

SE ACCEPTANCE PHASE METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Accepted*	Cigar	916	2,055	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	93	63	11
	Smokeless	60	40	17
	Waterpipe	199	678	132
	<b>Total</b>	<b>2,408</b>	<b>3,511</b>	<b>233</b>
Refuse-to-Accept* (RTA)	Cigar	58	133	7
	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>11</b>
Total Applications Received	Cigar	3,065	141	166
	Cigarette	136	101	281
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	3	5	49
	Pipe	1,695	97	2
	Roll-Your-Own	135	47	129
	Smokeless	60	45	38
	Waterpipe	2,327	249	73
	<b>Total</b>	<b>7,421</b>	<b>685</b>	<b>738</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: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Number of Discipline Reviews completed*	Cigar	257	2,359	2,911
	Cigarette	1,049	98	240
	ENDS	0	0	0
	Heated Tobacco Product	12	0	0
	Other	7	0	0
	Pipe	922	1,571	1,200
	Roll-Your-Own	340	204	79
	Smokeless	402	35	126
	Waterpipe	95	412	1,111
	<b>Total</b>	<b>3,084</b>	<b>4,679</b>	<b>5,667</b>
Deficiency letters issued*	Cigar	19	280	72
	Cigarette	143	2	10
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	1	0	0
	Pipe	139	100	51
	Roll-Your-Own	45	12	0
	Smokeless	54	2	0
	Waterpipe	7	42	15
	<b>Total</b>	<b>410</b>	<b>438</b>	<b>148</b>
Environmental Information Request letters issued*	Cigar	4	0	11
	Cigarette	34	2	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	138	40	3
	Roll-Your-Own	4	0	0
	Smokeless	17	0	0
	Waterpipe	0	0	0
	<b>Total</b>	<b>197</b>	<b>42</b>	<b>14</b>

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SE REVIEW AND ACTION METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)
Substantial Equivalence (SE) Orders*	Cigar	27	20	25
	Cigarette	105	15	10
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	0	0	0
	Pipe	29	130	100
	Roll-Your-Own	32	5	7
	Smokeless	16	0	1
	Waterpipe	6	11	1
	<b>Total</b>	<b>217</b>	<b>181</b>	<b>144</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	71
	ENDS	0	0	0
	Heated Tobacco Product	0	0	2
	Other	0	0	0
	Pipe	0	7	12
	Roll-Your-Own	6	5	3
	Smokeless	17	24	1
	Waterpipe	6	98	1
	<b>Total</b>	<b>94</b>	<b>181</b>	<b>139</b>

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## SE REVIEW AND ACTION METRICS

Data as of: 09/30/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 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	11
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	1	0	4
	<b>Total</b>	<b>13</b>	<b>11</b>	<b>15</b>

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