

## SE ACCEPTANCE PHASE METRICS

Data as of: 7/28/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total To-Date (Oct 1, 2020 - July 28, 2021)
Accepted*	Cigarette	158	93
	Roll-Your-Own	96	61
	Smokeless	59	38
	ENDS	0	0
	Cigar	916	2,068
	Pipe	1,010	556
	Waterpipe	204	617
	Other	1	0
	<b>Total</b>	<b>2,444</b>	<b>3,433</b>
Refuse-to-Accept* (RTA)	Cigarette	0	0
	Roll-Your-Own	8	11
	Smokeless	0	0
	ENDS	0	0
	Cigar	58	133
	Pipe	0	236
	Waterpipe	0	1,586
	Other	0	2
	<b>Total</b>	<b>66</b>	<b>1,968</b>
Total Applications Received	Cigarette	136	85
	Roll-Your-Own	135	45
	Smokeless	60	37
	ENDS	0	0
	Cigar	3,063	114
	Pipe	1,695	92
	Waterpipe	2,325	92
	Other	3	0
	<b>Total</b>	<b>7,417</b>	<b>465</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: 7/28/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total To-Date (Oct 1, 2020 - July 28, 2021)
Number of Discipline Reviews completed	Cigarette	968	91
	Roll-Your-Own	342	167
	Smokeless	408	45
	ENDS	0	0
	Cigar	257	1,986
	Pipe	931	894
	Waterpipe	99	366
	Other	7	0
	<b>Total</b>	<b>3,012</b>	<b>3,549</b>
Deficiency letters issued	Cigarette	122	2
	Roll-Your-Own	42	12
	Smokeless	54	2
	ENDS	0	0
	Cigar	19	258
	Pipe	26	89
	Waterpipe	5	39
	Other	1	0
	<b>Total</b>	<b>269</b>	<b>402</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: 7/28/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total To-Date (Oct 1, 2020 - July 28, 2021)
Substantial Equivalence (SE) Orders*	Cigarette	104	15
	Roll-Your-Own	31	6
	Smokeless	16	0
	ENDS	0	0
	Cigar	27	20
	Pipe	29	40
	Waterpipe	6	0
	Other	0	0
	<b>Total</b>	<b>213</b>	<b>81</b>
Not Substantially Equivalent (NSE) Orders*	Cigarette	9	2
	Roll-Your-Own	0	0
	Smokeless	8	0
	ENDS	0	0
	Cigar	0	8
	Pipe	0	0
	Waterpipe	0	0
	Other	0	0
	<b>Total</b>	<b>17</b>	<b>10</b>
Withdrawn by Applicant*	Cigarette	58	2
	Roll-Your-Own	6	4
	Smokeless	17	22
	ENDS	0	0
	Cigar	2	45
	Pipe	0	7
	Waterpipe	6	98
	Other	0	0
	<b>Total</b>	<b>89</b>	<b>178</b>

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## SE REVIEW AND ACTION METRICS

Data as of: 7/28/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total To-Date (Oct 1, 2020 - July 28, 2021)
Closure*	Cigarette	10	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	ENDS	0	0
	Cigar	2	11
	Pipe	0	0
	Waterpipe	1	0
	Other	0	0
	<b>Total</b>	<b>13</b>	<b>11</b>

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