PREMARKET TOBACCO PRODUCT APPLICATION (PMTA) REVIEW PROCESS

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AGENDA

- Statutory Requirements
- Review Process
  - Pre meeting
  - Acceptance
  - Filing
  - Review
  - Postmarket Reports
- Metrics
- Key Features
- Helpful Resources

STATUTORY REQUIREMENTS, SECTION 910

STATUTORY REQUIREMENTS

- Under section 910(a)(2) of the Federal Food, Drug, and Cosmetic Act, an order is required for a new tobacco product to be introduced and legally marketed in the United States

- PMTA is the primary pathway to market

STATUTORY REQUIREMENTS

- The standard required to be met for a PMTA is if marketing of the product is “appropriate for the protection of public health”, section 910(c)(4)
  - Considers risks and benefits to the population as a whole:
    - Impact on cessation
    - Impact on initiation

- The product must conform to any requirements of section 906(e) (manufacturing practices) which apply (if any)
- The proposed labeling must not be false or misleading
- The product must conform to product standards under section 907 which apply (if any), or must contain an adequate justification for such deviations

PMTA REVIEW PROCESS

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PRE-PMTA MEETING (PHASE 0)

- Pre-meeting
  - Forum to discuss and receive feedback prior to submitting your application
  - Most useful to be held well in advance of the planned pre-market submission
  - May result in a more complete application

- Guidance - Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised July 2016)

Pre-meeting

ACCEPTANCE (PHASE 1)

- Ensure the product falls under CTP jurisdiction
- Confirm the regulatory requirements of an application are included in submission
- Expected outcome:
  - Accepted and Acknowledged

    or
  - Refuse to Accept
- If the application is accepted, it moves to Filing phase

- Final Rule - Refuse To Accept Procedures for Premarket Tobacco Product Submissions

Acceptance

FILING (PHASE 2)

1. 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

2. A full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product

3. 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

Filing

FILING (PHASE 2) (continued)

4. 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

5. Such samples of such tobacco product and of components thereof as the Secretary may reasonably require

6. Specimens of the labeling proposed to be used for such tobacco product

7. Such other information relevant to the subject matter of the application as the Secretary may require

Filing

FILING (PHASE 2) (continued)

- Expected outcome:
  - Application filed

    or
  - Refuse to File

Filing

SUBSTANTIVE REVIEW (PHASE 3)

- Multi-disciplinary approach to determine if marketing the new product is appropriate for the protection of public health and can receive an order for the introduction or delivery for introduction into interstate commerce

- Conduct inspections, as needed
  - Clinical/Nonclinical
  - Manufacturing

- Sample testing may be conducted

- Determine whether application should go to the Tobacco Products Scientific Advisory Committee (TPSAC)

Review

ACTION (PHASE 3)

- Action result

  - Marketing Authorization

    or

  - No Marketing Authorization (Denial)

Action

POSTMARKET REPORTING (PHASE 4)

- Postmarket reporting, if appropriate, will be included in the Marketing Authorization letter
  - An order authorizing marketing under section 910(c)(1)(A)(i) of the FD&C Act may require that the sale and distribution of the tobacco product be restricted
  - FDA may require that you establish and maintain certain records and make certain reports available to FDA
  - Postmarket reports will vary based on submission
    - Serious and Unexpected Adverse Experience Reporting
    - Manufacturing Deviations
    - Annual reporting

Postmarket Reporting

METRICS, KEY FEATURES, AND RESOURCES

WITHDRAWAL OF AN APPLICATION

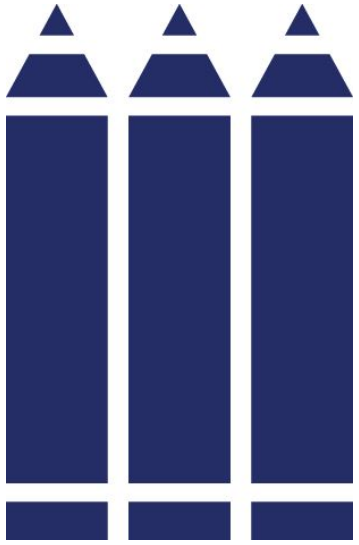
- Applicants may withdraw an application at any time prior to an action by CTP
  - If a withdrawal is requested, CTP issues a letter acknowledging the withdrawal request
  - A withdrawal is an action that closes the application

PMTA METRICS

Status	# of applications (through September 2018)
Received	396
Acknowledged	26
RTA	367
Filed	17
RTF	5
Marketing Authorization	8
No Marketing Authorization	0
Withdrawn	3

KEY PMTA FEATURES

- Primary pathway to legally market a new tobacco product
- PMTA does not require a predicate tobacco product
  - Not a valid SE predicate
- PMTA may have postmarket reporting
- May be referred TPSAC
- Samples may be required



KEY PMTA FEATURES

- Action on a PMTA occurs within 180 days (section 910(c)(1)(A))
- Bundled PMTA submissions
  - Applicant can include multiple tobacco products in one application
  - Clearly identify all tobacco products and unique characterization for each product

HELPFUL RESOURCES

- FDA/CTP PMTA webpage:
  - https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/PremarketTobaccoApplications/default.htm
- Rules:
  - Refuse To Accept Procedures for Premarket Tobacco Product Submissions
- Guidances:
  - Draft Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) (2016)
  - Final Guidance: Meetings with Industry and Investigators on the Research and Development of Tobacco Products (2016)
  - Draft Guidance: Applications for Premarket Review of New Tobacco Products (2011)
- Webinars:
  - Premarket Tobacco Product Applications (PMTA) for Electronic Nicotine Delivery System (ENDS)

THE END