

SE ACCEPTANCE PHASE METRICS

Data as of: 03/31/2024

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 Total-to-Date (Oct 2023 - Mar 2024)
Accepted*	Cigar	916	2,055	150	0	0
	Cigarette	129	110	20	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other	1	5	0	0	0
	Pipe	1,002	560	1	0	0
	Roll-Your-Own	94	63	11	0	4
	Smokeless	60	40	17	0	4
	Waterpipe	199	678	132	0	8
	<b>Total</b>	<b>2,401</b>	<b>3,511</b>	<b>331</b>	<b>0</b>	<b>16</b>
Refuse-to-Accept* (RTA)	Cigar	58	134	7	0	1
	Cigarette	0	1	3	0	10
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other	0	0	0	0	0
	Pipe	0	236	0	0	0
	Roll-Your-Own	8	11	0	0	0
	Smokeless	0	0	0	0	1
	Waterpipe	0	1,586	1	0	3
	<b>Total</b>	<b>66</b>	<b>1,968</b>	<b>11</b>	<b>0</b>	<b>15</b>
Total Applications Received*	Cigar	3,066	141	190	7	0
	Cigarette	137	101	320	105	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other	1	5	43	2	14
	Pipe	1,695	97	2	0	0
	Roll-Your-Own	136	47	133	31	8
	Smokeless	60	45	48	38	8
	Waterpipe	2,327	249	73	55	0
	<b>Total</b>	<b>7,422</b>	<b>685</b>	<b>809</b>	<b>238</b>	<b>30</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: 03/31/2024

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 Total-to-Date (Oct 2023 - Mar 2024)
Substantial Equivalence (SE) Orders*	Cigar	27	20	30	21	20
	Cigarette	105	15	10	16	1
	ENDS	0	0	0	0	0
	Heated Tobacco Product	2	0	0	0	0
	Other	0	0	0	0	0
	Pipe	29	130	100	5	7
	Roll-Your-Own	32	5	7	6	0
	Smokeless	16	0	1	12	8
	Waterpipe	6	11	1	37	14
	<b>Total</b>	<b>217</b>	<b>181</b>	<b>149</b>	<b>97</b>	<b>50</b>
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	21	21	1
	Cigarette	9	0	0	14	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other	0	0	0	0	0
	Pipe	0	0	15	0	4
	Roll-Your-Own	0	0	0	0	0
	Smokeless	8	0	1	0	0
	Waterpipe	0	0	15	0	13
	<b>Total</b>	<b>17</b>	<b>8</b>	<b>52</b>	<b>35</b>	<b>18</b>
Withdrawn by Applicant*	Cigar	2	45	52	0	0
	Cigarette	63	2	69	32	6
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	2	0	0
	Other	0	0	0	36	0
	Pipe	0	7	12	0	4
	Roll-Your-Own	6	5	3	4	0
	Smokeless	17	24	1	11	0
	Waterpipe	6	98	1	0	20
	<b>Total</b>	<b>94</b>	<b>181</b>	<b>140</b>	<b>83</b>	<b>30</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: 03/31/2024

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 Total-to-Date (Oct 2023 - Mar 2024)
Closure*	Cigar	2	11	0	1	1
	Cigarette	10	0	0	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other	0	0	0	0	0
	Pipe	0	0	11	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	1	0	4	0	0
	<b>Total</b>		<b>13</b>	<b>11</b>	<b>15</b>	<b>1</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%.