

PMTA ACCEPTANCE PHASE METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Accepted*	Cigarette	1	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	1,453	6,625,825	910
	Cigar	0	10	0
	Pipe	0	12	0
	Waterpipe	63	0	0
	Other	165	48	0
	Total	1,682	6,625,900	910
Refuse-to-Accept* (RTA)	Cigarette	0	1	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	150	1,310,942	10
	Cigar	0	5	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	461	1
	Total	150	1,311,409	11
Total Applications Received	Cigarette	2	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	8,009,969	40,844	0
	Cigar	15	0	0
	Pipe	12	0	0
	Waterpipe	63	11	0
	Other	666	9	0
	Total	8,010,727[#]	40,869	0

[#]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%.

PMTA FILING PHASE METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Filed*	Cigarette	1	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	751	974,322	0
	Cigar	0	10	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	161	35	0
	Total	913	974,372	0
Refuse-to-File* (RTF)	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	156	5,088,283	0
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	63	0	0
	Other	0	0	0
	Total	219	5,088,283	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Number of Discipline Reviews completed*	Cigarette	37	24	0
	Roll-Your-Own	0	0	0
	Smokeless	84	0	0
	ENDS	485	2,650,252	67,824
	Cigars	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	252	450	0
	Total	858	2,650,726	67,824
Deficiency letters issued*	Cigarette	1	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	40	1,001	0
	Cigars	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	20	45	0
	Total	61	1,051	0
Environmental Information Request letters issued*	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	0	0	0
	Cigars	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	0	0	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Marketing Granted Orders*	Cigarette	2	1	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	0	0	0
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	2	1	0
Marketing Denial Orders*	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	6	0	0
	ENDS	0	1,181,581	144
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	6	1,181,581	144
Withdrawn by Applicant*	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	0	561	0
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	0	561	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Closure*	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	0	79,881	0
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	0	79,881	0

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