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 Given that FDA was unable to fully process these submissions, they were issued Refuse to Accept Letters or withdrawn by the applicant.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: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Accepted	Cigar	0	10	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	1,456	6,635,824	56,715	72,006	73,214
	Heated Tobacco Product	1	5	0	10	8
	Other*	20	44	40	536	242
	Pipe	0	12	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	145	4	0	13	41
	Waterpipe	63	0	0	0	0
	Total	**1,685**	**6,635,899**	**56,755**	**72,565**	**73,505**
Refuse-to-Accept (RTA)	Cigar	0	5	0	0	0
	Cigarette	0	1	0	0	5
	ENDS	150	1,311,386	970,238	17,276,120	24,022
	Heated Tobacco Product	0	0	0	0	1
	Other*	0	17	31	164	4
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	54	0
	Waterpipe	0	0	11	0	0
	Total	**150**	**1,311,409**	**970,280**	**17,276,338**	**24,032**
Total Applications Received	Cigar	15	0	0	0	0
	Cigarette	1	0	5	0	0
	ENDS	8,015,786	17,362,570	1,219,257	14,168	3,127
	Heated Tobacco Product	1	5	12	1	8
	Other*	73	29	2,142	109	472
	Pipe	12	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	149	0	68	72	24
	Waterpipe	63	11	0	0	0
	Total	**8,016,100***	**17,362,615****	**1,221,484**	**14,350**	**3,631**

[#] This includes information on applications for over 1 million products received between Sept. 10 - 30, 2020.

[##] This includes a submission from a single company with applications for over 17 million products. Decisions on these applications were issued in FY23.

* "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: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Filed	Cigar	0	10	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	732	1,018,466	54,608	115,762	64,827
	Heated Tobacco Product	1	5	0	0	0
	Other*	20	27	17	0	0
	Pipe	0	0	12	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	141	8	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**894**	**1,018,516**	**54,637**	**115,762**	**64,827**
Refuse-to-File (RTF)	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	156	5,089,664	20,300	51,475	6,088
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	63	0	0	0	0
	Total	**219**	**5,089,664**	**20,300**	**51,475**	**6,088**

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PMTA REVIEW AND ACTION METRICS Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Deficiency letters issued	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	40	1,001	0	70	15
	Heated Tobacco Product	1	5	0	0	0
	Other*	20	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	45	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**61**	**1,051**	**0**	**70**	**15**
Environmental Information Request letters issued	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**0**	**0**	**0**	**0**	**0**

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PMTA REVIEW AND ACTION METRICS Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Marketing Granted Orders	Cigar	0	0	0	0	0
	Cigarette	2	0	0	0	0
	ENDS	0	0	23	0	11
	Heated Tobacco Product	0	1	0	3	0
	Other*	0	0	4	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**2**	**1**	**27**	**3**	**11**
Marketing Denial Orders	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	1,201,817	30,079	6,869	62,848
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	6	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**6**	**1,201,817**	**30,079**	**6,869**	**62,848**

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PMTA REVIEW AND ACTION METRICS Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Withdrawn by Applicant	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	561	1,820	12	33
	Heated Tobacco Product	0	0	0	0	2
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**0**	**561**	**1,820**	**12**	**35**
Closure	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	80,143	144	391	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**0**	**80,143**	**144**	**391**	**0**

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