

Petition Filed with FDA to Approve Xylitol as an Active Ingredient in Dental Hygiene Products

AMERICAN FORK, UT, UNITED STATES, October 1, 2025 /EINPresswire.com/ -- The American Dental Hygienist Association (ADHA) in conjunction with Xlear, a leader in hygiene products, filed a citizen petition with the U.S. Food & Drug Administration (FDA)



urging the FDA to formally recognize xylitol as an approved Over-the-Counter (OTC) active ingredient in dental hygiene products, including toothpaste, rinses, gels, mouthwashes, gums, and lozenges.

Xylitol-based dental hygiene products are already widely available in the US. FDA approval of xylitol as an OTC anti-caries ingredient would formally recognize xylitol's effectiveness in fighting cavities and offer American consumers a more effective alternative to fluoride-based dental hygiene approaches.

The petition highlights decades of scientific evidence showing that xylitol directly reduces the bacteria responsible for cavities (*Streptococcus mutans*) and reduces the bacteria's ability to produce the acid that eats away at our teeth. Xylitol addresses the root cause of tooth decay. In contrast, fluoride strengthens tooth enamel. Fluoride has almost no effect on the bacteria that causes tooth decay. Studies have shown that xylitol has a higher "protection factor" in fighting cavities than fluoride.

"Dental decay is the single most common communicable, chronic disease inflicting Americans today. Moreover, dental decay is also closely associated with driving other serious health risks - ranging from heart disease to diabetes," said Trisha O'Hehir, MS, RDH.

"For nearly a century, fluoride has been the singular solution for cavities, yet 90% of American adults still experience dental decay," said Nate Jones, CEO of Xlear. "Xylitol doesn't replace fluoride, but it offers something different: a safe, evidence-based way to target the bacteria that actually cause cavities. Together, enamel strengthening compounds and xylitol can provide a more complete approach to oral health."

If granted, the petition would amend the FDA's Anti-caries Monograph to include xylitol,

expanding consumer access to products that help improve oral health and stronger, healthier teeth.

Key Facts:

- Nearly 90% of U.S. adults have experienced tooth decay.
- Studies show xylitol can reduce cavities by up to 80%.
- Xylitol works by neutralizing acid-producing bacteria and protecting enamel at the source.
- Xylitol is safe if swallowed, a key benefit for children.
- Widely used internationally, xylitol is already found in gum and oral hygiene products.

About the Petition

The petition requests that FDA:

1. Amend 21 C.F.R. Part 355 to list xylitol as an approved anti-caries active ingredient.
2. Alternatively, issue a new OTC monograph under Section 505G of the FDCA.

[For a copy of the full petition click here.](#)

[To sign the petition, click here.](#)

About ADHA:

ADHA represents the 220,000 registered dental hygienists (RDHs) nationwide.

About Xlear:

Xlear is one of the nation's leaders in effective xylitol hygiene products, available in pharmacies, big box stores, natural retailers and online.

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EDITOR'S NOTE: For more information and to arrange to speak with a company spokesperson, please contact Nancy Trent or Pamela Wadler at 212-966-0024 or pam@trentandcompany.com.

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