PMTA Metrics for Acceptance, Filing and Review/Action Phases

DISCLAIMER: Please note that some metrics can change as FDA is processing an extremely large number of applications that move through many steps during the review process. The data reported here is generally accurate to within 10%.

The information in this report does not differentiate tobacco products by nicotine source.

FDA has received some submissions that could not be processed and ingested for various reasons, including but not limited to lack of required forms, use of an incorrect form, or use of an incorrect format on the application. Given that FDA was unable to fully process these submissions, they were issued Refuse to Accept Letters or withdrawn by the applicant. Since complete information was not available, metrics for these submissions are not provided in the reported tables.

Product categorization is provided by the applicant at submission. Upon scientific review, product categorization may be revised.

PMTA ACCEPTANCE PHASE METRICS

Data as of: 06/30/2026

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - June 2026)
Accepted	Cigar	0	0
	Cigarette	0	0
	ENDS	15,666	6,871
	Heated Tobacco Product	7	14
	Other*	1,266	939
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	143	233
	Waterpipe	57	0
	Total	**17,139**	**8,057**
Refuse-to-Accept (RTA)	Cigar	0	0
	Cigarette	0	0
	ENDS	169,391	23,575
	Heated Tobacco Product	0	0
	Other*	153	167
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	13	2
	Waterpipe	60	81
	Total	**169,617**	**23,825**
Total Applications Received	Cigar	0	0
	Cigarette	0	0
	ENDS	24,766	4,797
	Heated Tobacco Product	12	9
	Other*	1,350	649
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	121	222
	Waterpipe	198	0
	Total	**26,447**	**5,677**

* "Other" product category contains tobacco products that may not fall into the other eight established product categories; examples include but are not limited to, nicotine pouches, nicotine lozenges, and nicotine toothpicks.

PMTA FILING PHASE METRICS

Data as of: 06/30/2026

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - June 2026)
Filed	Cigar	0	0
	Cigarette	0	0
	ENDS	361	108
	Heated Tobacco Product	10	8
	Other*	187	343
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	3
	Waterpipe	0	0
	Total	**558**	**462**
Refuse-to-File (RTF)	Cigar	0	0
	Cigarette	0	0
	ENDS	37	8
	Heated Tobacco Product	0	0
	Other*	0	991
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	35
	Waterpipe	0	0
	Total	**37**	**1,034**

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PMTA REVIEW AND ACTION METRICS

Data as of: 06/30/2026

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - June 2026)
Deficiency letters issued	Cigar	0	0
	Cigarette	0	0
	ENDS	0	3
	Heated Tobacco Product	0	10
	Other*	0	312
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	**0**	**325**
Environmental Information Request letters issued	Cigar	0	0
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	**0**	**0**

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PMTA REVIEW AND ACTION METRICS

Data as of: 06/30/2026

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - June 2026)
Marketing Granted Orders	Cigar	0	0
	Cigarette	0	0
	ENDS	5	6
	Heated Tobacco Product	0	2
	Other*	20	6
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	**25**	**14**
Marketing Denial Orders	Cigar	0	0
	Cigarette	0	0
	ENDS	187,071	1,871
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	**187,071**	**1,871**
Withdrawn by Applicant	Cigar	0	0
	Cigarette	0	0
	ENDS	156	132
	Heated Tobacco Product	0	0
	Other*	0	274
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	11	0
	Waterpipe	0	0
	Total	**167**	**406**

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PMTA REVIEW AND ACTION METRICS

Data as of: 06/30/2026

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - June 2026)
Closure	Cigar	0	0
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	**0**	**0**

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