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November 22, 2022

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

**Re: Nonprescription Drug Product With an Additional Condition for Nonprescription Use**  
**[\[Docket No. FDA-2021-N-0862\]](#)**

Dockets Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback to FDA's Nonprescription Drug Product With an Additional Condition for Nonprescription Use proposed rule. NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA appreciates the proposed rule's intent to improve public health by broadening the types of nonprescription drug products that are available to consumers. However, we have significant concerns that the essential role a pharmacist plays in the dispensing process has not been appropriately considered.

According to the proposed rule, under an additional condition for nonprescription use (ACNU), a drug manufacturer must ensure that patients can appropriately self-select a medication. FDA states that under this new class of drugs, patients can complete a questionnaire or view a video with assessments to confirm their understanding of the medication. In addition, drug manufacturers could also provide information to customers via in-pharmacy kiosks, apps, and online. Unfortunately, this proposed rule envisions such medication as being administered without the supervision of a healthcare practitioner, and specifically, does not provide any scenarios or examples where a pharmacist would be involved in determining whether a medication is appropriate for an individual patient.

**NCPA opposes FDA's proposed ACNU class of drugs given our concerns with its safety, administrative burden, and payment implications.**

## **Safety Concerns**

We believe pharmacists should not be excluded from this patient self-selection process. **Pharmacists are primary guardians of the public health and must retain their ability to supervise and consult with prescribers and patients within their scope of practice. A pharmacist's primary responsibility is to ensure appropriate medications for their patients.** Additionally, pharmacists are an important part of the comprehensive health care team. They educate and counsel patients to help them find the best medication and use their medications correctly and safely. NCPA appreciates FDA's efforts to broaden access to safe medications. However, we strongly believe that this proposed rule undermines the pharmacist's essential role in ensuring the safety of medications for patients.

## **Administrative Burden Concerns**

The FDA's proposed rule also will likely create additional undue administrative burden for pharmacists. For example, while the ACNU category is designed to create drugs used by consumers without the supervision of a healthcare professional, pharmacists may still receive questions from consumers about the kiosk or questionnaire, or the drugs themselves. Despite being completely cut out of the ACNU category, pharmacists may nevertheless be held responsible for making sure that patients comply with the regulation. NCPA expresses concern that an ACNU class would cause incomplete and inaccurate patient profiles. Should patients receive a drug from a kiosk or video service, for example, this interaction may not be properly reported to the pharmacy. This in turn would affect patient safety, as pharmacists would not have full knowledge of the medications that their customers are taking.

## **Additional Payment Concerns**

Additionally, NCPA believes that the ACNU model will create increased confusion for consumers surrounding payment. Once drugs are in the ACNU category, payers and PBMs will likely cease any coverage, therefore shifting payment to the consumer. This may lead to increased consumer costs, which could deter adherence to needed medications. NCPA is also concerned that this additional class may face uncertain or lower reimbursement through FSA or HSA programs.

## **NCPA Supports Greater Prescriptive Authority in lieu of this Rule**

Pharmacists have prescribing authority in most states, and patients can benefit from greater access to medications through pharmacists increased prescriptive authority. NCPA opposes the FDA's proposed rule establishing a nonprescription i.e., OTC drug product with an additional condition for nonprescription use (ACNU) given the lack of healthcare practitioner supervision; a kiosk or 1-800 number or website cannot substitute for pharmacist expertise.

## **Conclusion**

NCPA support FDA's goal of improving patient access to needed medications. However, leaving out the pharmacist, and issues related to access create barriers to success of this initiative. Thank you again for holding a listening session on November 15 with us and the American Pharmacists Association, American Society of Consultant Pharmacists, National Association of Chain Drug Stores, and National Alliance of State Pharmacy Associations to hear our concerns. We hope you

will take the recommendations discussed in the listening session and in our comment letters submitted to the docket into consideration as FDA works to finalize this proposed rule.

While this proposed rule seems logical and easy to implement, there are significant issues related to operations, logistics for the patient and the pharmacist/pharmacies that need to be considered as FDA considers finalizing this rule. NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with FDA to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at [steve.postal@ncpa.org](mailto:steve.postal@ncpa.org) or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

Steve Postal, JD  
Director, Policy & Regulatory Affairs  
National Community Pharmacists Association