

SE ACCEPTANCE PHASE METRICS

Data as of: 6/2/2021

Metric	Product Category	FY 2020 Total (Oct 2019 - Sept 2020)	FY 2021 Total To-Date (Oct 2020 - May 2021)
Accepted*	Cigarette	158	70
	Roll-Your-Own	96	49
	Smokeless	59	36
	ENDS	0	0
	Cigar	916	2,031
	Pipe	1,010	543
	Waterpipe	204	616
	Other	1	0
	Total	2,444	3,345
Refuse-to-Accept* (RTA)	Cigarette	0	0
	Roll-Your-Own	8	9
	Smokeless	0	0
	ENDS	0	0
	Cigar	58	112
	Pipe	0	200
	Waterpipe	0	1,586
	Other	0	2
	Total	66	1,909
Total Applications Received	Cigarette	136	59
	Roll-Your-Own	135	39
	Smokeless	60	36
	ENDS	0	0
	Cigar	3,063	80
	Pipe	1,695	79
	Waterpipe	2,325	92
	Other	3	0
	Total	7,417	385

*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%.

SE REVIEW AND ACTION METRICS

Data as of: 6/2/2021

Metric	Product Category	FY 2020 Total (Oct 2019 - Sept 2020)	FY 2021 Total To-Date (Oct 2020 - May 2021)
Number of Discipline Reviews completed	Cigarette	968	91
	Roll-Your-Own	342	114
	Smokeless	408	43
	ENDS	0	0
	Cigar	257	1,669
	Pipe	931	585
	Waterpipe	99	252
	Other	7	0
	Total	3,012	2,754
Deficiency letters issued	Cigarette	122	2
	Roll-Your-Own	42	7
	Smokeless	54	2
	ENDS	0	0
	Cigar	19	243
	Pipe	26	74
	Waterpipe	5	39
	Other	1	0
	Total	269	367
Environmental Information Request letters issued	Cigarette	0	0
	Roll-Your-Own	2	0
	Smokeless	0	0
	ENDS	0	0
	Cigars	0	0
	Pipe	114	15
	Waterpipe	0	0
	Other	0	0
	Total	116	15

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SE REVIEW AND ACTION METRICS

Data as of: 6/2/2021

Metric	Product Category	FY 2020 Total (Oct 2019 - Sept 2020)	FY 2021 Total To-Date (Oct 2020 - May 2021)
Substantial Equivalence (SE) Orders*	Cigarette	104	15
	Roll-Your-Own	31	6
	Smokeless	16	0
	ENDS	0	0
	Cigar	27	18
	Pipe	29	11
	Waterpipe	6	0
	Other	0	0
	Total	213	50
Not Substantially Equivalent (NSE) Orders*	Cigarette	9	2
	Roll-Your-Own	0	0
	Smokeless	8	0
	ENDS	0	0
	Cigar	0	0
	Pipe	0	0
	Waterpipe	0	0
	Other	0	0
	Total	17	2
Withdrawn by Applicant*	Cigarette	58	2
	Roll-Your-Own	6	4
	Smokeless	17	22
	ENDS	0	0
	Cigar	2	28
	Pipe	0	0
	Waterpipe	6	98
	Other	0	0
	Total	89	154

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SE REVIEW AND ACTION METRICS

Data as of: 6/2/2021

Metric	Product Category	FY 2020 Total (Oct 2019 - Sept 2020)	FY 2021 Total To-Date (Oct 2020 - May 2021)
Closure*	Cigarette	10	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	ENDS	0	0
	Cigar	2	2
	Pipe	0	0
	Waterpipe	1	0
	Other	0	0
	Total	13	2

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