide more information regarding conditions of safe use for nonprescription drug products.

I. Key Considerations for Changes to the Nonprescription Drug Paradigm

To better address patient access to nonprescription drugs requiring conditions of safe use, APhA urges FDA to work with pharmacists and other stakeholders in the development of a plan for modernizing the nonprescription drug approval process in advance of rulemaking. We offer the following for considerations in that development.

a. Framework: Any nonprescription drug framework must consider input from pharmacists and other health care practitioners, be based on science, clinical evidence and patient safety in actual use.

   i. *Consistent definitions and processes:* The process for drug availability through "conditions of safe use" or new methods to reduce risks with products must be uniform and standardized. Any new paradigm must ensure care processes for the patient and stakeholders are not disjointed, variable or confusing across different practice settings.

   ii. *Risk:* When evaluating products' risks, FDA must consider all mechanisms and their impact on different risks, as well as factor in individuals' abilities to appropriately select and use medications, and the length of use (e.g., long-term use).

   iii. *Public Input:* There must be an opportunity for public input on any applicant's proposal for a product moving through an application process under a modified nonprescription drug framework.

   iv. *Evidence and Clinical Experience:* Approval of any product, including its components (e.g., innovative technologies, interventions) need to be based on science, clinical evidence of efficacy and patient safety in actual use, and input from pharmacists and other health care practitioners.

   v. *Engagement with Practitioners:* To supplement technology limitations, patient engagement with practitioners, such as pharmacists, must be required as part of a successful treatment plan.

   vi. *Provider Education:* Once a product is approved, education must focus on the availability of a product, the targeted patient population, processes and logistical requirements of the program, clinical nuances, and resource materials for the pharmacist.

b. Communication Technology: Patient care and its impact can be supported and optimized through use of communication technologies, such as the EHR eCare plan, which facilitate relevant health care practitioners' access and input of information in a standardized way.

c. Ability to Bill for Services: Pharmacists must be compensated for the services required to provide patients' nonprescription medications requiring conditions of safe use.
   i. FDA's initiatives should not preclude payment for pharmacists' services by the patient, third-party payers, state programs, Medicare, the sponsor, or others.

II. Considerations for the Use of Innovative Technology as Outlined in the Draft Guidance

a. Standardization and Interoperability of Innovative Technologies

In the Draft Guidance, FDA indicates videos, mobile applications, text, and consumer affirmations are potential innovative technology options applicants may utilize for nonprescription product approval. However, the Draft Guidance does not provide any parameters around the

development of these innovative options. Without carefully considering mechanisms to enhance standardization and interoperability, patients may be confused about the information presented and how to access the technologies, decreasing the effectiveness and safety of the products. In addition, too many different technologies place burdens on health care practitioners. Standardization and interoperability, as learned in the REMS program, helps improve efficiency and reduce burdens on practitioners, among other benefits. As FDA considers innovative technologies, APhA urges FDA to identify approaches to standardization, make technologies interoperable with current systems and improve patient access.

b. Integration at the Point-of-Sale

APhA believes there is an opportunity to better capture and record patient use of nonprescription drugs by utilizing the innovative technologies contemplated in the Draft Guidance. Currently, pharmacists and other health care practitioners rely on patient reported use of nonprescription products which is infrequent. Under the Draft Guidance, it is foreseeable patients will need to report use, take specific action or provide certain metrics before becoming eligible to purchase nonprescription products with conditions of safe use. APhA and its members believe this is an opportunity to better integrate care, particularly nonprescription medications.

The Draft Guidance does not indicate how patients may access nonprescription medications at the point-of-sale. For example, it remains unclear how pharmacists will be made aware a patient has viewed a video and therefore, is eligible to purchase the product. If properly structured, tools to increase access to nonprescription medications could incorporate pharmacist-patient interactions, some of which need to be reimbursed (*see below* f. Inclusion and Reimbursement for Practitioner Services), to reduce risk and capture and integrate patient data. Additionally, these innovative solutions could be integrated within pharmacy systems to better document care. Such processes could also help facilitate post-market safety surveillance. APhA recommends FDA work with pharmacists and other health care practitioners to identify mechanisms to effectively integrate nonprescription products' innovative technologies and associated interventions into existing systems to enhance patient care.

c. Development of Additional Labeling to Ensure Safe and Effective Use

The Draft Guidance provides several different examples of additional labeling the Agency may allow to supplement drug facts labeling (DFL) for safe and effective use of nonprescription drug products. Examples provided include, text or images on a video display, including interactive displays for consumers to review, information displayed on websites and statements or questions in a mobile application. As FDA reviews these products, APhA encourages FDA to consider types of patients who may have difficultly accessing or understanding additional labeling, such as individuals with disabilities, those who lack internet access and those who do not speak English. APhA believes applicants and FDA should work with health care practitioners, such as pharmacists, to identify solutions to enable broad patient access to medications in circumstances where technology in not effective. In addition, as previously mentioned, APhA encourages FDA to work with applicants to standardize technologies and make them interoperable so pharmacists and other practitioners are not inundated with a plethora of innovative technologies.

d. Goals of Labeling

Medication labeling serves many different functions in helping patients better understand different aspects of a product. From the Draft Guidance, it is unclear whether FDA will be evaluating innovative technologies based on a consumer's ability to retain information or whether the desired goal of the labeling is achieved. For example, labeling providing administration instructions should have tests proving the information conveyed leads to proper administration by consumers, as opposed to demonstrating patients' knowledge of the steps. APhA requests FDA carefully evaluate whether additional labeling actually has the desired effect when relied upon by consumers in a real-world setting.

In addition, when the goal of labeling is to replace a service otherwise provided by a health care practitioner, it is important for FDA to consider other implications on patient care. APhA reminds FDA that efforts to rely on technology to replace services provided by health care practitioners could negatively affect patient safety and increase health care expenditures if use of nonprescription products are isolated from other components of care.

e. FDA's Role in Approving Apps

The Draft Guidance makes clear apps may be used to help patients self-select products or to serve as an additional condition to mitigate risks. However, it is not clear whether apps require approval by FDA as a device. APhA recognizes different circumstances and device functions may warrant FDA approval. APhA recommends FDA clarify whether and what conditions apps will need the Agency's approval as a device.

f. Inclusion and Reimbursement for Practitioner Services

While the Draft Guidance identifies examples regarding additional conditions for safe and effective use, we believe FDA should make clear provider interventions can be an additional condition and reimbursement needs to be allowed and included. Additionally, should a practitioner intervention be an additional condition, reimbursement for such a service must not be contingent on the patient's eligibility or decision to purchase the product.

g. Approval and Oversight

Although the Draft Guidance requests applicants consider how to ensure proper implementation of any additional condition necessary for safe and effective use, it does not provide parameters for implementation. APhA is deeply concerned applicants will view implementation on a product-by-product basis and fail to consider the broad impact on health care practitioners, patients and health care and retail environments. The Draft Guidance does not indicate how FDA will monitor and/ or evaluate these products, including their implementation. APhA believes FDA should develop and communicate its plan for oversight, which should address implementation and evaluation of the impact of products approved in accordance with the Draft Guidance.

h. Resources and Education

As previously noted, the Draft Guidance requires the applicant to consider implementation. Because it is foreseeable that implementation plans will be product-specific, APhA encourages FDA to

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provide additional resources and education to health care practitioners and patients regarding FDA's new policies and how such policies are anticipated to impact patient care.

APhA appreciates FDA efforts to empower consumers and urges FDA to work with our organization and pharmacists in developing mechanisms to help increase patient access to cost-effective treatments safely. 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,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

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