

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 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	73	116	77	15	27
	Cigarette	221	209	369	892	251
	ENDS	0	0	0	0	10
	Heated Tobacco Product	0	0	0	5	0
	Other*	0	0	0	0	0
	Pipe	0	0	6	0	0
	Roll-Your-Own	10	2	0	17	8
	Smokeless	2	1	4	13	1
	Waterpipe	126	267	298	142	76
	Total	432	595	754	1,084	373
Refuse-to-Accept (RTA)	Cigar	2	82	1	1	16
	Cigarette	17	44	18	1	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	4	0	0	0	0
	Smokeless	0	0	3	0	0
	Waterpipe	0	565	626	10	0
	Total	23	691	648	12	16
Total Applications Received	Cigar	157	167	27	16	50
	Cigarette	247	439	199	1,002	140
	ENDS	0	0	0	0	10
	Heated Tobacco Product	0	0	0	5	0
	Other*	0	0	0	0	0
	Pipe	0	0	6	0	0
	Roll-Your-Own	14	2	0	17	8
	Smokeless	2	5	3	13	2
	Waterpipe	126	1,547	282	153	114
	Total	546	2,160	517	1,206	324

* "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 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	0	84	8	0	0
	Cigarette	12	20	0	1	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	4	2	0	0	0
	Smokeless	1	0	0	0	0
	Waterpipe	0	5	15	94	0
	Total	17	111	23	95	0
Environmental Information Request letters issued	Cigar	1	55	0	0	0
	Cigarette	23	11	0	61	28
	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	0	0	0	0	0
	Smokeless	0	0	0	1	0
	Waterpipe	25	0	0	0	0
	Total	49	66	0	62	28

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EX REQ REVIEW AND ACTION METRICS

Data as of: 12/31/2025

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Found Exempt Orders	Cigar	0	66	31	41	0
	Cigarette	183	117	40	641	53
	ENDS	0	0	0	0	0
	Heated Tobacco Product	0	0	0	0	5
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	6	0	2	17	4
	Smokeless	1	0	0	2	0
	Waterpipe	29	130	3	21	0
	Total	219	313	76	722	62
Not Exempt Orders	Cigar	7	4	0	38	0
	Cigarette	62	10	0	56	33
	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	0	0	0	0	0
	Smokeless	1	0	0	1	1
	Waterpipe	0	0	0	263	1
	Total	70	14	0	358	35
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Withdrawn by Applicant	Cigar	0	0	19	0	6
	Cigarette	0	1	53	0	0
	ENDS	0	0	0	0	4
	Heated Tobacco Product	0	0	0	0	0
	Other*	0	0	0	0	0
	Pipe	0	0	0	0	0
	Roll-Your-Own	4	0	0	0	0
	Smokeless	0	0	0	1	0
	Waterpipe	0	1	1	0	0
	Total	4	2	73	1	10
Closure	Cigar	0	0	0	21	0
	Cigarette	0	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	0	0	0
	Roll-Your-Own	0	0	0	0	0
	Smokeless	0	0	0	0	0
	Waterpipe	0	0	0	0	0
	Total	0	0	0	21	0

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