



Deeming and Its Impact
A How-To Guide on the FDA Deeming Rule
June 9, 2016
Lansdowne Resort, Leesburg, Virginia

- 8:00 AM** Breakfast **Amphitheater Foyer**
- 9:00 AM** Welcome: **Farrell Delman**, TMA President **Amphitheater**
- 9:05 AM** Introduction: Deeming Rule – Automatic / General Provisions
Ben Haas – Latham & Watkins LLP
- 9:15 AM** **Session 1:** Small-Scale Tobacco Product Manufacturers
Regulatory Affairs: **Michael Gold**, Arango Cigar Co.
Attorney: **Seth Mailhot**, Michael Best & Friedrich LLP
Technical / Science: **John Lauterbach**, Lauterbach & Associates
- 9:45 AM** Q & A
- 9:55 AM** **Session 2:** Substantial Equivalence Applications
Regulatory Affairs: **Patricia Kovacevic**, Nicopure Labs
Attorney: **Ben Haas**, Latham & Watkins LLP
Technical / Science: **Dean Cirotta**, EAS Consulting Group
- 10:35 AM** Q & A
- 10:45 AM** Coffee Break
- 11:00 AM** **Session 3:** Pre-Market Tobacco Product Applications, Master Files and Product Standards
Regulatory Affairs: **David Graham**, NJOY
Attorney: **John Manthei**, Latham & Watkins LLP
Technical / Science: **Karen Carter**, Enthalpy Analytical
- 11:30 AM** Q & A
- 11:40 AM** **Session 4:** One Application Strategy
Regulatory Affairs: **Raymond Keller**, GoodCat LLC
Attorney: **Eric Heyer**, Thompson Hine LLP
Technical / Science: **Samina Qureshi**, PSI International
- 12:10 PM** Q & A

