Meeting of the Tobacco Products Scientific Advisory Committee

January 22, 2026

TPSAC Committee Members (Voting)	**FDA Participants (Non-Voting)**
Cristine Delnevo, Ph.D., M.P.H., (Chairperson)	Bret Koplow, J.D., Ph.D.
Mignonne C. Guy, Ph.D.	Benjamin Apelberg, Ph.D.
Sven-Eric Jordt, Ph.D.	Cindy Chang, Ph.D., M.P.H.
Lyudmila (Lucy) Popova, Ph.D.	Apoorva Rajan-Sharma, Ph.D., M.A.
Nancy A. Rigotti, M.D.	Amanda Fidalgo, Ph.D., M.A.
Risa J. Robinson, Ph.D.	
NFN Scout, Ph.D., M.A.*	**FDA Advisory Consultants and Staff (Non-Voting)**
Dona Upson, M.D., M.A.**	Jennifer Schmitz, M.P.H.
	Rachel Jang, Pharm.D. (Designated Federal Officer)
Industry Representatives (Non-Voting)	
William Andy Bailey, Ph.D. (Growers)	
Maria Gogova, M.D., Ph.D. (Manufacturers)	
Amy Madl, Ph.D., DABT (Small Business)	
Ex-Officio Participants (Non-Voting)	
Alberta Becenti, M.P.H.	
Lisa Postow, Ph.D.	
Temporary Members (Non-Voting)	
Neal Benowitz, Ph.D.	
Olivia Wackowski, Ph.D., M.P.H.	

Legend
* General Public Representative
**State, Local, or Federal Government Representative

Tobacco Products Scientific Advisory Committee (TPSAC)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Virtual Meeting

January 22, 2026

These summary minutes for the January 22, 2026, meeting of the Tobacco Products Scientific Advisory Committee were approved by the TPSAC Chair on March 13, 2026, and by Office of Science, CTP, on March 16, 2026.

I certify that I participated in the January 22, 2026, meeting of the Tobacco Products Scientific Advisory Committee and that these minutes accurately reflect the matters presented and discussed at the meeting.

Rachel Jang

Rachel Jang, Pharm.D.
Designated Federal Officer

Cristine Delnevo, Ph.D., M.P.H.
Chair

The Tobacco Products Scientific Advisory Committee (TPSAC) of the U.S. Food and Drug Administration (FDA), Center for Tobacco Products (CTP), met virtually on January 22, 2026. Prior to the meeting, FDA provided committee members and invited participants with copies of the background materials. Cristine Delnevo, Ph.D., M.P.H. (Chairperson), called the meeting to order. Rachel Jang, Pharm.D. (Designated Federal Officer, DFO), took roll call and read the conflict-of-interest statement into the record. Approximately 507 people attended virtually. A total of 21 people spoke during the Open Public Hearing session.

Agenda: *On January 22, 2026, the committee met in open session to discuss the modified risk tobacco product applications (MRTPAs) submitted by Swedish Match USA, Inc., for the following products:*

- *MR0000268.PD1: ZYN Cool Mint 3 mg*
- *MR0000268.PD2: ZYN Cool Mint 6 mg*
- *MR0000268.PD3: ZYN Peppermint 3 mg*
- *MR0000268.PD4: ZYN Peppermint 6 mg*
- *MR0000268.PD5: ZYN Spearmint 3 mg*
- *MR0000268.PD6: ZYN Spearmint 6 mg*
- *MR0000268.PD7: ZYN Wintergreen 3 mg*
- *MR0000268.PD8: ZYN Wintergreen 6 mg*
- *MR0000268.PD9: ZYN Citrus 3 mg*
- *MR0000268.PD10: ZYN Citrus 6 mg*
- *MR0000268.PD11: ZYN Coffee 3 mg*
- *MR0000268.PD12: ZYN Coffee 6 mg*
- *MR0000268.PD13: ZYN Cinnamon 3 mg*
- *MR0000268.PD14: ZYN Cinnamon 6 mg*
- *MR0000268.PD15: ZYN Smooth 3 mg*
- *MR0000268.PD16: ZYN Smooth 6 mg*
- *MR0000268.PD17: ZYN Chill 3 mg*
- *MR0000268.PD18: ZYN Chill 6 mg*
- *MR0000268.PD19: ZYN Menthol 3 mg*
- *MR0000268.PD20: ZYN Menthol 6 mg*

Bret Koplow, J.D., Ph.D., FDA CTP Acting Center Director, provided FDA opening remarks. Keagan Lenihan, Vice President and Chief External Affairs Officer at Philip Morris International (PMI), introduced the applicant's presentation and gave an overview of the products included in the applications. Additional presentations from Swedish Match USA, Inc., and PMI were given by Tryggve Ljung, M.D., Ph.D., Global Medical Head of Oral Products at Swedish Match USA, Inc.; Jessica Seifert, Ph.D., M.P.H., Head of Regulatory Insights at PMI; and Ms. Lenihan. These presentations focused on MRTP statutory requirements; clinical and nonclinical scientific assessment; consumer understanding, perceptions, and behavior; and responsible marketing for communicating the proposed modified risk claim. Several TPSAC members asked the applicant clarifying questions prior to a brief morning break.

The meeting resumed with presentations from FDA, beginning with an overview of the relative health risks of the products in question by Cindy Chang, Ph.D., M.P.H., Chief of Epidemiology

Branch I. Presentations from Apoorva Rajan-Sharma, Ph.D., M.A., Social Scientist, and Amanda Fidalgo, Ph.D., M.A., Social Scientist, on consumer understanding, risk perceptions, likelihood of use, and impacts to the population as a whole followed. Dr. Chang provided overall conclusions, and TPSAC members asked clarifying questions. The meeting proceeded to lunch break.

The meeting resumed after lunch with the Open Public Hearing (OPH) session, where 20 OPH speakers representing 21 organizations provided their comment virtually:

OPH Speakers:

1. Brad Rodu, University of Louisville
2. Lauren Lempert, University of California, San Francisco
3. Alex Weatherall, convenience store owner
4. Lindsey Stroud (filling in for Julie Gunlock), Independent Women's Forum
5. Ed Lopez-Reyes, 60 Plus Association
6. Guy Bentley, Reason Foundation
7. Raquel Mitchell, Moms for America
8. Mario Lopez, Hispanic Leadership Fund
9. Lindsey Stroud, Tobacco Harm Reduction 101
10. Drew Tardiff, Campaign for Tobacco-Free Kids
11. Amanda Smith, Native American Business Association
12. Gretchen Wartman, National Minority Quality Forum
13. Jasjit Ahluwalia, Brown University
14. Leah Vukmir, National Taxpayers Union
15. Christina Smith, Taxpayers Protection Alliance
16. Sherwin Herring, Southco Distributing Company
17. Akashleena Mallick, National Center for Health Research
18. Scott Ellis, Michigan Licensed Beverage Association
19. Jessi Troyan, Cardinal Institute for West Virginia Policy
20. Jennie Salyer, Gallatin Redrying and Storage Company
21. Tim Hwang, Foundation for American Innovation

Following the OPH session, Benjamin Apelberg, Ph.D., Deputy Director in the Office of Science, provided a Charge to the Committee and introduced the discussion questions. Dr. Delnevo led the committee through discussion topics 1 through 3 before a brief afternoon break. After the break, the committee discussed question 4.

The discussion questions and committee comments/responses were as follows.

Discussion 1: Accuracy of Proposed Modified Risk Claim

Background:

- The proposed modified risk claim: "Using ZYN instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis."
- The majority of harmful and potentially harmful constituents (HPHCs) are below the level of quantification in ZYN, and the biomarker study of people who use nicotine pouches are consistent with the product chemistry data.
- In the absence of long-term health risk studies of nicotine pouches, Swedish snus

epidemiological studies show that snus use is lower risk compared to combusted cigarette smoking for mouth cancer, heart disease, stroke, lung cancer, emphysema, and chronic bronchitis.

Discuss whether the proposed modified risk claim is substantiated by the scientific evidence.

Committee Discussion:

TPSAC members agreed that the proposed modified risk claim is substantiated by the scientific evidence. However, some committee members raised concern that Swedish Match USA, Inc., relied too heavily on a comparison with General Snus products rather than providing original data on the Zyn products under consideration. Some committee members also noted the lack of long-term epidemiological evidence of the health risks of the products. One committee member raised concerns about the incidence of respiratory conditions, including asthma, in children in countries with high childhood snus use. Another committee member urged FDA to update the HPHC list to include potential toxins in non-combustible products. In all, committee members agreed that these products are almost certainly less risky than combustible cigarettes, but not risk free, and that long-term monitoring is necessary.

Discussion 2: Consumer Understanding and Perceptions

Background:

- The applicant provided evidence about whether consumers understood:
    - The risk reduction described in the claim (i.e., ZYN confers lower risk than combusted cigarettes).
    - Although conferring lower risk than combusted cigarettes, ZYN still confers health risks.
    - How to use ZYN to confer lower health risks.

Discuss the available evidence about consumers' understanding of the proposed modified risk claim and their perceptions of ZYN.

Committee Discussion:

Based on the evidence provided by the applicant, TPSAC members agreed that consumers understand that ZYN products confer fewer health risks than combusted cigarettes but are not risk free. However, some committee members stated that these perceptions are preconceived and that the added modified risk claim will not increase understanding. One committee member urged FDA to review the non-publicly available data provided by the applicant on comparative risk perceptions between ZYN and other products, including e-cigarettes, other nicotine pouch products, nicotine cessation therapies, and complete cessation. Some committee members expressed concern that not all consumers will understand that they need to completely switch away from combusted cigarettes to ZYN pouches to confer lower health risks. One limitation that committee members flagged was the reliance on data collected about Swedish snus, not ZYN products. One committee member highlighted the need for health risks and adverse

effects to be prominently displayed on product cans to increase public awareness of the risks the products pose. Another committee member expressed concern that some consumers may mistake the meaning of "tobacco-free" in the products' descriptions to be "nicotine-free," and wrongly assume that the products are not addictive.

Discussion 3: Impact to People Who Use Combusted Cigarettes

Background:

- Nicotine pouch use is most common among adults who recently quit other tobacco products.
- Twenty-four percent of participants in the premarket tobacco product application Patterns of Use study who used ZYN completely switched from other tobacco products to ZYN by the end of a 10-week study.
- In the Consumer Perceptions and Likelihood of Use study, viewing the proposed claim did not impact intentions to use ZYN among those who were using tobacco products.

If ZYN is marketed with the proposed claim, discuss the evidence regarding the likelihood that people who currently use combusted cigarettes will completely switch to ZYN and/or will dual use ZYN and combusted cigarettes long-term.

Committee Discussion:

TPSAC members generally agreed that there was not enough evidence to support the point that the modified risk claim would cause combusted cigarette users to experiment with and/or switch to ZYN products. One committee member noted that prior evidence suggests that youth e-cigarette users may transition to using nicotine pouches because the perceived risk is less and suggested increased public education on the risks of nicotine versus combusted cigarettes. Another committee member noted that the success of this claim depends on how it is intended to be used in marketing and if it reaches the intended audience. Swedish Match USA, Inc., and TPSAC members both noted that the evidence for switching may have been stronger if the study participants had been exposed to the message more than once.

Discussion 4: Impact to People Who Do Not Use Tobacco Products

Background:

- Based on the information currently available, youth use of nicotine pouches is relatively low.
- Viewing the proposed claim did not increase intentions to use ZYN.

If ZYN is marketed with the proposed claim, discuss the evidence regarding the likelihood that persons who do not use tobacco products will start using ZYN.

Committee Discussion:

TPSAC members emphasized the need for updated nicotine pouch use data among youth, given reports from communities about youth initiating tobacco use with nicotine pouches. Some members raised the concern that continued exposure to the modified risk claim may

increase the likelihood of young people initiating nicotine pouch use, while others on the committee did not share the same concern. Committee members highlighted the need for FDA post-market surveillance of marketing strategies that may appeal to young people and youth prevalence data to ensure negligible uptake among nonusers. One committee member warned that Sweden has experienced a large increase in youth oral tobacco product use (either snus or nicotine pouches) as evidence that the United States should not follow their policies. Others discussed the concern of social media influencers promoting ZYN use that nonusers may encounter, while others discussed the importance of access control. One committee member raised concerns about public statements made by the CEO of the applicant's parent company about purported cognitive benefits of nicotine.

TPSAC members and non-voting industry representatives, ex-officio participants, and temporary committee members provided final closing summary statements. Dr. Apelberg provided closing remarks and Dr. Jang adjourned the meeting.

Additional information and details may be obtained from the transcript and meeting recording on the 2026 TPSAC Meeting Materials and Information webpage.