Food and Drug Law Institute
Introduction to Tobacco Law and Regulation

Pathways to Market

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Overview

- Pre-Existing Tobacco Products
- New Tobacco Products
- Pathways to Market
  - Substantial Equivalence
  - Exemption to Substantial Equivalence
  - Premarket Tobacco Product Application
  - Supplemental Premarket Tobacco Product Application
- Modified Risk Tobacco Product Applications

Pre-Existing Tobacco Products

- A Tobacco Product that was commercially marketed in the United States as of February 15, 2007
  - FDA has interpreted “as of” to mean “on”
  - Voluntary process to establish a tobacco product as a pre-existing tobacco product
  - Database of products that CTP has established as pre-existing tobacco products https://www.accessdata.fda.gov/scripts/ctppx/
  - Currently there are close to 12,000 products that have been established as pre-existing tobacco products

New Tobacco Products

- The term ‘new tobacco product’ means—
  - any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or
  - any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.
  - A change to a product’s label or name does not create a new tobacco product

Pathways to Market

- Substantial Equivalence
- Exemption to Substantial Equivalence
- Premarket Tobacco Product Application
- Supplemental Premarket Tobacco Product Application

Timing

- Originally Regulated Products – March 2011
- Newly Deemed Tobacco Products – September 9, 2020

Substantial Equivalence

- (i) has the *same characteristics* as the predicate tobacco product; or
- (ii) has *different characteristics* and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product *does not raise different questions of public health*.
- the term ‘characteristics’ means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

Substantial Equivalence

- Predicate Product is a pre-existing tobacco product
  - Established as a pre-existing tobacco product; or
  - Provide commercial evidence dated 2/15/07 or bracketing that date
- New Product is “compared” to the Predicate Product
- Final Rule governing content and format of SE Reports effective November 2021
  - “Same characteristics” and “Different characteristics”
  - Requirements of SE Reports

Exemption to Substantial Equivalence

- Streamlined pathway outlined in the Tobacco Control Act
  - Tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive
  - Minor Modification
- Can only be filed by the manufacturer of a product
- Must be modifying a product legally on the market
- Final Rule in place outlines specific requirements

Premarket Tobacco Product Applications

- Products that cannot be compared to a pre-existing tobacco product (*i.e*. e-cigarettes, oral nicotine products)
- FDA must find that authorizing the product is “appropriate for the protection of public health”

Premarket Tobacco Product Applications

- Full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;
- A full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;
- A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

Premarket Tobacco Product Applications

- An identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;
- Such samples of such tobacco product and of components thereof as the Secretary may reasonably require;
- Specimens of the labeling proposed to be used for such tobacco product; and
- Such other information relevant to the subject matter of the application as the Secretary may require.

Premarket Tobacco Product Applications

- Final Rule effective November 2021 (currently subject of legal challenge)
- Created Supplemental PMTA pathway for changes to products authorized through the PMTA pathway

Modified Risk Tobacco Product Application

- Any tobacco product sold legally may submit an application to market the product with a “modified risk claim”
  - Lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products
  - The tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance