Cigar Association of America, Inc.

Meeting with Office of Information and Regulatory Affairs

Proposed Rule Format and Content of Reports Intended to Demonstrate Substantial Equivalence

November 28, 2018

Background Information

- CAA's 35 member companies come from all sectors of the cigar industry and include major manufacturers of premium cigars and major manufacturers of machine-made cigars
- CAA supports FDA in creating "rules of the road" based on a "transparent, modern and science-based framework" for development of tobacco product applications that meet legal requirements

Background Information

- Tobacco Industry has submitted Substantial Equivalence Reports (SE Reports) since March 2011
- Current Guidance Issued January 2011
- Proposed Rule on Content and Format of Substantial Equivalence Reports Published and Withdrawn January 20, 2017

Background Information

- **July 27, 2017** – FDA announces new plan for nicotine and tobacco product regulation and extends SE deadline to August 2021 in order to issue "foundational rules"
- **April 2018** – FDA removes from review 1,500 provisional SE Reports
  - "With the years of experience conducting thousands of SE reviews, and with a greater understanding of tobacco products"
  - "focus resources on provisional product reviews that are likely to raise more significant public health questions – rather than those that don't"
- **August 2, 2018** - Public Meeting Announced on Pre-Market Tobacco Product Applications, including SEs
- **September 26, 2018** – FDA opens docket for comments on Public Meeting
- **October 5, 2018** – Proposed Rule of SEs sent to OMB
- **October 22-23, 2018** – Public Meeting on Pre-Market Tobacco Product Applications
- **November 13, 2018** – FDA publishes on website slides from Public Meeting and "Appendix" documents (dated Oct. 2, 2018), including "Information to Consider for Cigars"
- **December 7, 2018** – Docket for comments on the Public Meeting closes

Format and Content of SE Reports

- Core, Foundational Definitions
- Categorical Exemptions
- Product Specific Guidance
- Not a Substitute for Tobacco Product Manufacturing Regulations
- Co-Packaged Products

Format and Content of SE Reports

Core, Foundational Definitions

- FDA has yet to define:
  - "same characteristics"
  - "different characteristics"
  - "different questions of public health"
    - Must be product-specific, i.e. a different question of public health outside of those that may be associated with the product class
- Any Proposed Rule on Format and Content of SE Reports must:
  - contain definitions of these foundational terms
  - acknowledge Congressional intent for two different SE pathways, depending on the characteristics of the tobacco product

Format and Content of SE Reports

Categorical Exemptions

- Certain changes to products should be categorically exempt from the SE process
  - Packaging changes not intended to modify the product
    - This would include all so-called "**container closure systems**" unless the manufacturer intended for the packaging to alter the characteristics of tobacco product
  - Any changes mandated by law, including product quantity and changes made due to compliance with product standards
  - Supplier changes or interchangeable ingredients
    - SE Reports should be required only for permanent changes to products that are actually likely to raise a different question of public health
  - Minor changes in non-tobacco additives that do not have a public health impact

Format and Content of SE Reports

Categorical Exemptions

- Certain changes to products should be categorically exempt from the SE process
  - Product Quantity Changes
    - Product Quantity changes for cigars should not require SE Review
    - Many product quantity changes for cigars were made in response to local ordinances requiring minimum pack sizes
    - Product quantity changes do not change any characteristics of the consumable unit of the cigar

Format and Content of SE Reports

Product Specific Guidance

- FDA needs to craft content requirements for SE Reports that are specific to each class of tobacco products
- Cigars are a unique category of products with questions of public health potentially different from other tobacco products

Format and Content of SE Reports

Predicate Products

- Cigars will need to look back over ten years for predicate products
- FDA should allow manufacturers to use multiple predicates if the changes at issue were both in different predicate products
  - For instance: a new cigar is size "z" and blend "y"
  - There is a blend "y" cigar that is a predicate but is size "w," and there is a size "z" cigar but is blend "q"
  - The manufacturer should be able to rely on both predicates
- FDA's proposed definition of "test marketing" could remove numerous predicate options for cigars
  - Cigars are routinely made as "limited editions" or a private labels for one retailer in one geographic location; these products were commercially marketed as of February 15, 2007 and should be able to be used as predicate products

Format and Content of SE Reports

Not a Substitute for Tobacco Product Manufacturing Regulations

- SE Reports should be required only to detail what is actually different between the predicate and new tobacco product
- Manufacturers should not have to submit voluminous "foundational information that allows FDA to better understand the tobacco product"
  - SE Report is so that FDA can compare a new tobacco product to a predicate tobacco product and determine if, even with changes, the products are "substantially equivalent"
  - FDA has other mechanisms to "better understand" products such as product listing, ingredient reporting and manufacturer inspections

Format and Content of SE Reports

Co-Packaged Cigars

- Two or more finished cigars packaged together
- Do not raise different questions of public health
- Retailers and wholesalers will not have access to underlying manufacturer information
- Challenge of selecting predicate product if a scientific evaluation is required
- Huge drain on agency resources

"Appendix: Information to Consider for Cigars"

- Not a Guidance Document
- Not a Rule
- Are the information and content requirements of the Appendix contained in the Proposed Rule under review by OMB?
  - No opportunity for OMB review of the Appendix
  - No opportunity for notice and comment procedures for the Appendix
  - No opportunity for industry input

CAA thanks OMB for the opportunity share concerns and ideas concerning the Proposed Rule on Format and Content of Reports Intended to Demonstrate Substantial Equivalence