

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 Given that FDA was unable to fully process these submissions, they were issued Refuse to Accept Letters or withdrawn by the applicant.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: 12/31/2025

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - Dec 2025)
Accepted	Cigar	68	18
	Cigarette	30	7
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	36	0
	Pipe	1	1
	Roll-Your-Own	56	20
	Smokeless	55	19
	Waterpipe	23	182
	Total	269	247
Refuse-to-Accept (RTA)	Cigar	1	1
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	3	0
	Pipe	14	0
	Roll-Your-Own	6	0
	Smokeless	2	0
	Waterpipe	64	1
	Total	90	2
Total Applications Received	Cigar	20	13
	Cigarette	10	5
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	1	5
	Roll-Your-Own	34	8
	Smokeless	4	3
	Waterpipe	47	160
	Total	116	194

* "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: 12/31/2025

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - Dec 2025)
Deficiency letters issued	Cigar	367	51
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	108	0
	Roll-Your-Own	0	0
	Smokeless	2	0
	Waterpipe	33	0
	Total	510	51
Environmental Information Request letters issued	Cigar	0	4
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	11	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	17	0
	Total	28	4

* "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: 12/31/2025

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - Dec 2025)
Substantial Equivalence (SE) Orders	Cigar	76	0
	Cigarette	2	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	12	13
	Roll-Your-Own	1	0
	Smokeless	0	0
	Waterpipe	38	17
	Total	129	30
Not Substantially Equivalent (NSE) Orders	Cigar	18	15
	Cigarette	1	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	26	8
	Roll-Your-Own	2	0
	Smokeless	0	0
	Waterpipe	13	0
	Total	60	23
* "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: 12/31/2025

Metric	Product Category	FY 2025 (Oct 2024 - Sept 2025)	FY 2026 Total-To-Date (Oct 2025 - Dec 2025)
Withdrawn by Applicant	Cigar	221	31
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	101	1
	Roll-Your-Own	11	0
	Smokeless	0	0
	Waterpipe	25	0
	Total	358	32
Closure	Cigar	19	0
	Cigarette	0	0
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	0	0
	Waterpipe	0	0
	Total	19	0
* "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.			