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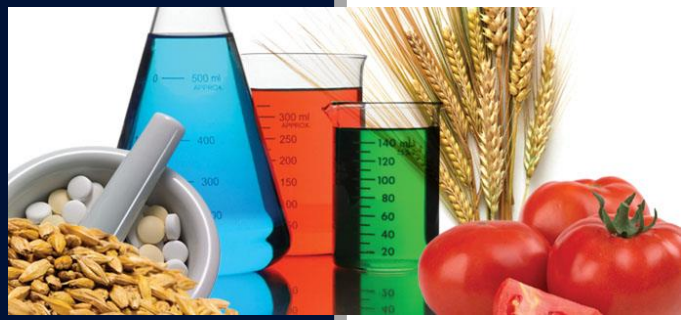

Food, Drug and Cosmetic Law Section Annual Meeting – January 25, 2018

Embracing the Continuum of Risk: New FDA Policies in the Aftermath of the Deeming Rule

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FDA's Comprehensive Policy Announcement

- On July 28, 2017, Commissioner Gottlieb announced FDA's multi-year comprehensive plan for tobacco and nicotine regulation
- Plan includes:
  - Delaying current regulatory deadlines
  - Issuance of final rules on tobacco product applications, final guidance, and product standards
  - Issuance of ANPRMs regarding: (1) nicotine in cigarettes, (2) flavors; and (3) premium cigars
  - Reassessment of current policies on provisional SE reports

Additional Priorities

- Director Mitch Zeller of the Center for Tobacco Products gave the keynote speech at FDLI's annual tobacco products regulation conference
- He identified a need for a sustained national dialogue to:
  - Correct common misperceptions
  - Address nicotine's role in continuum of risk
  - Address nicotine and youth
  - Address nicotine and adult populations
  - Identify vulnerable populations

Stakeholder Response

- Stakeholder analysis of the plan has focused on:
  - Feasibility of the plan
  - Implementation process and timeline
  - Gaps in the comprehensive plan
  - Identifying “common ground” between industry, public health community, and FDA
  - Scientific research efforts
  - Necessary improvements in current regulatory regime

Key Components of FDA's Plan

Delay of Current Regulatory Deadlines

- Under the Final Deeming Rule, FDA set deadlines for submission of premarket review applications for newly-regulated tobacco products that were on the market as of August 8, 2016
- FDA extended the deadline to submit tobacco product applications for newly deemed tobacco products
  - Combustible products: August 8, 2021
  - Non-combustible products: August 8, 2022
- **Can continue to market** these products during this period and while the application is pending with FDA
  - Only applies to products on market as of Aug. 8, 2016

Issuance of Final Rules

- With additional time to submit applications, FDA intends to initiate and complete rulemaking for:
  - Premarket Tobacco Product Applications
  - Substantial Equivalence Applications
  - Modified Risk Tobacco Product Applications
  - Tobacco Product Manufacturing Practices
- In the near-term, FDA intends to finalize the draft guidance, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS)

Stakeholder Concerns

- **Feasibility** – can FDA finalize these rules in five years, with sufficient time for industry to implement in advance of submitting their applications
- **Attainable Standards** – will these final rules set forth reasonable, predictable, and practical processes to submit applications
  - Altria's PMTA/MRTPA application is roughly 2.5 million pages
- **Marketing Freeze** – this extension only applies to products on the market as of August 8, 2016, limiting further innovation and improvement upon these products

Stakeholder Engagement

- FDA intends to issue ANPRMs on the following:
  - Lowering nicotine in cigarettes to non-addictive or minimally addictive levels
  - Role of flavors (including menthol) in attracting youth and helping smokers switch to potentially less harmful forms of nicotine delivery
  - Patterns of use and resulting public health impacts from premium cigars
- As of December 2017, ANPRMs for premium cigars and "kid-appealing flavors" are under OMB review

Product Standards

- Utilizing FDA's product standard authority, FDA intends to lower nicotine in cigarettes to non-addictive or minimally addictive levels
- In January 2017, FDA issued proposed product standard for NNN in smokeless tobacco products
  - Received over 7,700 comments on the proposed rule

Stakeholder Concerns

- **Lowering Nicotine in Cigarettes:**
  - Creation of an illicit market
  - Overcompensation
  - Unintended consequences
- **Lowering NNN in Smokeless Tobacco Products:**
  - Feasibility: For NNN proposed product standard, the maximum permitted would be significantly lower than the majority of products on the market today

Stakeholder Concerns (cont'd)

- **Flavors:**
  - Issue of appeal to children versus role in converting adults from combustible to non-combustible tobacco products
- **Premium Cigars:**
  - Would require amending the Final Deeming Rule
  - Impact on the market without a change to the existing rule

Reassessment of Current Policies

- Commissioner Gottlieb asked FDA's Center for Tobacco Products to analyze the Agency's current plan to review all provisional SE reports and assess the following:
  - Effective use of agency resources?
  - More appropriate approach to provisional SE reports?
  - Whether greater clarity could be provided to the market?

Stakeholder Concerns

- Provisional SE reports have been pending with FDA since March 22, 2011
  - Over 3,500 submitted by March 22, 2011, but FDA has resolved only 28% of these provisional SE reports
- Effective use of resources – significant resources involved in undertaking review of these products
- Cost and time involved in responding to deficiencies
- FDA is constantly moving the goalpost

Questions or Comments?

Thank you!