

FDA Challenges & Practical Implications

How manufacturers can win in the market when the regulatory landscape is often murky.

BRYAN BURD
COO/General Manager
Bryan.Burd@chemular.com

CDC Website

Cigarette smoking remains the leading cause of preventable disease, disability, and death in the United States, accounting for more than 480,000 deaths every year, or about 1 in 5 deaths.

Complex Variety of Players

+ FDA

+ Lawmakers

+ State Tax

+ Illicit Market

+ Industry

+ Tobacco Control Groups

+ Health Care Companies

CHEMULAR

FDA Challenges

Applications

Enforcement

Trust

History



Deadline for PMTA Applications.



Deadline for NTN.



TDN applications after 9.9.2020 and NTN after 5.14.2022.

FDA Challenges:

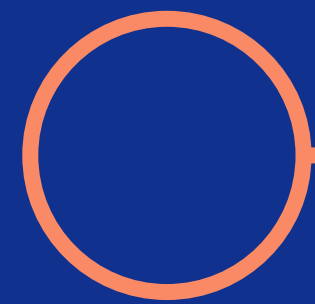
FDA Metrics* on Applications

PMTA ACCEPTANCE PHASE METRICS					Data as of: 09/30/2023
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)
Accepted*	Cigar	0	10	0	0
	Cigarette	0	0	0	0
	ENDS	1460	6,634,356	56,735	72,006
	Heated Tobacco Product	1	5	0	10
	Other	20	44	40	536
	Pipe	0	12	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	145	4	0	13
	Waterpipe	63	0	0	0
	Total	1,689	6,634,431	56,775	72,565
Refuse-to-Accept* (RTA)	Cigar	0	5	0	0
	Cigarette	0	1	0	0
	ENDS	150	1,311,386	970,238	17,277,288
	Heated Tobacco Product	0	0	0	0
	Other	0	17	31	272
	Pipe	0	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	0	0	0	54
	Waterpipe	0	0	11	0
	Total	150	1,311,409	970,280	17,277,614
Total Applications Received	Cigar	15	0	0	0
	Cigarette	1	0	0	0
	ENDS	8,014,325	17,362,568	1,210,184	14,415
	Heated Tobacco Product	1	5	12	0
	Other	73	29	2,114	72
	Pipe	12	0	0	0
	Roll-Your-Own	0	0	0	0
	Smokeless	149	0	70	73
	Waterpipe	63	11	0	0
	Total	8,014,639**	17,362,613**	1,212,380	14,560

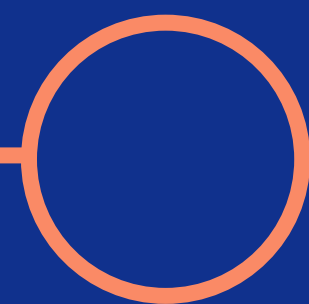
NOTES * This includes information on applications for over 1 million products received between Sept. 10 - 30, 2020.
 ** This includes a submission from a single company with applications for over 17 million products. Decisions on these application were issued in FY23.
 *Please note that some metrics 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%.
 The information in this report does not differentiate tobacco products by nicotine source. Non-tobacco nicotine products submitted to CTP by the May 14, 2022 deadline are included within these charts.

*www.fda.gov/media/169533/download?attachment

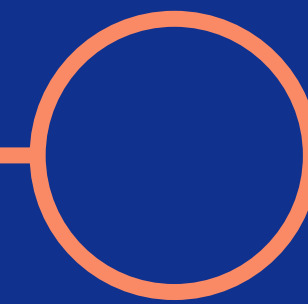
Application Reviews



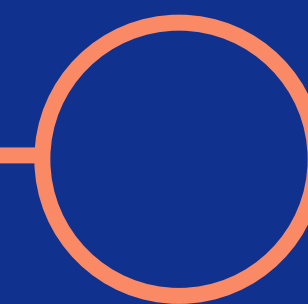
More than anticipated



Legal Challenges



Another round with NTN



Even more applications

CHEMULAR

Enforcement

+ Only Know Numerator

+ Warning Letters

+ Work With Other Agencies

+ State & Other Agency Actions

+ Alternatives – Non Nicotine

Predictions on What the FDA Will Do

- + Stay laser focused on appeasing anti-tobacco groups
- + Zero youth usage
- + Punish any and all US manufacturers, rewarding Foreign manufacturers
- + Inadvertently be responsible for rapid growth in illicit tobacco trade

Re-Balancing Decision Making

Define Success

Re-Build Trust

Harm Reduction



Questions?

CHEMULAR

Thank You

Visit us at: Chemular.com
For more info call: 1.844.888.7847

CHEMULAR