



# Deemed Tobacco Product Applications: A Public Meeting

**U.S. Food & Drug Administration (FDA), White Oak Campus  
10903 New Hampshire Avenue  
Building 31, Conference Center, the Great Room (Rm 1503)  
Silver Spring, MD 20993-0002**

## **October 28, 2019**

- 8:30 am      **Welcome Address**—Matthew Holman, Ph.D., CTP Office of Science  
**Opening Remarks**—David Graham, M.P.A., NJOY  
**Overview of the Meeting**—Anne Radway, M.S., CTP Office of Science
- 8:45 am      **Session 1: Communications & IT Resources**  
**CTP Website: What's New**—Stephanie Redus, M.S., CTP Office of Science  
**Overview of Electronic Submissions: Preparation and Tools**—Crystal Allard, CTP Office of Science
- 10:00 am      **Panel Discussion #1 on Communications & IT Resources**  
Moderator: Anne Radway, M.S., CTP Office of Science  
  
Leanne Campbell, Ph.D., RAI  
Anuschka Merson, M.S., ITG Brands, LLC  
Crystal Allard, CTP Office of Science  
Cristi Stark, M.S., CTP Office of Science
- 10:45 am      *Break*

- 11:00 am **Session 2: Premarket Tobacco Product Applications (PMTAs)—Review Process and Resources**  
**PMTA Review Process**—Emily Busta, M.S., CTP Office of Science  
**Tobacco Product Master Files (TPMF)**—Sarah Amyot, M.P.H., CTP Office of Science
- 12:15 pm *Lunch*
- 1:15 pm **Application-Related Inspections**—Chad Burger, M.S., CTP Office of Compliance and Enforcement
- 1:45 pm **Panel Discussion #2 on PMTA Review Process**  
Moderator: Anne Radway, M.S., CTP Office of Science  
  
Kevin Burd, North America Nicotine  
Charlotte Owen, Matrix Minds LLC  
Cristi Stark, M.S., CTP Office of Science  
Lillian Ortega, M.P.H., CTP Office of Compliance and Enforcement
- 2:30 pm **Session 3: Premarket Tobacco Product Applications (PMTAs)—Scientific Content**  
**PMTA Content Overview**—Ouida Holmes, M.P.H. & Priscilla Callahan-Lyon, M.D., CTP Office of Science  
**PMTA Post-Marketing Requirements**—Christine Saba, M.P.A., M.P.H., CTP Office of Science
- 3:45 pm **Closing Remarks**—Anne Radway, M.S., CTP Office of Science
- 4:00 pm *End of Day 1*

## **October 29, 2019**

- 8:30 am      **Welcome**—Todd Cecil, Ph.D., CTP Office of Science
- 8:45 am      **Session 3 (Continued): PMTAs—Scientific Content**  
**Lessons Learned from PMTA Reviews**—Hans Rosenfeldt, Ph.D., CTP Office of Science
- 9:30 am      **Panel Discussion #3 on PMTA Scientific Content**  
Moderator: Todd Cecil, Ph.D., CTP Office of Science  
  
Jason Flora, Ph.D., Altria  
Elaine Round, Ph.D., RAI  
Steve Seiferheld, M.S., Venebio  
Iilun Murphy, M.D., CTP Office of Science  
Emily Talbert, M.P.H., CTP Office of Health Communication and Education  
Hans Rosenfeldt, Ph.D., CTP Office of Science
- 10:30 am      *Break*
- 10:45 pm      **Session 4: Substantial Equivalence (SE) Scientific Content & Exemption Requests**  
**SE Program Overview**—Lauren DeBerry, M.P.H., CTP Office of Science  
  
**Grandfathered Tobacco Product Reviews**—Bryan Hills, J.D., CTP Office of Compliance and Enforcement
- 11:30 am      *Lunch*
- 12:30 pm      **SE Scientific Content, Including HPHC Testing & Reporting**—Salome Bhagan, M.S., Ph.D., & Melis Coraggio, M.S., CTP Office of Science  
  
**Request for Exemption from SE Marketing Pathway**— Jennifer Schmitz, M.P.H. & Matt Walters, M.P.H., Ph.D., CTP Office of Science

1:30 pm

**Panel Discussion #4 on SE Scientific Content**

Moderator: Todd Cecil, Ph.D., CTP Office of Science

Christopher Junker, Ph.D., RAI

Gerald Long, M.S., ITG Brands LLC

Colleen Rogers, Ph.D., CTP Office of Science

Laurie Sternberg, J.D., CTP Office of Compliance and Enforcement

Matthew Walters, Ph.D., CTP Office of Science

Rosanna Beltre, M.P.H., CTP Office of Science

2:15 pm

**“Ask CTP Leadership” Q&A Session**

Moderator: Todd Cecil, Ph.D., CTP Office of Science

Matthew Holman, Ph.D., CTP Office of Science

Cristi Stark, M.S., CTP Office of Science

Crystal Allard, CTP Office of Science

Swati Kabaria, Pharm.D., J.D., CTP Office of Compliance and Enforcement

3:15 pm

**Closing Remarks**

Brittani Cushman, J.D., Turning Point

Julia McGinn-Rodriguez, M.S.P.P.M., CTP Office of Science

3:30 pm

*End of Day 2*

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