SE Metrics for Acceptance and Review/Action Phases

DISCLAIMER: 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%.

FDA has received some submissions that could not be processed and ingested for various reasons, including but not limited to lack of required forms, use of an incorrect form, or use of an incorrect format on the application. Given that FDA was unable to fully process these submissions, they were issued Refuse to Accept Letters or withdrawn by the applicant. Since complete information was not available, metrics for these submissions are not provided in the reported tables.

Product categorization is provided by the applicant at submission. Upon scientific review, product categorization may be revised.

SE ACCEPTANCE PHASE METRICS

Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Accepted	Cigar	916	2,055	150	0	2
	Cigarette	129	110	20	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	1	5	0	0	0
	Pipe	1,008	560	1	0	0
	Roll-Your-Own	94	63	11	0	4
	Smokeless	60	40	17	0	4
	Waterpipe	199	678	132	0	8
	Total	**2,407**	**3,511**	**331**	**0**	**18**
Refuse-to-Accept (RTA)	Cigar	58	134	7	0	1
	Cigarette	0	1	3	0	14
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	236	0	0	0
	Roll-Your-Own	8	11	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	1,586	1	0	3
	Total	**66**	**1,968**	**11**	**0**	**18**
Total Applications Received	Cigar	3,066	141	169	21	0
	Cigarette	137	101	335	106	5
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	1	5	49	2	14
	Pipe	1,695	97	2	0	14
	Roll-Your-Own	136	47	87	33	12
	Smokeless	60	45	42	41	10
	Waterpipe	2,327	249	50	35	25
	Total	**7,422**	**685**	**734**	**236**	**80**

* "Other" product category contains tobacco products that may not fall into the other eight established product categories; examples include but are not limited to, nicotine pouches, nicotine lozenges, and nicotine toothpicks.

SE REVIEW AND ACTION METRICS

Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Deficiency letters issued	Cigar	19	280	72	190	167
	Cigarette	144	0	10	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	2	0	0	0	0
	Other*	1	0	0	0	0
	Pipe	139	100	52	63	0
	Roll-Your-Own	45	12	0	24	4
	Smokeless	54	2	0	8	0
	Waterpipe	7	42	15	46	93
	Total	**411**	**436**	**149**	**331**	**264**
Environmental Information Request letters issued	Cigar	0	0	11	0	2
	Cigarette	0	2	0	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	1	0	3	0	5
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	**1**	**2**	**14**	**0**	**7**

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SE REVIEW AND ACTION METRICS

Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Substantial Equivalence (SE) Orders*	Cigar	27	20	30	21	31
	Cigarette	105	15	10	16	3
	ENDS	0	0	0	0	0
	Heated Tobacco Product	2	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	29	130	100	5	9
	Roll-Your-Own	32	5	7	6	6
	Smokeless	16	0	1	12	10
	Waterpipe	6	11	1	37	22
	Total	**217**	**181**	**149**	**97**	**81**
Not Substantially Equivalent (NSE) Orders*	Cigar	0	8	21	21	52
	Cigarette	9	0	0	14	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	15	0	23
	Roll-Your-Own	0	0	0	0	0
	Smokeless	8	0	1	0	0
	Waterpipe	0	0	15	0	13
	Total	**17**	**8**	**52**	**35**	**88**

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SE REVIEW AND ACTION METRICS

Data as of: 03/31/2026

Metric	Product Category	FY 2020 (Oct 2019 - Sept 2020)	FY 2021 (Oct 2020 - Sept 2021)	FY 2022 (Oct 2021 - Sept 2022)	FY 2023 (Oct 2022 - Sept 2023)	FY 2024 (Oct 2023 - Sept 2024)
Withdrawn by Applicant	Cigar	2	45	52	0	7
	Cigarette	63	2	69	32	367
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	2	0	0
	Other*	0	0	0	36	0
	Pipe	0	7	12	0	4
	Roll-Your-Own	6	5	3	4	0
	Smokeless	17	24	1	11	19
	Waterpipe	6	98	1	0	20
	Total	**94**	**181**	**140**	**83**	**417**
Closure	Cigar	2	11	0	1	1
	Cigarette	10	0	0	0	0
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	11	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	1	0	4	0	0
	Total	**13**	**11**	**15**	**1**	**1**

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