



**Department of Health and Human Services
Food and Drug Administration
[Docket No. FDA-2025-N-4731]**

January 22nd, 2026

As a nonpartisan advocacy organization focused on advancing preventive health for all women and girls, the Alliance for Women's Health and Prevention (AWHP) is invested in policies that expand access to safe nonprescription medications. As such, AWHP appreciates the opportunity to provide input in response to the Food and Drug Administration's (FDA) Request for Information (RFI) on Increasing Access to Nonprescription Drugs (Docket No. FDA-2025-N-4731). We commend the FDA and administration for advancing self-care, a core component of empowering individual health, and for mobilizing around safe, accessible nonprescription medications as a core tenet of this agenda.

Nonprescription, over-the-counter (OTC) drugs are essential for Americans nationwide, every single day. That value was especially evident during three years of pandemic-driven disruptions, when consumers relied on OTC tools — even rapidly adopting OTC COVID-19, and later flu, diagnostics. For many women, nonprescription options remain a practical way to access timely care while balancing work, caregiving, and other responsibilities — particularly when cost and scheduling barriers delay routine visits.

Women are often the healthcare decision-makers for both themselves and their households, and they, among other Americans, are navigating rising costs and persistent barriers to timely care. Expanding access to safe and effective nonprescription options can help women manage common health needs earlier, more conveniently, and at lower cost. This benefit spills over to the broader healthcare system by reducing unnecessary utilization of higher-cost care settings.

The most direct way to expand access to nonprescription drugs is to ensure that appropriate, safe therapies can move efficiently from prescription status to nonprescription, OTC availability. The switch pathway has long been a proven mechanism for improving access, supporting self-care, and lowering healthcare costs. Though it has been available and used for years, its utilization has not kept pace with today's healthcare needs and environment, as well as the broader shift to patient empowerment. A more transparent, predictable, and modernized switch pathway would help increase access to innovative nonprescription options — including for health needs that women manage across the lifespan for themselves and their families.

To that end, we're pleased to share the appended white paper, "[Empowering Consumers, Reducing Costs, Improving Health: Reforming the Prescription to Over-the-Counter Drug Pathway – A Patient Centric Approach](#)." Based on input from 16 patient organizations, this paper was created in collaboration with the

Alliance for Aging Research and outlines practical steps that the FDA, industry, and patient advocates can all take to increase access to nonprescription drugs via a strengthened OTC switch pathway.

Our recommendations are grounded in the principle that access is not just about availability — it's about safe, empowered decision-making for all Americans. Of note, the paper highlights where appropriate OTC switches could improve access and affordability for women specifically, including urinary and sexual health conditions.

Thank you for considering AWHP's perspectives and taking the time to request input and meet later this year regarding such an important issue. We look forward to continued engagement with FDA on policies that expand safe access, strengthen consumer confidence, and ensure women can benefit from innovative nonprescription options.