

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)

**Roundtable on Premarket Tobacco Application Submissions for
Electronic Nicotine Delivery Systems Products**
[February 10, 2026]

FINAL AGENDA

The roundtable discussion with small sized tobacco manufacturers will solicit input on premarket tobacco product application (PMTA) submissions for electronic nicotine delivery systems (ENDS) products.

9:00 a.m.	FDA Opening Remarks	Matthew Farrelly, Ph.D. Director, Office of Science (OS), CTP
9:10 a.m.	Panel I: Product Characterization	Todd Cecil, Ph.D. - Moderator Deputy Director for Regulatory Management, OS
	FDA Presentation	Matthew Walters, Ph.D., MPH CDR, US Public Health Service Deputy Director, Division of Product Science (DPS), OS
	Roundtable Discussion	
10:25 a.m.	Break (10 min)	
10:35 a.m.	Panel II: Manufacturing Controls	Todd Cecil, Ph.D. - Moderator Deputy Director for Regulatory Management, OS
	FDA Presentation	Karen Coyne, Ph.D. Associate Director, DPS, OS
	Roundtable Discussion	
11:50 a.m.	Lunch (60 min)	
12:50 p.m.	Panel III: Pharmacological Profile	Lynn Hull, Ph.D. – Moderator Acting Senior Science Advisor, OS
	FDA Presentation	Carolina Ramôa, Ph.D. Supervisory Pharmacologist Division of Individual Health Science (DIHS), OS

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Roundtable Discussion

2:05 p.m. **Panel IV: Studies of Adult Benefit** **Benjamin Apelberg, Ph.D.**
Deputy Director for Regulatory Science
OS

FDA Presentation

Mollie Miller, Ph.D.
Health Scientist
Behavioral and Clinical Pharmacology
DIHS, OS

Amy L. Gross, Ph.D., M.H.S.
Epidemiologist, Epidemiology Branch 1
Division of Population Health Science, OS

Roundtable Discussion

3:20 p.m. Break (10 min)

3:30 p.m. **Comments from the Commissioner** **Marty Makary, M.D., M.P.H.**
FDA Commissioner

3:35 p.m. **Panel V: Toxicological Profile** **Todd Cecil, Ph.D. - Moderator**
Deputy Director for
Regulatory Management, OS

FDA Presentation

Mary Irwin, Ph.D.
Supervisory Pharmacologist
Division of Nonclinical Science (DNCS)
Office of Science

Hans Rosenfeldt, Ph.D.
Director, DNCS, OS

Roundtable Discussion

4:45 p.m. Summary, Closing Comments &
Adjournment **Matthew Farrelly, Ph.D.**
Director, OS