

PMTA ACCEPTANCE PHASE METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Accepted*	Cigar	0	10	0
	Cigarette	0	0	0
	ENDS	1,459	6,634,842	56,736
	Heated Tobacco Product	1	5	0
	Other	120	48	40
	Pipe	0	12	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	63	0	0
	Total	1,643	6,634,917	56,776
Refuse-to-Accept* (RTA)	Cigar	0	5	0
	Cigarette	0	1	0
	ENDS	150	1,310,942	970,914
	Heated Tobacco Product	0	0	0
	Other	0	461	31
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	0	0	11
	Total	150	1,311,409	970,956
Total Applications Received	Cigar	15	0	0
	Cigarette	1	0	0
	ENDS	8,013,850	77,946	955,073
	Heated Tobacco Product	1	5	8
	Other	666	29	947
	Pipe	12	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	3
	Waterpipe	63	11	0
	Total	# 8,014,608	77,991	956,031

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.

PMTA FILING PHASE METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Filed*	Cigar	0	10	0
	Cigarette	0	0	0
	ENDS	751	1,019,449	56,529
	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	56,558
Refuse-to-File* (RTF)	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	156	5,088,283	20,339
	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	20,339

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PMTA REVIEW AND ACTION METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Number of Discipline Reviews completed*	Cigar	0	0	0
	Cigarette	28	0	0
	ENDS	424	2,401,544	114,117
	Heated Tobacco Product	7	22	14
	Other	208	0	20
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	78	0	0
	Waterpipe	0	0	0
	Total	745	2,401,566	114,151
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: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Marketing Granted Orders*	Cigar	0	0	0
	Cigarette	2	0	0
	ENDS	0	0	23
	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	27
Marketing Denial Orders*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	1,204,339	30,133
	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	1,204,339	30,133
Withdrawn by Applicant*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	561	1,820
	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	1,820

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PMTA REVIEW AND ACTION METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Closure*	Cigar	0	0	0
	Cigarette	0	0	0
	ENDS	0	263	144
	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	263	144

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