American Pharmacists Association

FDA Public Meeting: Recommendations for
Over-the-Counter Monograph Drug User Fee Program (OMUFA)
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Statement of the American Pharmacists Association
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Good morning, my name is Heather Boyd, Director of Health Policy for the American Pharmacists Association (APhA). APhA is the only organization advancing the entire pharmacy profession.

I would like to thank the FDA for holding this public meeting to solicit stakeholder input and discuss recommendations for the reauthorization of the Over-the-Counter Monograph Drug User Fee program. APhA supports FDA's timely and efficient review of the efficacy and safety of all OTC products and ingredients.

Millions of patients and other health care professionals, especially pharmacists, rely on FDA's review of OTC ingredients and the accuracy of products' labeling to make recommendations regarding these OTC products. This significance is amplified by the number of OTC products on the market and the risks of these medications interacting with other OTC and prescription medications.

As you know, pharmacists are the medication experts on patient care teams and the most accessible health care professionals - with almost 90% of Americans living within 5 miles of a community pharmacy. Pharmacists play an important role in ensuring the safe and effective use of OTC medications. The inappropriate use of OTC drugs could lead to unanticipated and potentially harmful side effects. Pharmacists provide patients with the necessary information to make an informed decision on which OTC products to choose. Pharmacists also liaise with other health care providers in the management of self-care practices by patients. Pharmacists advise patients on the best OTC-medications and give advice on how to take their medication safely. Often, pharmacists provide the only advice that patients receive regarding OTC medications. When pharmacists take the time to counsel patients about OTC products, the results are significant. In one study, following pharmacist consultations, 42.6% of patients changed their OTC choice, 8% made no purchase, 4.3% were referred to a physician, and 7.1% avoided a potential adverse drug effect (drug–disease interaction, drug–drug interaction, additive side effects, duplication of therapy). Surveys have shown that over 41 percent of pharmacists make recommendations for six to 10 OTC products per day.

FDA is also in the process of finalizing the Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU) proposed rule. The ACNU proposed rule does not fully recognize the essential role a pharmacist plays in assessing the appropriate use and

dispensing of medications and the significant operational and logistical issues associated with implementation of this rule.

Safety concerns must be mitigated and there is currently no established pathway for this in the United States. FDA must ensure pharmacists play their essential role in assisting patients to determine whether a particular ACNU or OTC product is appropriate for each individual patient's healthcare needs. Given the large number of OTC medications on the market accessible to millions of consumers, OMUFA provides an opportunity to develop a pathway that provides greater access to prescription drugs that may have some conditions for use and capitalize on the knowledge, experience, trust, and access of the pharmacist.

Thank you for the opportunity to provide APhA's perspective at today's meeting. APhA looks forward to continuing to support FDA's efforts to broaden access to safe medications under OMUFA that maximizes the expertise of our nation's pharmacists.