Introduction to Tobacco and Nicotine Products Law and Regulation

October 19, 2022
Virtual Event

Tuesday, October 18

10:00–11:15 AM **FDLI Welcome and First Session**

FDLI Welcome and Announcements
Bianca Cardona Melendez, Assistant Director, Educational Programs, FDLI

I. The Family Smoking Prevention and Tobacco Control Act (TCA) and the Deeming Regulation – Add Synthetic Nicotine authority

A. Brief history of tobacco and nicotine product regulation in the United States
B. Overview of Family Smoking Prevention and Tobacco Control Act (TCA)
    1. Terms and Definitions
    2. Section-by-Section Overview
C. Overview of the Deeming Regulation
    1. Products to which it applies
    2. Distinction between components and accessories
    3. Requirements for covered products
D. Synthetic Nicotine
    1. H.R. 2471, also known as the Consolidated Appropriations Act—the spending bill, signed by President Biden, granted FDA authority over synthetic nicotine.

Vanessa Fulton, Associate, Kleinfeld, Kaplan, & Becker LLP

11:25 AM–12:15 PM **II. Pathways to Market**

A. Grandfathered products
B. Substantial Equivalence
C. Substantial Equivalence exemption
D. Premarket Tobacco Applications (PMTAs)
E. Modified Risk Tobacco Product (MRTP) applications

Beth G. Oliva, Partner, Fox Rothschild LLP

12:15–1:00 PM **Break**

1:00–1:30 PM **III. The Public Health Standard**

A. Research on health consequences of tobacco and nicotine product use
    1. Data on tobacco and nicotine product use in the US
    2. Why regulation of these products is/remains important
B. Overview of public health standard
    1. What is the public health standard?
    2. Definitions
    3. Data needed in applying public health standard

Darlene Huang Briggs, Legislative and Policy Counsel, Campaign for Tobacco-Free Kids

1:40–2:30 PM **IV. Product Compliance**

A. Labeling and warning requirements
B. Product registration and ingredient submission
C. User Fees and Tobacco Taxation
D. Marketing and advertising limitations and requirements
E. Retailer requirements
F. Product standards

Mark J. Vaders, Associate, Womble Bond Dickinson (US) LLP

2:45–3:35 PM **V. Food and Drug Administration (FDA) Inspections and Enforcement**

A. Overview of Food, Drug, and Cosmetic Act (FDCA) Inspection Power
B. FDA Inspections of Manufacturing Facilities
C. FDA Inspections of Retail Establishments
D. FDA Warning letters and other enforcement tools

Seth Gitner, Associate, Saul Ewing Arnstein & Lehr LLP

3:45–4:30 PM **VII. Hot Topics and Current Issues Panel Discussion *(Topics Subject to Change)***

A. PMTA orders and pending applications
B. Pending Litigation and Recent Rulings
C. MRTP orders and pending applications
D. Proposed Product Standards for Menthol and Characterizing Flavors
E. Proposed Nicotine Cap for Combustible Products
F. Q & A

Barry Schaevitz, Partner, Fox Rothschild LLP
Eric Heyer, Partner, Thompson Hine LLP

4:30 PM **Adjournment**