

PMTA ACCEPTANCE PHASE METRICS

Data as of: 03/31/2024

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 Total-to-Date (Oct 2023 - Mar 2024)
Accepted*	Cigar	0	10	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	1,456	6,635,772	56,735	72,006	29,984
	Heated Tobacco Product	1	5	0	10	8
	Other	20	44	40	536	124
	Pipe	0	12	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	145	4	0	13	25
	Waterpipe	63	0	0	0	0
	Total	1,685	6,635,847	56,775	72,565	30,141
Refuse-to-Accept* (RTA)	Cigar	0	5	0	0	0
	Cigarette	0	1	0	0	0
	ENDS	150	1,311,386	970,238	17,276,120	6,454
	Heated Tobacco Product	0	0	0	0	0
	Other	0	17	31	164	0
	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	17276338^{##}	6,454
Total Applications Received	Cigar	15	0	0	0	0
	Cigarette	1	0	0	0	0
	ENDS	8,015,715	17,362,568	1,212,004	14,144	582
	Heated Tobacco Product	1	5	12	1	8
	Other	73	29	2,112	72	0
	Pipe	12	0	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	149	0	68	62	32
	Waterpipe	63	11	0	0	0
	Total	8,016,029[#]	17,362,613^{##}	1,214,196	14,279	622

NOTES[#] 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 application were issued in FY23.

*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.

PMTA FILING PHASE METRICS

Data as of: 03/31/2024

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 Total-to-Date (Oct 2023 - Mar 2024)
Filed*	Cigar	0	10	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	732	1,018,444	56,047	115,784	0
	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	1,018,494	56,076	115,784	0
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	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	63	0	0	0	0
	Total	219	5,089,664	20,300	51,475	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 03/31/2024

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 Total-to-Date (Oct 2023 - Mar 2024)
Deficiency letters issued*	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	40	1,001	0	70	0
	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	0
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: 03/31/2024

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Marketing Granted Orders*	Cigar	0	0	0	0	0
	Cigarette	2	0	0	0	0
	ENDS	0	0	23	0	0
	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	0
Marketing Denial Orders*	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	1,204,531	30,085	6,869	22,369
	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	1,204,531	30,085	6,869	22,369
Withdrawn by Applicant*	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	561	1,820	12	4
	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	6

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Closure*	Cigar	0	0	0	0	0
	Cigarette	0	0	0	0	0
	ENDS	0	80,143	144	390	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	390	0

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