

SE ACCEPTANCE PHASE METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Accepted*	Cigarette	158	104	0
	Roll-Your-Own	96	63	0
	Smokeless	59	43	0
	ENDS	0	0	0
	Cigar	916	2,071	0
	Pipe	1,010	561	0
	Waterpipe	204	669	0
	Other	1	0	0
	Total	2,444	3,511	0
Refuse-to-Accept* (RTA)	Cigarette	0	0	0
	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
	Other	0	2	0
	Total	66	1,968	0
Total Applications Received	Cigarette	136	92	0
	Roll-Your-Own	135	47	0
	Smokeless	60	42	0
	ENDS	0	0	0
	Cigar	3,064	141	0
	Pipe	1,695	97	0
	Waterpipe	2,326	145	0
	Other	3	0	0
	Total	7,419	564	0

*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: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Number of Discipline Reviews completed	Cigarette	968	91	0
	Roll-Your-Own	342	179	0
	Smokeless	408	45	0
	ENDS	0	0	0
	Cigar	257	2,328	0
	Pipe	931	1,216	0
	Waterpipe	99	406	0
	Other	7	0	0
	Total	3,012	4,265	0
Deficiency letters issued	Cigarette	122	2	0
	Roll-Your-Own	42	12	0
	Smokeless	54	2	0
	ENDS	0	0	0
	Cigar	19	280	0
	Pipe	26	74	0
	Waterpipe	5	42	0
	Other	1	0	0
	Total	269	412	0
Environmental Information Request letters issued	Cigarette	0	0	0
	Roll-Your-Own	2	0	0
	Smokeless	0	0	0
	ENDS	0	0	0
	Cigars	0	0	0
	Pipe	114	15	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	116	15	0

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SE REVIEW AND ACTION METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 2021)
Substantial Equivalence (SE) Orders*	Cigarette	104	15	0
	Roll-Your-Own	31	6	0
	Smokeless	16	0	0
	ENDS	0	0	0
	Cigar	27	35	0
	Pipe	29	130	0
	Waterpipe	6	11	0
	Other	0	0	0
	Total	213	197	0
Not Substantially Equivalent (NSE) Orders*	Cigarette	9	2	0
	Roll-Your-Own	0	0	0
	Smokeless	8	0	0
	ENDS	0	0	0
	Cigar	0	8	0
	Pipe	0	0	0
	Waterpipe	0	0	0
	Other	0	0	0
	Total	17	10	0
Withdrawn by Applicant*	Cigarette	58	2	0
	Roll-Your-Own	6	5	0
	Smokeless	17	22	0
	ENDS	0	0	0
	Cigar	2	45	0
	Pipe	0	7	0
	Waterpipe	6	98	0
	Other	0	0	0
	Total	89	179	0

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SE REVIEW AND ACTION METRICS

Data as of: 10/06/2021

Metric	Product Category	FY 2020 Total (Oct 1, 2019 - Sept 30, 2020)	FY 2021 Total (Oct 1, 2020 - Sept 30, 2021)	FY 2022 Total To-Date (Oct 1, 2021 - Oct 6, 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
	Other	0	0	0
	Total	13	11	0

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