NATIONAL CONSUMERS LEAGUE
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**Comments to the Food and Drug Administration (FDA)**
**Expert Panel on Menopause and Hormone Replacement Therapy for Women**
**July 17, 2025, Convening**
**Docket ID: FDA-2025-N-2589**

*Submitted electronically September 24, 2025*

The National Consumers League (NCL) requests that FDA remove the boxed warning for local vaginal estrogen products, the most effective treatment for the Genitourinary Syndrome of Menopause (GSM).

NCL is the nation's pioneering consumer organization, providing government, businesses, and other organizations with the consumer's perspective on key issues including healthcare, food safety, child labor, and privacy. NCL advocates for policies that increase access to more affordable healthcare and is a member of the Menopause Advocacy Working Group, which works to change the conversation around menopause, so women get the information they need and the healthcare they deserve, including for GSM.

## The FDA Should Remove the Boxed Warning in Labeling for Local Vaginal Estrogen Products

GSM is a chronic and progressive condition that causes genital, sexual, and urinary symptoms that can impair quality of life, health, and sexual function. GSM impacts up to 50–90% of postmenopausal women; however less than 25% seek help with their symptoms and even fewer are aware or know of the condition.

Local vaginal estrogen is an FDA-approved medicine that is considered the 'gold standard' for treatment of GSM. However, the FDA's boxed warning is based on class labeling for systemic estrogen products and has not been updated to reflect the evidence for local estrogen, which has not been shown to increase the risk of heart attack, breast cancer, or stroke (for additional information, see Appendix A, Menopause Advocacy Working Group letter to Commissioner Makary and Associate Commissioner for Women's Health Vasisht). As a result, the labeling is not consistent with current recommendations from major medical societies,

including the American Urological Association[1], the American College of Obstetricians and Gynecologists[2], and The Menopause Society[3], which supports the use of local estrogen products.

The boxed warning has significant real-world consequences. It deters doctors from prescribing local estrogen to treat GSM and women do not adhere to their medications after they see the warning. As a result, many women suffer unnecessarily from avoidable conditions such as urinary tract infections and painful intercourse, which could otherwise be effectively treated.

Misinformation continues to create confusion in healthcare, including when public health agencies and major medical societies diverge significantly in their recommendations. When patients turn to public health agencies for guidance on medication risks and benefits, they need confidence that the information is grounded in the most up-to-date science. In reviewing the labeling, FDA should strongly consider the evidence-based recommendations from leading medical societies to ensure that patients are provided with consistent guidance.

Given the advancements in understanding the risks and benefits of local vaginal estrogen in treating GSM, NCL requests that FDA remove the boxed warning. NCL appreciates the opportunity to share our position on the issues women face while navigating menopause and its related conditions.

Sincerely,

Sally Greenberg
Chief Executive Officer
National Consumers League

[1] Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline (2025) - American Urological Association
[2] Treatment of Urogenital Symptoms in Individuals With a History of Estrogen-dependent Breast Cancer | ACOG
[3] nams-2022-hormone-therapy-position-statement.pdf