

EX REQ 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%.

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

EX REQ 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	29	0
	Cigarette	156	2
	ENDS	40	9
	Heated Tobacco Product	0	0
	Other*	0	20
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	4	1
	Waterpipe	38	12
	Total	267	44
Refuse-to-Accept (RTA)	Cigar	4	3
	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	1	0
	Total	5	3
Total Applications Received	Cigar	32	0
	Cigarette	144	16
	ENDS	40	9
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	4	1
	Waterpipe	0	0
	Total	220	26

* "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.

EX REQ 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	0	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	1
	Waterpipe	0	0
	Total	0	1
Environmental Information Request letters issued	Cigar	0	0
	Cigarette	0	3
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	4
	Smokeless	1	6
	Waterpipe	0	0
	Total	1	13

* "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.

EX REQ 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)
Found Exempt Orders	Cigar	10	0
	Cigarette	45	9
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	0	0
	Roll-Your-Own	0	0
	Smokeless	3	0
	Waterpipe	15	0
	Total	73	9
Not Exempt Orders	Cigar	15	4
	Cigarette	652	3
	ENDS	0	0
	Heated Tobacco Product	0	0
	Other*	0	0
	Pipe	6	0
	Roll-Your-Own	0	0
	Smokeless	0	1
	Waterpipe	0	0
	Total	673	8
* "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.			

EX REQ 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	0	0
	Cigarette	50	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	50	0
Closure	Cigar	0	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	0	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.			