

PMTA ACCEPTANCE PHASE METRICS

Data as of: 4/30/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - April 2023)
Accepted*	Cigar	0	10	0	0
	Cigarette	0	0	0	0
	ENDS	1460	6,634,884	56,735	6,662
	Heated Tobacco	1	5	0	10
	Other	20	44	40	464
	Pipe	0	12	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	145	4	0	13
	Waterpipe	63	0	0	0
	Total	1,689	6,634,959	56,775	7,149
Refuse-to-Accept* (RTA)	Cigar	0	5	0	0
	Cigarette	0	1	0	0
	ENDS	150	1,311,386	970,238	17,277,068
	Heated Tobacco	0	0	0	0
	Other	0	17	31	344
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	54
	Waterpipe	0	0	11	0
	Total	150	1,311,409	970,280	17,277,466
Total Applications Received	Cigar	15	0	0	0
	Cigarette	1	0	1	0
	ENDS	8,014,303	17,362,568	1,117,557	2,865
	Heated Tobacco	1	5	12	0
	Other	73	29	942	14
	Pipe	12	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	149	0	85	10
	Waterpipe	63	11	0	0
	Total	#8,014,617	##17,362,613	1,118,597	2,889

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: 4/30/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - April 2023)
Filed*	Cigar	0	10	0	0
	Cigarette	0	0	0	0
	ENDS	751	1,019,498	56,529	116,459
	Heated Tobacco Product	1	5	0	0
	Other	20	27	17	0
	Pipe	0	0	12	0
	Roll-Your-Own	0	0	0	0
	Smokeless	141	8	0	0
	Waterpipe	0	0	0	0
	Total	913	1,019,548	56,558	116,459
Refuse-to-File* (RTF)	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	156	5,088,273	20,300	49,085
	Heated Tobacco Product	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	63	0	0	0
	Total	219	5,088,273	20,300	49,085

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PMTA REVIEW AND ACTION METRICS

Data as of: 04/30/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - April 2023)
Deficiency letters issued*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	40	1,001	0	60
	Heated Tobacco	1	5	0	0
	Other	20	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	45	0	0
	Waterpipe	0	0	0	0
	Total	61	1,051	0	30
Environmental Information Request letters issued*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	0	0	0
	Heated Tobacco	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	0	0	0	0
	Total	0	0	0	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 04/30/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - April 2023)
Marketing Granted Orders*	Cigar	0	0	0	0
	Cigarette	2	0	0	0
	ENDS	0	0	23	0
	Heated Tobacco	0	1	0	3
	Other	0	0	4	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	0	0	0	0
	Total	2	1	27	3
Marketing Denial Orders*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	1,204,382	30,085	39
	Heated Tobacco	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	6	0	0	0
	Waterpipe	0	0	0	0
	Total	6	1,204,382	30,085	39
Withdrawn by Applicant*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	561	1,820	4
	Heated Tobacco	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	0	0	0	0
	Total	0	561	1,820	4

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PMTA REVIEW AND ACTION METRICS

Data as of: 04/30/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - April 2023)
Closure*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	80,144	144	36
	Heated Tobacco	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	0	0	0	0
	Total	0	80,144	144	36

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