

PMTA ACCEPTANCE PHASE METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Accepted*	Cigarette	0	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	1,459	6,625,543	37,776
	Cigar	0	10	0
	Pipe	0	12	0
	Waterpipe	63	0	0
	HTP	1	0	0
	Other	165	48	0
	Total	1,688	6,625,618	37,776
Refuse-to-Accept* (RTA)	Cigarette	0	1	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	150	1,310,942	77,436
	Cigar	0	5	0
	Pipe	0	0	0
	Waterpipe	0	0	11
	HTP	0	0	0
	Other	0	461	1
	Total	150	1,311,409	77,448
Total Applications Received	Cigarette	1	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	8,010,404	68,247	2,104
	Cigar	15	0	0
	Pipe	12	0	0
	Waterpipe	63	11	0
	HTP	1	0	0
	Other	666	9	0
	Total	8,011,162[#]	68,272	2,104

[#]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: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Filed*	Cigarette	0	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	751	971,032	4,997
	Cigar	0	10	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	1	0	0
	Other	161	35	0
	Total	913	971,082	4,997
Refuse-to-File* (RTF)	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	156	5,088,273	1,089
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	63	0	0
	HTP	0	0	0
	Other	0	0	0
	Total	219	5,088,273	1,089

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PMTA REVIEW AND ACTION METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Number of Discipline Reviews completed*	Cigarette	30	21	0
	Roll-Your-Own	0	0	0
	Smokeless	84	0	0
	ENDS	485	2,682,273	107,959
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	7	3	0
	Other	252	450	4
	Total	858	2,682,747	107,963
Deficiency letters issued*	Cigarette	0	5	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	40	1,001	0
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	1	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
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	0	0	0
	Other	0	0	0
	Total	0	0	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Marketing Granted Orders*	Cigarette	2	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	ENDS	0	0	3
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	0	1	0
	Other	0	0	4
	Total	2	1	7
Marketing Denial Orders*	Cigarette	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	6	0	0
	ENDS	0	1,205,133	29,575
	Cigar	0	0	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	0	0	0
	Other	0	0	0
	Total	6	1,205,133	29,575
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
	HTP	0	0	0
	Other	0	0	0
	Total	0	561	0

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PMTA REVIEW AND ACTION METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 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
	HTP	0	0	0
	Other	0	0	0
	Total	0	79,881	0

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