

SE ACCEPTANCE PHASE METRICS

Data as of: 07/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - July 2022)
Accepted*	Cigar	916	2,055	52
	Cigarette	129	110	20
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	1	5	0
	Pipe	1,010	560	1
	Roll-Your-Own	93	63	11
	Smokeless	60	40	17
	Waterpipe	199	678	132
	Total	2,408	3,511	233
Refuse-to-Accept* (RTA)	Cigar	58	133	7
	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	1
	Total	66	1,968	11
Total Applications Received*	Cigar	3,065	141	127
	Cigarette	136	101	87
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	3	5	31
	Pipe	1,695	97	1
	Roll-Your-Own	135	47	98
	Smokeless	60	45	32
	Waterpipe	2,327	249	73
	Total	7,421	685	449

*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: 07/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - July 2022)
Number of Discipline Reviews completed*	Cigar	257	2,359	3,123
	Cigarette	1,049	98	170
	ENDS	0	0	0
	Heated Tobacco Product	12	0	0
	Other	7	0	0
	Pipe	922	1,571	1,205
	Roll-Your-Own	340	204	65
	Smokeless	402	35	134
	Waterpipe	95	412	994
	Total	3,084	4,679	5,691
Deficiency letters issued*	Cigar	19	280	54
	Cigarette	143	2	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	1	0	0
	Pipe	139	100	40
	Roll-Your-Own	45	12	0
	Smokeless	54	2	0
	Waterpipe	7	42	15
	Total	410	438	109
Environmental Information Request letters issued*	Cigar	4	0	11
	Cigarette	34	2	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	138	40	0
	Roll-Your-Own	4	0	0
	Smokeless	17	0	0
	Waterpipe	0	0	0
	Total	197	42	11

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SE REVIEW AND ACTION METRICS

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Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - July 2022)
Substantial Equivalence (SE) Orders*	Cigar	27	20	24
	Cigarette	105	15	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	0	0	0
	Pipe	29	130	100
	Roll-Your-Own	32	5	4
	Smokeless	16	0	1
	Waterpipe	6	11	1
	Total	217	181	130
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	21
	Cigarette	9	0	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	0	0	15
	Roll-Your-Own	0	0	0
	Smokeless	8	0	1
	Waterpipe	0	0	15
	Total	17	8	52
Withdrawn by Applicant*	Cigar	2	45	49
	Cigarette	63	2	61
	ENDS	0	0	0
	Heated Tobacco Product	0	0	2
	Other	0	0	0
	Pipe	0	7	8
	Roll-Your-Own	6	5	3
	Smokeless	17	24	1
	Waterpipe	6	98	1
	Total	94	181	125

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SE REVIEW AND ACTION METRICS

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Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - July 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	4
	Total	13	11	4

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