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FDA Launches PMTA Review Pilot Program in Effort to Increase Efficiency with Nicotine Pouch Applications

The FDA has launched a pilot program that aims to increase efficiency and streamline the review process for premarket tobacco product applications (PMTAs) for nicotine pouch products.

In its press release, the FDA said it would use tobacco harm reduction and the continuum of risk in reviewing applications since there is evidence that nicotine pouches can help some adults switch away from more harmful tobacco products. The FDA will consider available evidence to assess impact of the applicant products to users, non-users and the population as a whole.

Additionally, the pilot will aim to increase transparency of the PMTA process by increasing real-time communication between FDA and applicants with the goal of providing more frequent feedback and shorter review timeframes, which includes ongoing conversations with applicants to discuss missing information or request clarification with the hope to address issues sooner.

Earlier this year, The FDA issued the first PMTA authorizations for nicotine pouches when it issued Marketing Granted Orders (MGO) for 20 Zyn pouch products. The FDA cited that Zyn's PMTA applications demonstrated substantially lower amounts of harmful constituents than cigarettes and most smokeless tobacco products and provided evidence from a study showing that a substantial proportion of adults who use cigarette and/or smokeless tobacco products completely switched to the newly authorized nicotine pouch products.

State Legislative Sessions

California: Adjourned its 2025 session. As result, the following bills did not pass, but will carry over to the 2026 session:

- AB957 would prohibit a pharmacy from engaging in the retail sale of cigarettes or tobacco products.
- AB 762 would ban the sale of disposable vapor products.
- SB501 adds regulation to the management and handling of hazardous waste and hazardous materials, to include a vape take back program.

All 50 states are holding state legislative sessions in 2025. The following 8 states are currently in session:

- MA, MI, NJ, NC, OH, OR (special session) PA, WI

40 states have adjourned their 2025 legislative session:

- AL, AK, AR, AZ, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MN, MO, MT, NE, NH, NY, ND, MS, MO, NV, NM, OK, RI, SC, SD, TN, TX, UT, VA, VT, WA, WV & WY