

PMTA ACCEPTANCE PHASE METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Accepted*	Cigar	0	10	0
	Cigarette	0	0	0
	ENDS	1,459	6,634,842	51,595
	Heated Tobacco Product	1	5	0
	Other	120	48	0
	Pipe	0	12	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	63	0	0
	Total	1,643	6,634,917	51,595
Refuse-to-Accept* (RTA)	Cigar	0	5	0
	Cigarette	0	1	0
	ENDS	150	1,310,942	92,079
	Heated Tobacco Product	0	0	0
	Other	0	461	1
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	11
	Total	150	1,311,409	92,091
Total Applications Received	Cigar	15	0	0
	Cigarette	1	0	0
	ENDS	8,013,850	77,942	12,856
	Heated Tobacco Product	1	5	8
	Other	666	29	47
	Pipe	12	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	63	11	0
	Total	#8,014,608	77,987	12,911

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

*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 is continuing to process applications for non-tobacco nicotine products submitted to CTP by the May 14, 2022 deadline; data on the applications that have been processed to date are included within these charts.

PMTA FILING PHASE METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Filed*	Cigar	0	10	0
	Cigarette	0	0	0
	ENDS	751	1,019,449	28,507
	Heated Tobacco Product	1	5	0
	Other	116	35	17
	Pipe	0	0	12
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	868	1,019,499	28,536
Refuse-to-File* (RTF)	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	156	5,088,283	7,277
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	63	0	0
	Total	219	5,088,283	7,277

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PMTA REVIEW AND ACTION METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Number of Discipline Reviews completed*	Cigar	0	0	0
	Cigarette	30	0	0
	ENDS	424	2,724,734	113,728
	Heated Tobacco Product	7	24	14
	Other	208	0	4
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	84	0	0
	Waterpipe	0	0	0
	Total	753	2,724,758	113,746
Deficiency letters issued*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	40	1,001	0
	Heated Tobacco Product	0	5	0
	Other	20	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	60	1,006	0
Environmental Information Request letters issued*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	0	0	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Marketing Granted Orders*	Cigar	0	0	0
	Cigarette	2	0	0
	ENDS	0	0	21
	Heated Tobacco Product	0	1	0
	Other	0	0	4
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	2	1	25
Marketing Denial Orders*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	1,204,785	30,075
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	6	0	0
	Waterpipe	0	0	0
	Total	6	1,204,785	30,075
Withdrawn by Applicant*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	561	1,730
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	0	561	1,730

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PMTA REVIEW AND ACTION METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Closure*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	80,144	88
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	0
	Total	0	80,144	88

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