

PMTA ACCEPTANCE PHASE METRICS

Data as of: 02/28/2023

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 - Feb 2023)
Accepted*	Cigar	0	10	0	0
	Cigarette	0	0	0	0
	ENDS	1,505	6,634,836	56,735	6,662
	Heated Tobacco Product	1	5	0	0
	Other	20	44	40	464
	Pipe	0	12	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	100	4	0	13
	Waterpipe	63	0	0	0
	Total	1,689	6,634,911	56,775	7,139
Refuse-to-Accept* (RTA)	Cigar	0	5	0	0
	Cigarette	0	1	0	0
	ENDS	150	1,311,386	970,913	17,277,018
	Heated Tobacco Product	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	970,955	17,277,416
Total Applications Received	Cigar	15	0	0	0
	Cigarette	1	0	1	0
	ENDS	8,014,290	17,362,495	995,298	212
	Heated Tobacco Product	1	5	10	0
	Other	73	29	942	0
	Pipe	13	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	149	0	85	10
	Waterpipe	63	11	0	0
	Total	#8,014,605	##17,362,540	996,336	222

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: 02/28/2023

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 - Feb 2023)
Filed*	Cigar	0	10	0	0
	Cigarette	0	0	0	0
	ENDS	796	1,019,498	56,529	11,585
	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	96	8	0	0
	Waterpipe	0	0	0	0
	Total	913	1,019,548	56,558	11,585
Refuse-to-File* (RTF)	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	156	5,088,273	20,360	2,315
	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	20,360	2,315

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PMTA REVIEW AND ACTION METRICS

Data as of: 02/28/2023

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 - Feb 2023)
Deficiency Letters Issued*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	40	1,001	0	0
	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	0	0	0
	Waterpipe	0	0	0	0
	Total	61	1,006	0	0
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: 02/28/2023

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 - Feb 2023)
Marketing Granted Orders*	Cigar	0	0	0	0
	Cigarette	2	0	0	0
	ENDS	0	0	23	0
	Heated Tobacco Product	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	1,204,387	30,085	37
	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	6	0	0	0
	Waterpipe	0	0	0	0
	Total	6	1,204,387	30,085	37
Withdrawn by Applicant*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	561	1,820	0
	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	0	0	0	0
	Total	0	561	1,820	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 02/28/2023

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 - Feb 2023)
Closure*	Cigar	0	0	0	0
	Cigarette	0	0	0	0
	ENDS	0	80,144	144	17
	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	0	0	0	0
	Total	0	80,144	144	17

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