American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

April 19, 2017

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Medical Product Communications That Are Consistent With the FDA Required Labeling – Questions and Answers (Docket No. FDA-2016-D-2285)**

Dear Sir/Madam:

Thank you for the opportunity to comment on the draft guidance, "Medical Product Communications That Are Consistent With the FDA Required Labeling – Questions and Answers" (hereinafter, "Draft Guidance"). Founded in 1852 as the American Pharmaceutical Association, APhA represents 64,000 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, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

The accuracy and appropriateness of communications regarding drugs and devices is of great interest to pharmacists. APhA appreciates the Food and Drug Administration's (FDA) efforts to carefully consider communications that are consistent with FDA-required labeling for drugs and devices, including those that are licensed as biological products, and animal drugs. Accordingly, we support FDA providing guidance to firms to help clarify and provide consistency regarding the type of information that can be communicated.

## I. Communications to Consumers

As medication experts, pharmacists are often consulted by other health care practitioners and patients regarding the safety and effectiveness of medications. Pharmacists also provide valuable patient care services, such as medication therapy management (MTM) which helps optimize the impact of medications and limit harm to patients. Pharmacists possess a unique understanding of the pharmacokinetics and pharmacodynamics of medications, adverse

reactions, and dosing, among other topics. Since pharmacists are on the front-lines responding to patient questions that are the result of advertising, APhA recommends that health care professionals, including pharmacists, receive new product information on direct-to-consumer advertising campaigns prior to this information being made available to consumers.

In addition, APhA's House of Delegates policy[1] supports legislative and regulatory activities that allow direct-to-consumer (DTC) advertising concerning health conditions treatable by prescription or non-prescription drug products so long as the advertisements conform to rules and regulations that assure complete, comprehensive and understandable information that informs consumers of potential benefits and risks of the product. In its Draft Guidance, FDA attempted to clarify the scope of information that may be communicated with patients, including "information based on a comparison of the safety or efficacy of a medical product for its approved/cleared indication to another medical product approved/cleared for the same indication" and "information about the long-term safety and/or efficacy of products that are approved/cleared for chronic use." APhA cautions against allowing firms to communicate information that could lead to variable messaging from labeling requirements with regard to therapeutic equivalence, biosimilarity, and/ or interchangeability. Such variability could incorrectly imply differences between products, such as brand and generic products, making communications difficult to understand or misleading.

## II. Evaluating communications

APhA anticipates that many firms will expand their communications to patients and health care providers if the Draft Guidance is finalized as currently written since FDA interprets medical product communications to include promotional materials. APhA is concerned that there is currently not a process in place for FDA to adequately evaluate these communications and believes any system developed should not be overly burdensome for stakeholders to participate in or the Agency to administer. APhA encourages FDA to utilize a wide range of stakeholders, including pharmacists, patients and other members of the health care team, when developing and managing processes that will yield accurate communications about drugs and devices that are consistent with labeling.

Thank you for the opportunity to provide feedback on the promotion of regulated drug and medical products through communications consistent with FDA-approved labeling. APhA looks forward to continuing to work with FDA as well as other stakeholders on the development and implementation of a framework regarding such communications that balances the need to communicate relevant information with patient safety. If you have any questions or require

[1] *See* APhA House of Delegates policy regarding Direct-to-Consumer Advertising of Medications available at: /http://pharmacist.com/sites/default/files/files/Current%20Adopted%20Policy%2016088.pdf, last accessed March 27, 2017. The House of Delegates policy reads as following: 1. APhA supports legislative and regulatory activities permitting direct-to-consumer advertising concerning medical or health conditions treatable by prescription or nonprescription drug products. These advertisements must conform to rules and regulations that assure complete, comprehensive, and understandable information that informs consumers of potential benefits and risks of the product. 2. APhA opposes false or misleading advertising for prescription or nonprescription drugs or any promotional efforts that encourage indiscriminate use of medication. 3. APhA supports the availability of accurate information to consumers about medication use, and recognizes the responsibility of pharmacists to provide appropriate responses to consumer inquiries stimulated by direct-to-consumer advertising as a compensated pharmaceutical service. In addition, APhA recommends that health care professionals, including but not limited to pharmacists, receive new product information on direct-to-consumer advertising campaigns prior to this information being made available to consumers.(JAPhA 39(4): 447 July/August 1999)(Reviewed 2004) (Reviewed 2006)(Reviewed 2011) (Reviewed 2016)

additional information, please contact Jenna Ventresca, JD, Associate Director of Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

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

Cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs