

SE ACCEPTANCE PHASE METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Accepted*	Cigarette	128	110	20
	Roll-Your-Own	96	63	11
	Smokeless	58	45	11
	ENDS	0	0	0
	Cigar	915	2,070	52
	Pipe	1,005	560	1
	Waterpipe	199	677	133
	HTP	0	0	0
	Other	1	0	0
	<b>Total</b>	<b>2,402</b>	<b>3,525</b>	<b>228</b>
Refuse-to-Accept* (RTA)	Cigarette	0	0	3
	Roll-Your-Own	8	11	0
	Smokeless	0	0	0
	ENDS	0	0	0
	Cigar	58	133	0
	Pipe	0	236	0
	Waterpipe	0	1,586	0
	HTP	0	0	0
	Other	0	2	0
	<b>Total</b>	<b>66</b>	<b>1,968</b>	<b>3</b>
Total Applications Received*	Cigarette	136	100	30
	Roll-Your-Own	135	47	11
	Smokeless	60	44	11
	ENDS	0	0	0
	Cigar	3,064	141	123
	Pipe	1,695	97	1
	Waterpipe	2,327	248	38
	HTP	0	0	0
	Other	3	0	0
	<b>Total</b>	<b>7,420</b>	<b>677</b>	<b>214</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: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Number of Discipline Reviews completed*	Cigarette	943	92	10
	Roll-Your-Own	341	175	4
	Smokeless	402	40	6
	ENDS	0	0	0
	Cigar	257	2,396	227
	Pipe	925	1,193	31
	Waterpipe	95	412	90
	HTP	12	0	0
	Other	7	0	0
	<b>Total</b>	<b>2,982</b>	<b>4,308</b>	<b>368</b>
Deficiency letters issued*	Cigarette	125	0	0
	Roll-Your-Own	36	12	0
	Smokeless	50	2	0
	ENDS	0	0	0
	Cigar	19	278	21
	Pipe	26	85	19
	Waterpipe	4	42	15
	HTP	2	0	0
	Other	1	0	0
	<b>Total</b>	<b>263</b>	<b>419</b>	<b>55</b>
Environmental Information Request letters issued*	Cigarette	0	0	0
	Roll-Your-Own	2	0	0
	Smokeless	0	0	0
	ENDS	0	0	0
	Cigar	0	0	4
	Pipe	114	15	0
	Waterpipe	0	0	0
	HTP	0	0	0
	Other	0	0	0
	<b>Total</b>	<b>116</b>	<b>15</b>	<b>4</b>

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SE REVIEW AND ACTION METRICS

Data as of: 12/14/2021

Metric	Product Category	FY 2020 Total	FY 2021 Total	FY 2022 Total To-Date (Oct 2021 - Dec 2021)
Substantial Equivalence (SE) Orders*	Cigarette	105	15	0
	Roll-Your-Own	32	5	0
	Smokeless	16	0	1
	ENDS	0	0	0
	Cigar	27	35	0
	Pipe	29	130	0
	Waterpipe	6	11	0
	HTP	2	0	0
	Other	0	0	0
	<b>Total</b>	<b>217</b>	<b>196</b>	<b>1</b>
Not Substantially Equivalent (NSE) Orders*	Cigarette	9	2	0
	Roll-Your-Own	0	0	0
	Smokeless	8	0	1
	ENDS	0	0	0
	Cigar	0	8	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	HTP	0	0	0
	Other	0	0	0
	<b>Total</b>	<b>17</b>	<b>10</b>	<b>1</b>
Withdrawn by Applicant*	Cigarette	63	2	0
	Roll-Your-Own	6	5	0
	Smokeless	17	24	0
	ENDS	0	0	0
	Cigar	2	45	15
	Pipe	0	7	13
	Waterpipe	6	98	0
	HTP	0	0	2
	Other	0	0	0
	<b>Total</b>	<b>94</b>	<b>181</b>	<b>30</b>

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SE REVIEW AND ACTION METRICS

Data as of: 12/14/2021

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

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