

SE ACCEPTANCE PHASE METRICS

Data as of: 02/28/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 -Feb 2023)
Accepted*	Cigar	916	2,055	52	0
	Cigarette	129	108	20	0
	ENDS	0	0	0	0
	Heated Tobacco Product	0	0	0	0
	Other	1	5	0	0
	Pipe	1,002	560	1	0
	Roll-Your-Own	93	63	11	0
	Smokeless	60	40	17	0
	Waterpipe	199	678	132	0
	Total	2,400	3,509	233	0
Refuse-to-Accept* (RTA)	Cigar	58	134	7	0
	Cigarette	0	1	3	0
	ENDS	0	0	0	0
	Heated Tobacco	0	0	0	0
	Other	0	0	0	0
	Pipe	0	236	0	0
	Roll-Your-Own	8	11	0	0
	Smokeless	0	0	0	0
	Waterpipe	0	1,586	1	0
	Total	66	1,968	11	0
Total Applications Received*	Cigar	3,066	141	180	4
	Cigarette	137	101	320	37
	ENDS	0	0	0	0
	Heated Tobacco	0	0	0	0
	Other	1	5	31	0
	Pipe	1,695	97	2	0
	Roll-Your-Own	135	47	130	10
	Smokeless	60	45	59	21
	Waterpipe	2,327	249	73	4
	Total	7,421	685	795	76

*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: 02/28/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - Feb 2023)
Substantial Equivalence (SE) Orders*	Cigar	27	20	25	0
	Cigarette	105	15	10	16
	ENDS	0	0	0	0
	Heated Tobacco Product	2	0	0	0
	Other	0	0	0	0
	Pipe	29	130	100	0
	Roll-Your-Own	32	5	7	3
	Smokeless	16	0	1	0
	Waterpipe	6	11	1	25
	Total	217	181	144	44
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	21	15
	Cigarette	9	0	0	14
	ENDS	0	0	0	0
	Heated Tobacco Product	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	15	0
	Roll-Your-Own	0	0	0	0
	Smokeless	8	0	1	0
	Waterpipe	0	0	15	0
	Total	17	8	52	29
Withdrawn by Applicant*	Cigar	2	45	52	0
	Cigarette	63	2	67	0
	ENDS	0	0	0	0
	Heated Tobacco Product	0	0	2	0
	Other	0	0	0	0
	Pipe	0	7	12	0
	Roll-Your-Own	6	5	3	0
	Smokeless	17	24	1	0
	Waterpipe	6	98	1	0
	Total	94	181	138	0

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SE REVIEW AND ACTION METRICS

Data as of: 02/28/2023

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 Total To-Date (Oct 2022 - Feb 2023)
Closure*	Cigar	2	11	0	0
	Cigarette	10	0	0	0
	ENDS	0	0	0	0
	Heated Tobacco Product	0	0	0	0
	Other	0	0	0	0
	Pipe	0	0	11	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	0
	Waterpipe	1	0	4	0
	Total		13	11	15

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