

SE ACCEPTANCE PHASE METRICS

Data as of: 1/31/2022

Metric	Product Category	FY 2020 Total	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Jan 2022)
Accepted*	Cigar	917	2,070	52
	Cigarette	128	110	20
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	1	1	0
	Pipe	1,011	560	1
	Roll-Your-Own	96	63	11
	Smokeless	60	44	17
	Waterpipe	199	676	133
	Total	2,412	3,524	234
Refuse-to-Accept* (RTA)	Cigar	58	133	0
	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	0
	Total	66	1,968	3
Total Applications Received*	Cigar	3,064	141	126
	Cigarette	136	101	41
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	3	1	1
	Pipe	1,695	97	1
	Roll-Your-Own	135	47	61
	Smokeless	60	49	13
	Waterpipe	2,327	249	42
	Total	7,420	685	285

*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: 1/31/2022

Metric	Product Category	FY 2020 Total	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Jan 2022)
Number of Discipline Reviews completed*	Cigar	257	2,408	341
	Cigarette	943	98	10
	ENDS	0	0	0
	Heated Tobacco Product	12	0	0
	Other	7	0	0
	Pipe	927	1,571	315
	Roll-Your-Own	341	175	20
	Smokeless	402	40	6
	Waterpipe	95	410	116
	Total	2,984	4,702	808
Deficiency letters issued*	Cigar	19	280	36
	Cigarette	125	2	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	1	0	0
	Pipe	140	100	19
	Roll-Your-Own	45	12	0
	Smokeless	54	2	0
	Waterpipe	7	42	14
	Total	393	438	69
Environmental Information Request letters issued*	Cigar	4	0	11
	Cigarette	23	2	0
	ENDS	0	0	0
	HTP	0	0	0
	Other	0	0	0
	Pipe	139	40	0
	Roll-Your-Own	6	0	0
	Smokeless	16	0	0
	Waterpipe	0	0	0
	Total	188	42	11

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SE REVIEW AND ACTION METRICS

Data as of: 1/31/2022

Metric	Product Category	FY 2020 Total	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Jan 2022)
Substantial Equivalence (SE) Orders*	Cigar	27	35	0
	Cigarette	105	15	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	0	0	0
	Pipe	29	130	27
	Roll-Your-Own	32	5	0
	Smokeless	16	0	1
	Waterpipe	6	11	0
	Total	217	196	28
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	0
	Cigarette	9	0	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	0
	Roll-Your-Own	0	0	0
	Smokeless	8	0	1
	Waterpipe	0	0	0
	Total	17	8	1
Withdrawn by Applicant*	Cigar	2	45	17
	Cigarette	63	2	30
	ENDS	0	0	0
	Heated Tobacco Product	0	0	2
	Other	0	0	0
	Pipe	0	7	13
	Roll-Your-Own	6	5	2
	Smokeless	17	24	0
	Waterpipe	6	98	0
	Total	94	181	64

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SE REVIEW AND ACTION METRICS

Data as of: 1/31/2022

Metric	Product Category	FY 2020 Total	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Jan 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	0
	Roll-Your-Own	0	0	0
	Smokeless	0	0	0
	Waterpipe	1	0	0
	Total	13	11	0

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