

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC) Meeting

January 22, 2026

Virtual Meeting: <https://youtube.com/live/yrYtTTjlv8A?feature=share>

DRAFT AGENDA

The Committee will discuss modified risk tobacco product applications submitted by Swedish Match USA, Inc. for the following products¹:

- 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

Discussion generally will focus on evidence related to the relative health risks of the products, consumer understanding and perceptions of the applicant's proposed modified risk claim, and the potential public health impact of a modified risk marketing order.

9:00 a.m. Call to Order

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

9:05 a.m. Administrative Announcements

Rachel Jang, Pharm.D.

¹ Swedish Match might also market some products under alternative product names.

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DRAFT AGENDA continued

| | | |
|------------|--|--|
| | Introduction of Committee | Designated Federal Officer |
| | Conflict of Interest Statement | Office of Science (OS), CTP, FDA |
| 9:15 a.m. | FDA Opening Remarks | Bret Koplow, Ph.D., J.D. Acting Center Director CTP, FDA |
| 9:20 a.m. | APPLICANT PRESENTATIONS (60 min) | Swedish Match U.S.A., Inc. |
| | Introduction | Keagan Lenihan Vice President and Chief External Affairs Officer, U.S. PMI US Corporate Services Inc. |
| | ZYN Overview and MRTP Statutory Requirements | |
| | Clinical & Non-Clinical Scientific Assessment | Tryggve Ljung, M.D., Ph.D. Global Medical Head of Oral Products Swedish Match AB |
| | Consumer Understanding, Perceptions, & Behavior | Jessica Seifert, Ph.D., M.P.H. Head of Regulatory Insights PMI US Corporate Services Inc. |
| | Responsible Marketing and Communicating the Claim | Keagan Lenihan Vice President and Chief External Affairs Officer, U.S. PMI US Corporate Services Inc. |
| | Conclusion | |
| 10:20 a.m. | Clarifying Questions for Applicant (15 min) | |
| | Responder | JB Simko VP US International Affairs and Chief US Underage Prevention Officer PMI US Corporate Services Inc. |
| 10:35 a.m. | Break | |

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DRAFT AGENDA continued

10:45 a.m. **FDA PRESENTATIONS (60 min)**

Relative Health Risks to Individuals

Cindy Chang, Ph.D., M.P.H.

Chief, Epidemiology Branch 1
OS, CTP, FDA

Consumer Understanding and Risk
Perceptions

Apoorva Rajan-Sharma, Ph.D., M.A.

Social Scientist
OS, CTP, FDA

Likelihood of Use and Impacts to the
Population

Amanda Fidalgo, Ph.D., M.A.

Social Scientist
OS, CTP, FDA

Overall Conclusions

Cindy Chang, Ph.D., M.P.H.

Chief, Epidemiology Branch 1
OS, CTP, FDA

11:45 p.m. Clarifying Questions for FDA (15 min)

12:00 p.m. Lunch Break

1:00 p.m. **OPEN PUBLIC HEARING (60 min)**

2:00 p.m. Charge to the Committee

Benjamin Apfelberg, Ph.D.

Deputy Director
OS, CTP, FDA

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DRAFT AGENDA continued

2:05 p.m. QUESTIONS TO THE COMMITTEE
/COMMITTEE DISCUSSION

3:05 p.m. Break

3:20 p.m. QUESTIONS TO THE COMMITTEE
/COMMITTEE DISCUSSION (cont.)

4:15 p.m. Closing Remarks

Benjamin Apelberg, Ph.D.

Deputy Director

OS, CTP, FDA

4:25 p.m. ADJOURNMENT

Rachel Jang, Pharm.D.

Designated Federal Officer

Office of Science (OS), CTP, FDA