APhA
American Pharmacists Association

October 26, 2023

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

RE: Docket No. FDA-2023-N-3575: Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments

Submitted electronically via www.regulations.gov to Docket No. FDA-2023-N-3575

Dear Food and Drug Administration staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) request for comments titled "Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments." APhA's comments include our statement given at the Public Meeting on the Reauthorization of the Over-the-Counter Monograph Drug User Fee Program (OMUFA) on September 28, 2023.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA's statement from FDA's September 28th meeting is below.

FDA Public Meeting: Recommendations for
Over-the-Counter Monograph Drug User Fee Program (OMUFA)
September 28, 2023

Statement of the American Pharmacists Association
Heather Boyd, MPP
Director, Health Policy

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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 there are significant operational and logistical issues associated with implementation of this rule. These operational and logistical issues must be addressed for an ACNU to be successful in the marketplace.

There currently is no clear pathway for greater access to drugs that could be available without a prescription but have some safety concerns that could be mitigated with an intervention of a pharmacist. We urge FDA to ensure that 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 fix the gaps in the ACNU scheme and 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.

Conclusion

APhA would like to thank FDA for giving us the opportunity to provide our perspective at FDA's public meeting on OMUFA held September 28, 2023. We look 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. If you have any questions, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice & Government Affairs