

SE ACCEPTANCE PHASE METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Accepted*	Cigar	909	2,062	52
	Cigarette	129	110	20
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	1	5	0
	Pipe	1,010	560	1
	Roll-Your-Own	96	63	11
	Smokeless	60	40	17
	Waterpipe	199	678	132
	<b>Total</b>	<b>2,404</b>	<b>3,518</b>	<b>233</b>
Refuse-to-Accept* (RTA)	Cigar	58	133	0
	Cigarette	0	0	3
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	2	0
	Pipe	0	236	0
	Roll-Your-Own	8	11	0
	Smokeless	0	0	0
	Waterpipe	0	1,586	1
	<b>Total</b>	<b>66</b>	<b>1,968</b>	<b>4</b>
Total Applications Received*	Cigar	3,065	141	127
	Cigarette	136	101	87
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	3	5	31
	Pipe	1,695	97	1
	Roll-Your-Own	135	47	88
	Smokeless	60	45	24
	Waterpipe	2,327	249	73
	<b>Total</b>	<b>7,421</b>	<b>685</b>	<b>431</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: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Number of Discipline Reviews completed*	Cigar	257	2,336	2,165
	Cigarette	660	90	85
	ENDS	0	0	0
	Heated Tobacco Product	12	0	0
	Other	7	0	0
	Pipe	922	1,571	662
	Roll-Your-Own	339	191	44
	Smokeless	310	17	6
	Waterpipe	95	412	915
	<b>Total</b>	<b>2,602</b>	<b>4,617</b>	<b>3,877</b>
Deficiency letters issued*	Cigar	19	280	48
	Cigarette	123	2	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	1	0	0
	Pipe	139	100	40
	Roll-Your-Own	45	12	0
	Smokeless	54	2	0
	Waterpipe	7	42	15
	<b>Total</b>	<b>390</b>	<b>438</b>	<b>103</b>
Environmental Information Request letters issued*	Cigar	4	0	11
	Cigarette	23	2	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	138	40	0
	Roll-Your-Own	4	0	0
	Smokeless	17	0	0
	Waterpipe	0	0	0
	<b>Total</b>	<b>186</b>	<b>42</b>	<b>11</b>

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SE REVIEW AND ACTION METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Substantial Equivalence (SE) Orders*	Cigar	27	20	11
	Cigarette	105	15	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	0	0	0
	Pipe	29	130	27
	Roll-Your-Own	32	5	4
	Smokeless	16	0	1
	Waterpipe	6	11	0
	<b>Total</b>	<b>217</b>	<b>181</b>	<b>43</b>
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	21
	Cigarette	9	0	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	15
	Roll-Your-Own	0	0	0
	Smokeless	8	0	1
	Waterpipe	0	0	15
	<b>Total</b>	<b>17</b>	<b>8</b>	<b>52</b>
Withdrawn by Applicant*	Cigar	2	45	49
	Cigarette	63	2	41
	ENDS	0	0	0
	Heated Tobacco Product	0	0	2
	Other	0	0	0
	Pipe	0	7	1
	Roll-Your-Own	6	5	2
	Smokeless	17	24	0
	Waterpipe	6	98	1
	<b>Total</b>	<b>94</b>	<b>181</b>	<b>96</b>

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## SE REVIEW AND ACTION METRICS

Data as of: 05/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - May 2022)
Closure*	Cigar	2	11	0
	Cigarette	10	0	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	1	0	4
	<b>Total</b>	<b>13</b>	<b>11</b>	<b>4</b>

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