

## SE ACCEPTANCE PHASE METRICS

Data as of: 4/1/2021

Metric	Product Category	FY 2020 Total (October 2019 - September 2020)	FY 2021 Total To-Date (October 2020 - March 2021)
Accepted*	Cigarette	158	48
	Roll-Your-Own	96	25
	Smokeless	59	16
	ENDS	0	0
	Cigars	916	1,987
	Pipe	1,010	501
	Waterpipe	204	526
	Other	1	0
	<b>Total</b>	<b>2,444</b>	<b>3,103</b>
Refuse-to-Accept* (RTA)	Cigarette	0	0
	Roll-Your-Own	8	2
	Smokeless	0	0
	ENDS	0	0
	Cigars	58	112
	Pipe	0	200
	Waterpipe	0	1,584
	Other	0	2
	<b>Total</b>	<b>66</b>	<b>1,900</b>
Total Applications Received	Cigarette	136	36
	Roll-Your-Own	135	26
	Smokeless	60	16
	ENDS	0	0
	Cigars	3,063	69
	Pipe	1,695	46
	Waterpipe	2,323	2
	Other	3	0
	<b>Total</b>	<b>7,415</b>	<b>195</b>

\*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: 4/1/2021

Metric	Product Category	FY 2020 Total (October 2019 - September 2020)	FY 2021 Total To-Date (October 2020 - March 2021)
Number of Discipline Reviews completed	Cigarette	968	90
	Roll-Your-Own	342	110
	Smokeless	408	14
	ENDS	0	0
	Cigars	257	1,448
	Pipe	931	458
	Waterpipe	99	252
	Other	7	0
	<b>Total</b>	<b>3,012</b>	<b>2,372</b>
Deficiency letters issued	Cigarette	122	2
	Roll-Your-Own	42	7
	Smokeless	54	2
	ENDS(VAPES)	0	0
	Cigars	19	190
	Pipe	26	59
	Waterpipe	5	39
	Other	1	0
	<b>Total</b>	<b>269</b>	<b>299</b>
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
	<b>Total</b>	<b>116</b>	<b>15</b>

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## SE REVIEW AND ACTION METRICS

Data as of: 4/1/2021

Metric	Product Category	FY 2020 Total (October 2019 - September 2020)	FY 2021 Total To-Date (October 2020 - March 2021)
Substantial Equivalence (SE) Orders*	Cigarette	104	14
	Roll-Your-Own	31	5
	Smokeless	16	0
	ENDS	0	0
	Cigars	27	18
	Pipe	29	11
	Waterpipe	6	0
	Other	0	0
	<b>Total</b>	<b>213</b>	<b>48</b>
Not Substantially Equivalent (NSE) Orders*	Cigarette	9	2
	Roll-Your-Own	0	0
	Smokeless	8	0
	ENDS	0	0
	Cigars	0	0
	Pipe	0	0
	Waterpipe	0	0
	Other	0	0
	<b>Total</b>	<b>17</b>	<b>2</b>
Withdrawn by Applicant*	Cigarette	58	2
	Roll-Your-Own	6	4
	Smokeless	17	22
	ENDS	0	0
	Cigars	2	21
	Pipe	0	0
	Waterpipe	6	96
	Other	0	0
	<b>Total</b>	<b>89</b>	<b>145</b>

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## SE REVIEW AND ACTION METRICS

Data as of: 4/1/2021

Metric	Product Category	FY 2020 Total (October 2019 - September 2020)	FY 2021 Total To-Date (October 2020 - March 2021)
Closure*	Cigarette	10	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	ENDS	0	0
	Cigars	2	2
	Pipe	0	0
	Waterpipe	1	0
	Other	0	0
	<b>Total</b>	<b>13</b>	<b>2</b>

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