Introduction to Tobacco Law and Regulation

Hot Topics and Current Issues:

PMTA Orders and Pending Applications
and
Pending Litigation and Recent Rulings

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PMTA Orders and Pending Applications

- Premarket Tobacco Applications (PMTAs) are governed by Section 910 of the FDCA (21 U.S.C. § 387j)
- Statutory Requirements:
  - 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, addititves, 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;

PMTA Orders and Pending Applications

- Statutory Requirements (cont.):
  - an identifying reference to any tobacco product standard under section 387g of this title 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.

PMTA Orders and Pending Applications

- Standard for Authorization:
- “whether permitting such tobacco product to be marketed would be appropriate for the protection of the public health”
- How to determine?

PMTA Orders and Pending Applications

- For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

  (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

  (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

PMTA Orders and Pending Applications

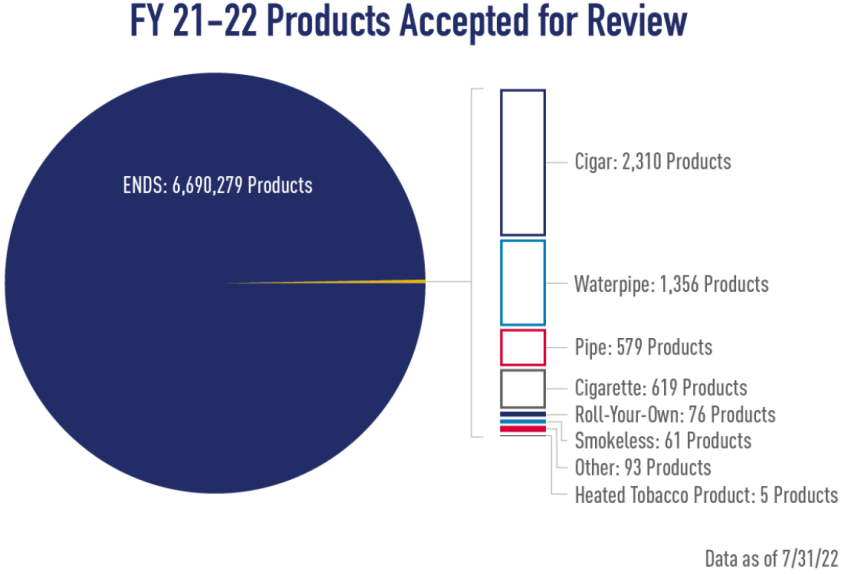
- 42 discreet products have received marketing granted orders since 2015:
  - Swedish Match snus (8 products)
  - Philip Morris IQOS heat-not-burn (5 products)
  - 22nd Century VLN cigarettes (2 products)
  - U.S. Smokeless Tobacco Company Verve Discs/Chews (4 products)
  - ENDS products from RJ Reynolds, Logic, and NJOY (23 products)

PMTA Orders and Pending Applications

- District Court order and FDA required PMTAs for newly deemed tobacco products, including ENDS, containing tobacco-derived nicotine by September 9, 2020
- Applications filed for over 6.7 million products
- April 2022 legislation expanded “tobacco product” definition to include non-tobacco nicotine products
- Applications submitted for over 1 million additional products

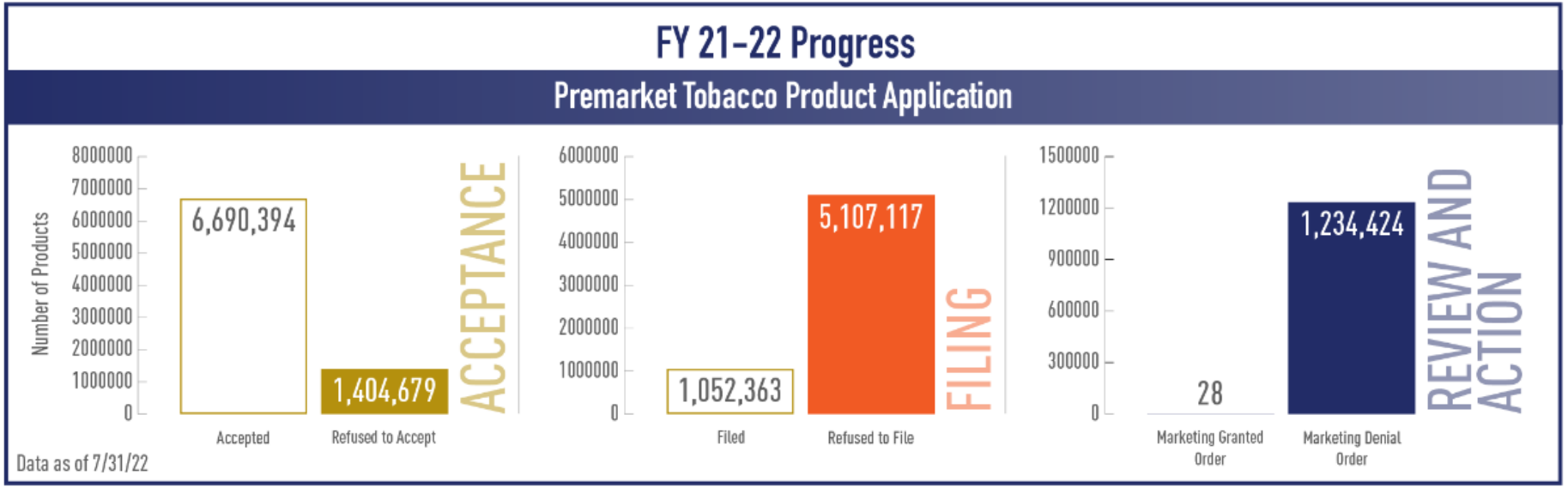
PMTA Orders and Pending Applications

- Applications overwhelmingly for ENDS products:



PMTA Orders and Pending Applications

- Many applications still at various stages of review:



Pending Litigation and Recent Rulings

- Between August and October 2021, FDA issued marketing denial orders for over one million flavored ENDS products
- Over 40 cases filed in federal circuit courts under direct review provisions of Section 912 of the FDCA
- Focus of appeals has been FDA's requirement that applicants show flavored ENDS products provide marginal benefit over tobacco-flavored ENDS products at promoting cigarette reduction or cessation

Pending Litigation and Recent Rulings

- Thus far, two published opinions on motions to stay MDOs and four published merits opinions with a 3-1 circuit split (D.C., Fifth, Seventh, and Eleventh Circuits)
- Lead cases remain pending in Second, Third, Fourth, Ninth, and Tenth Circuits
- Other important MDO challenges also remain pending
  - Fontem Ventures / blu
  - JUUL
- Second round of challenges to RTA decisions on NTN products is emerging

Questions?

Food and Drug Law Institute
Introduction to Tobacco Law and Regulation

Hot Topics – MRTPs and Product Standards

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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

Modified Risk Tobacco Products

- Products that have MRTP Orders
  - General Snus (October 2019)
    - Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis.
  - IQOS (July 2020; March 2022)
    - AVAILABLE EVIDENCE TO DATE:
      - The IQOS system heats tobacco but does not burn it.
      - This significantly reduces the production of harmful and potentially harmful chemicals.
      - Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

Modified Risk Tobacco Products

- Products that have MRTP Orders (cont.)
  - VLN Cigarettes (December 2021)
    - 95% less nicotine
    - Helps reduce your nicotine consumption
    - ...greatly reduces your nicotine consumption
    - *Helps you smoke less*

Modified Risk Tobacco Products

- Pending MRTP Applications
  - Camel Snus (TPSAC Meeting September 2018)
    - Proposed Claims:
      - Smokers who **switch completely** from cigarettes to Camel SNUS can significantly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease
      - Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS greatly reduce their risk of lung cancer, oral cancer, respiratory disease, and heart disease
      - Smokers who **SWITCH COMPLETELY** from cigarettes to Camel SNUS can greatly reduce their risk of lung cancer and respiratory disease
  - Copenhagen Fine Snuff (TPSAC Meeting February 2019)
    - Proposed Claim:
      - IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer.

Product Standards

- Section 907 of the Tobacco Control Act grants FDA the power to issue “Product Standards”
  - Considerations to issue a Product Standard
    - The risks and benefits to the population as a whole, including users and non-users of tobacco products
    - The increased or decreased likelihood that existing users will stop using such products; and
    - The increased or decreased likelihood that those who do not user tobacco products will start using such products

Product Standards

- Section 907 of the Tobacco Control Act grants FDA the power to issue “Product Standards”
  - Product Standard “shall include provisions that are appropriate for the protection of the public health, including provisions where appropriate –
    - For the nicotine yield of the product
    - For the reduction or elimination of other constituents, or harmful components of the products; or
    - Relating to any other requirement of the [considerations above]”

Product Standards

- Sec. 907 of the Tobacco Control Act
  - Only product standard currently in place is prohibiting characterizing flavors (other than menthol) in cigarettes
  - Proposed Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products (January 2017)

Product Standards

- May 2022
  - Proposed Tobacco Product Standard for Menthol in Cigarettes
    - Over 175,00 public comments submitted
  - Proposed Tobacco Product Standard for Characterizing Flavors in Cigars
    - Over 72,000 public comments submitted

Proposed Tobacco Product Standard Menthol in Cigarettes

- The rule would provide that a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or cigarette component or part that is not in compliance with the product standard.

Proposed Tobacco Product Standard Menthol in Cigarettes

- Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:
  - The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
  - The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
  - Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and
  - Any other means that impart flavor or represent that the tobacco products has a characterizing flavor.

Proposed Tobacco Product Standard Characterizing Flavors in Cigars

- This rule would provide that a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) must not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke.

Proposed Tobacco Product Standard Characterizing Flavors in Cigars

- Among the factors that FDA believes are relevant in determining whether a cigar has a characterizing flavor are:
  - The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
  - The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
  - Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of a tobacco product; and
  - Any other means that impart flavor or represent that a tobacco product has a characterizing flavor.

Nicotine Level in Cigarettes

- March 2018 - Advanced Notice of Proposed Rulemaking
- June 2022 - Proposed Product Standard placed on 2022 Spring Unified Regulatory Agenda
  - “The Biden-Harris Administration published plans for future potential regulatory actions that include the U.S. Food and Drug Administration’s plans to develop a proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other combusted tobacco products.”