

The Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems (ENDS): A Public Seminar



FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR TOBACCO PRODUCTS (CTP)
The Marriott Inn and Conference Center
University of Maryland University College
Hyattsville, Maryland 20783
October 17-18, 2016

Agenda

(Times are approximate)

October 17, 2016

- 8:30 am **Welcome and Introduction of Office Director**
Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences, Office of Science, CTP/FDA
- Opening Remarks**
David Ashley, PhD
RADM (retired), US Public Health Service (USPHS)
Director, Office of Science (OS), CTP/FDA
- Overview of the Workshop**
Kimberly Lindsey, MD, CAPT, USPHS
Medical Officer, Division of Individual Health Science, OS/CTP/FDA
- 9:00 am **Session 1: General Information**
- Good Guidance Practices at FDA**
Colleen Lee, JD
Regulatory Counsel, Office of Regulations, CTP/FDA
- Regulatory Overview of a Premarket Tobacco Product Application**
Caliope Sarago, MHSA
Team Lead, Division of Regulatory Project Management, OS/CTP/FDA
- Primer on CTP Electronic Submissions**
Jeff K. Smith, MPH
Regulatory Health Information Specialist, Division of Regulatory Science Informatics,
OS/CTP/FDA
- The Concept of Bridging Information**
Kimberly Lindsey, MD, CAPT, USPHS
Medical Officer, Division of Individual Health Science, OS/CTP/FDA
- Session 1 Panel Discussion**
- 10:15 am **Break**

10:30 am

Session 2: Product Science Overview

Chemistry of ENDS Products

Tianrong Cheng, PhD

Chemist, Division of Product Science, OS/CTP/FDA

Engineering Considerations for ENDS Products

Komal Singh, MS

Engineer, Division of Product Science, OS/CTP/FDA

Toxicology Topics on Premarket Tobacco Product Applications

Steven Yee, PhD

Toxicologist, Division of Nonclinical Science, OS/CTP/FDA

Environmental Considerations for Premarket Tobacco Product Applications Submitted to CTP

Gregory Gagliano, MS

Toxicologist, Division of Nonclinical Science, OS/CTP/FDA

Session 2 Panel Discussion

12:30 pm

LUNCH

1:30 pm

Session 3: Data Sources

National Estimates of E-Cigarette Use: Review of Publicly Available Literature

Catherine G. Corey, MSPH

Epidemiologist, Division of Population Health Science, OS/CTP/FDA

Literature Review Methodology: An Overview

Carol H. Christensen, PhD, MPH

Epidemiologist, Division of Population Health Science, OS/CTP/FDA

Session 3 Panel Discussion

2:30 pm

BREAK

2:45 pm

Session 4: Health Risks

Biomarkers of Tobacco Exposure and Potential Harm

Cindy M. Chang, PhD, MPH

Epidemiologist, Division of Population Health Science, OS/CTP/FDA

Health Outcomes

Jeannie Limpert, MD

Medical Officer, Division of Individual Health Science, OS/CTP/FDA

Comparator Products

Ii-Lun Chen, MD

Director, Division of Individual Health Science, OS/CTP/FDA

Session 4 Panel Discussion

4:30 pm

End of Day 1

October 18, 2016

8:30 am **Welcome**
Carolyn Dresler, MD, MPA
Associate Director for Medical and Health Sciences, Office of Science, OS/CTP/FDA

8:35 am **Session 5: Human Factors and Labeling**

General Principles of Human Factors in Product Design
James Cheng, MS
CAPT, USPHS, Senior Engineer, Division of Product Science, OS/CTP/FDA

Label Comprehension
Priscilla Callahan-Lyon, MD
Deputy Director, Division of Individual Health Science, OS/CTP/FDA

Session 5 Panel Discussion

9:30 am **Session 6: Addiction and Abuse Liability**

Abuse Liability Assessment and Addiction
Chad J. Reissig, PhD
Addiction Branch Chief, Division of Individual Health Science, OS/CTP/FDA

Clinical Pharmacology to Inform Abuse Liability
Megan J. Schroeder, PhD
Lead Pharmacologist, Division of Individual Health Science, OS/CTP/FDA

Session 6 Panel Discussion

11:00 am **Break**

11:15 am **Session 7: Initiation, Cessation and Consumer Perception**

Principles Related to the Likelihood of Tobacco Product Initiation and Cessation
Benjamin J. Apelberg, PhD, MHS
Acting Division Director, Division of Population Health Science, OS/CTP/FDA

Consumer Perception Studies
David B. Portnoy, PhD, MPH
Supervisory Social Scientist, Division of Population Health Science, OS/CTP/FDA

Qualitative Studies
Katherine A. Margolis, PhD
Social Scientist, Division of Population Health Science, OS/CTP/FDA

Investigational Tobacco Products and Support of Premarket Tobacco Product Applications
Priscilla Callahan-Lyon, MD
Deputy Director, Division of Individual Health Science, OS/CTP/FDA

Session 7 Panel Discussion

1:00 pm **END OF DAY 2**