Proposed Premarket Tobacco Product Application (PMTA) Post-Market Reporting Requirements for Industry

Presented by
Christine Saba, MPA, MPH
Office of Science, CTP, FDA

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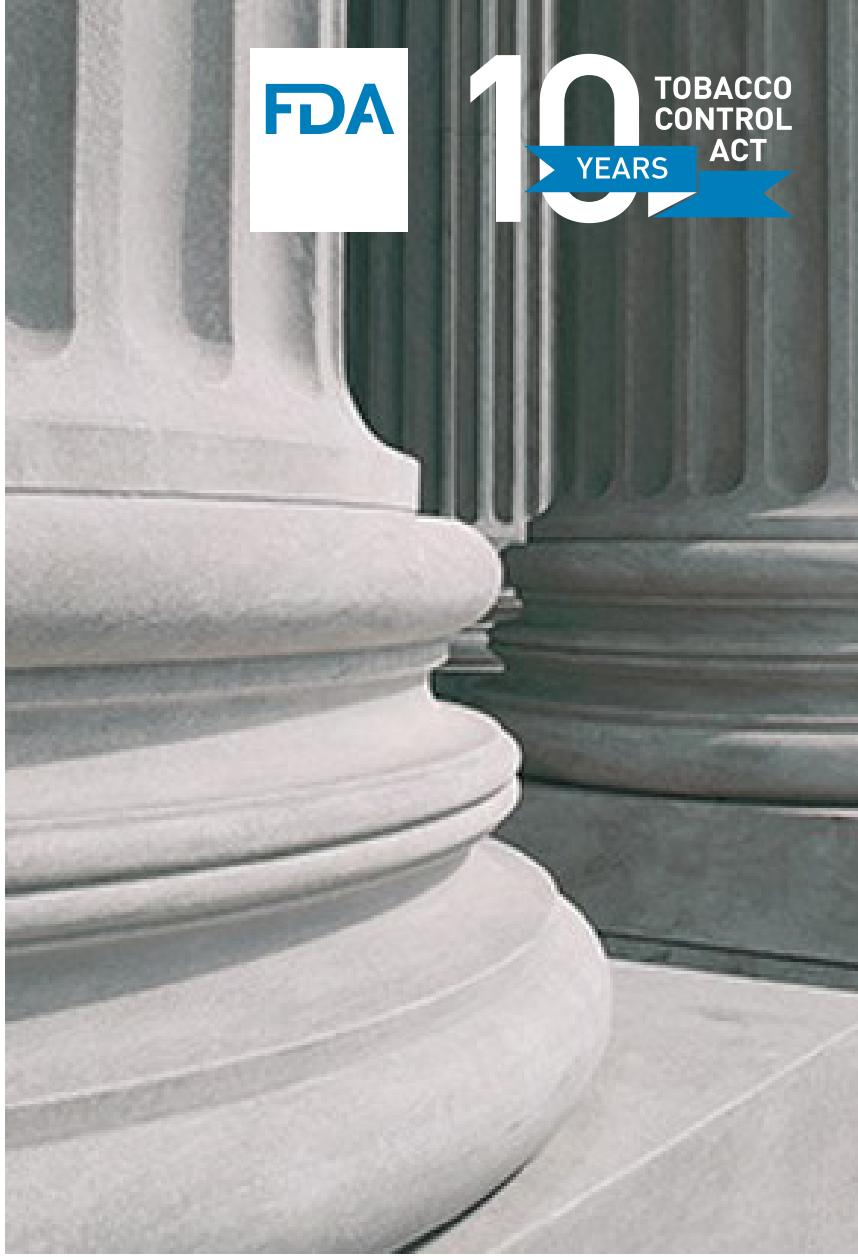

Premarket Tobacco Product Applications Notice of Proposed Rule Making (PMTA NPRM)

On September 25, 2019 FDA gave notice of a proposed “Premarket Tobacco Product Applications and Recordkeeping Requirements Rule” (PMTA NPRM).

This proposed rule is available and open for public comment through November 25, 2019.

This presentation will review postmarket reporting requirements outlined in the PMTA NPRM. These are subject to change in the final rule.

PMTA NPRM Postmarket Reporting: Proposed Administrative Requirements

PMTA NPRM **Subpart D** outlines proposed postmarket reporting requirements:

- **Periodic Reports** would be required to be submitted within **60 calendar days** of the reporting date specified in the marketing order for the life of the order
- **Adverse Experience Reports** would be required to be submitted within **15 calendar days** of receipt or identification

Includes a **cover letter** that contains:

- PMTA STN
- Tobacco product name(s)
- Company name
- Date of report
- Reporting period

High Level Overview of Proposed PMTA Postmarket Reporting Requirements

	Adverse Experience Reporting	Periodic Reporting
Data Elements	• **Serious adverse experiences, such as:** – Death – Life-threatening event – Inpatient hospitalization – Incapacitation of user – Birth defect – Any other adverse or serious condition affecting quality of life • **Unexpected adverse experiences**	• Description of the changes made to the manufacturing, facilities, or controls that do not modify the finished tobacco product • Inventory of ongoing and completed studies of the tobacco product • Summary of sales and distribution data • Data on current product purchasers • Final labeling specimens and labeling changes • Marketing and advertising implementation plans and reports
Reporting Date	• Within 15 calendar days of receipt or identification	• Annually, unless otherwise specified in marketing order

PMTA Proposed Reporting Requirements: Adverse Experience Reporting

Proposed Requirements for Adverse Experience Reporting

Serious and Unexpected Adverse Experiences

- Would be required to be reported to CTP through the HHS Safety Reporting Portal within **15 calendar days** after report is received

Manufacturing Deviations

- That could cause serious, adverse health consequences or death would be required to be reported to FDA within **15 calendar days** of identification

PMTA Proposed Reporting Requirements: Periodic Reporting

PMTA Periodic Reporting Proposed Requirements: Manufacturing Changes, Deviations, and Adverse Experiences

- **Summary and analysis of serious and unexpected adverse experiences** identified during the reporting period
- **Summary of all manufacturing deviations**, including those associated with processing, testing, packing, labeling, storage, holding and distribution
- **Summary of changes made to manufacturing, facilities, or controls** that do not modify the finished tobacco product (i.e., manufacturing process changes) compared to what was submitted in PMTA and rationale for change(s)

Proposed Reporting of Modifications to Authorized Tobacco Products

- FDA issues marketing orders for the specific new tobacco product described in the PMTA
- An applicant **may not make any modification** to the product that is the subject of the order that would result in a new tobacco product under the definition in section 910(a)(1), 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, 2017
- Changes that do not result in a new tobacco product should be reported under periodic reporting

Authorization of New Tobacco Products

- Applicants seeking to make modifications to the tobacco product authorized under a standing order may submit the following for the **new tobacco product**:
  - Standard PMTA
  - Supplemental PMTA
  - Request for an exemption from substantial equivalence
- The new tobacco product **cannot be legally marketed** until FDA has authorized marketing of the new tobacco product

PMTA Periodic Reporting Proposed Requirements: Research & Scientific Literature

- **Inventory of completed and ongoing studies about the tobacco product:** conducted either by, or on behalf of, the applicant that were not previously reported

- Any reports concerning **scientific investigations and/or literature** about the tobacco product

- **Assessment of how product continues to be appropriate for protection of public health (APPH)** with information regarding the existing tobacco product market, tobacco use behaviors, and associated health risks

PMTA Periodic Reporting Proposed Requirements: Sales and Distribution Data

- **Summary of sales and distribution data for the reporting period:**
  - **Total US sales** in dollars, units, and volume with breakdown by US census region, major retail markets, and channels in which product is sold
  - **UPC code(s)** corresponding to product(s) identified in PMTA
  - **Demographic characteristics** of product purchasers

PMTA Periodic Reporting Proposed Requirements: Labeling & Advertising

- **Specimens of all labeling and descriptions of all labeling changes** not previously submitted, including:
  - Original date of dissemination
  - Date dissemination was terminated
- **Final color copies of all advertising, marketing, and promotional materials** (e.g. print ads, point of sale signs) not previously submitted, including:
  - Original date of dissemination
  - Date dissemination was terminated

PMTA Periodic Reporting Proposed Requirements: Marketing & Advertising Plans (1 of 2)

- **Description and implementation of all marketing and advertising plans, by channel and by product, including a description of any:**
  - Use of **data sources, methodologies, and technologies** to establish, maintain, and monitor highly targeted marketing plans and media buys
  - Use of owned or earned media, public relations outreach, social media, partners, influencers, or brand ambassadors to create labeling for, advertise, market, or promote the product(s)
  - **Consumer engagements** conducted by the applicant or on its behalf
  - Analysis of delivery of **advertising impressions**

PMTA Periodic Reporting Proposed Requirements: Marketing & Advertising Plans (2 of 2)

- **Description and implementation of all marketing and advertising plans, by channel and by product, including a description of any:**
  - Targeting of specific adult audiences **by age-range**, including young adults
  - Actions taken to **restrict youth-access** and limit **youth-exposure** to the product(s)' labeling, advertising, marketing, or promotion

PMTA Additional Proposed Reporting

- Proposed § 1114.31(b)(3) would allow FDA, using its authority in section 910(f) of the FD&C Act, to require an applicant to submit postmarket reports **in addition** to those described § 1114.41

PMTA Postmarket Reporting References

- PMTA NPRM (open for public comment until November 25, 2019)
- IQOS Marketing Authorization
- HHS Safety Reporting Portal