Food and Drug Law Institute

Tobacco Products Regulation and Policy Conference

Substantial Equivalence: Is it in Need of a Tune-up or Modification?

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Substantial Equivalence: Regulatory Opportunities
What FDA has said about SE Reports

- January 2011 “Section 905(j) Reports: Demonstrating Substantial Equivalence”
- Recommends Reports Contain
  - Cover Letter
  - Summary Section
  - Listing of Design Features for both predicate and new product
  - Listing of Ingredients for both predicate and new product
  - Listing of Materials for both predicate and new product
  - Description of Heating Source for both predicate and new product
  - Description of Composition of both predicate and new product
  - Other Features (HPHC data) of both predicate and new product
  - Health Information Summary or Statement
  - Environmental Assessment Report
- December 2016 – Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions
  - Product Quantity Change Streamlined Substantial Equivalence Report

Substantial Equivalence: Regulatory Opportunities

FDA Should Treat Different Products Differently

SE Section	Opportunity
Section 906 – Good Manufacturing Practices	• FDA can issue regulations that "may differ based on the type of tobacco product involved" • must "take into account the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers…"
Section 907 – Product Standards	• Technical achievability of compliance • Ban on Characterizing Flavors only in combustible cigarettes • Proposed NNN Rule for Smokeless Tobacco • Proposed ANPR for nicotine levels in combustible cigarettes
Section 909 – Record Keeping	• Regulations shall "not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter."
Section 910 – New Product Review	• Substantial Equivalence report shall contain information "whether such tobacco product presents less risk than other tobacco products." • Deeming Rule "FDA recognizes the existence of a continuum of nicotine-delivering products and will continue to consider this continuum in regulating future tobacco products."
Health Warnings	• Combustible Cigarettes – proposed graphic warnings • Smokeless Tobacco – 4 rotating warnings • Cigars – 6 rotating warnings • Pipe Tobacco – 1 warning • E-cigarettes – 1 warning

Substantial Equivalence: Regulatory Opportunities
A Path Forward for Cigars

- Relevant criteria in a Substantial Equivalence determination for cigars
  - Cigar composition
    - Type of tobacco (e.g., dark)
    - Type of filler (e.g., long filler)
    - Type of wrapper (e.g., whole leaf)
    - Curing Method (e.g., air cured)
  - Cigar size
    - Length
    - Ring gauge
    - Weight
  - Whether the cigar has additives
  - Tar, Nicotine, Carbon Monoxide (TNCO) levels

Substantial Equivalence: Legislative Opportunities

- February 15, 2007 -- Predicate Date for Originally Regulated Products
- Deeming Rule "FDA has determined it lacks the authority to change the grandfather date which is set by statute."
- Proposed Predicate Dates for Newly Deemed Products:
  - April 25, 2014 (Date Proposed Rule published)
  - May 10, 2016 (Date Final Rule published)

Substantial Equivalence: Industry Opportunities

- Schedule Meetings with CTP
- Submit Comments
  - Review of Existing Center for Tobacco Products Regulatory and Information Collection Requirements 82 Fed. Reg. 42,501
  - Announced Proposed Rule on Form and Content of Substantial Equivalence Reports
  - Announced ANPR on Whether and How to Regulate Premium Cigars
  - Announced ANPR on Flavors in Tobacco Products
- Work with CTP to Develop Product Standards under Section 907
  - Possible alternative to full Substantial Equivalence Report
  - Create limits/ranges for certain constituents, i.e., TNCO
  - Use Section 905(j) minor modification provisions