

SE ACCEPTANCE PHASE METRICS

Data as of: 03/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Mar 2022)
Accepted*	Cigar	916	2,062	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	96	63	11
	Smokeless	60	40	17
	Waterpipe	199	677	132
	Total	2,411	3,517	233
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	1
	Total	66	1,968	4
Total Applications Received*	Cigar	3,065	141	126
	Cigarette	136	101	55
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	3	5	25
	Pipe	1,695	97	1
	Roll-Your-Own	135	47	72
	Smokeless	60	45	20
	Waterpipe	2,327	249	65
	Total	7,421	685	364

*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: 03/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Mar 2022)
Number of Discipline Reviews completed*	Cigar	257	2,336	1,471
	Cigarette	975	126	65
	ENDS	0	0	0
	Heated Tobacco Product	12	0	0
	Other	7	0	0
	Pipe	922	1,571	480
	Roll-Your-Own	365	199	20
	Smokeless	402	40	6
	Waterpipe	95	412	120
	Total	3,035	4,684	2,162
Deficiency letters issued*	Cigar	19	280	45
	Cigarette	125	2	0
	ENDS	0	0	0
	Heated Tobacco Product	2	0	0
	Other	1	0	0
	Pipe	139	100	34
	Roll-Your-Own	45	12	0
	Smokeless	54	2	0
	Waterpipe	7	42	15
	Total	392	438	94
Environmental Information Request letters issued*	Cigar	4	0	11
	Cigarette	23	2	0
	ENDS	0	0	0
	Heated Tobacco Product	0	0	0
	Other	0	0	0
	Pipe	138	40	0
	Roll-Your-Own	6	0	0
	Smokeless	16	0	0
	Waterpipe	0	0	0
	Total	187	42	11

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SE REVIEW AND ACTION METRICS

Data as of: 03/31/2022

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 Total To-Date (Oct 2021 - Mar 2022)
Substantial Equivalence (SE) Orders*	Cigar	27	20	11
	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	181	39
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	40
	Cigarette	63	2	41
	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	1
	Waterpipe	6	98	0
	Total	94	181	99

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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 - Mar 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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