

Review

To File: PM0004879.PD1-PM0004879.PD8, see Appendix A

From: Matthew Farrelly, Ph.D. **MATTHEW C.** Digitally signed by MATTHEW C.
Director **FARRELLY -S** FARRELLY -S
Office of Science Date: 2026.02.17 16:29:23 -05'00'

Company: Glas Inc.

Subject: Decision on Glas PMTAs (PM0004879.PD1-PM0004879.PD4, PM0004879.PD6, and PM0004879.PD8)

BACKGROUND

On December 18, 2025, a Technical Project Lead (TPL) review for premarket tobacco product applications (PMTAs) from Glas Inc for eight products¹ was signed by Selvin Edwards. The review recommends issuing marketing granted orders for all products.

The review noted that there is a large range across the new products with respect to cancer risk utilizing the estimated cumulative excess lifetime cancer risks (ELCRc) calculation. In short, five of the seven e-liquids (PM0004879.PD1-PM0004879.PD4 and PM0004879.PD6) had a significantly lower calculated risk compared to combusted cigarettes and to two e-liquid products (PM0004879.PD5 and PM0004879.PD7). The flavored new products and blonde tobacco-flavored product have ELCRc estimates of 2% - 10% of the ELCRc of CC (Table 1). The signature and blue tobacco-flavored new products (PM0004879.PD5 and PM0004879.PD7) have ELCRc estimates ranging from 32.8% - 38.1% of the ELCRc of CC. The TPL stated that the ELCRc for PM0004879.PD5 is 2780% above the median ELCRc for FDA-authorized ENDS. Similarly, PM0004879.PD7 is 2380% above the median.

DISCUSSION

FDA evaluates each application to ensure it independently demonstrates complete product characterization, consistent manufacturing, the benefits outweigh the risks, that the new product conforms to applicable product standards, and the labeling is not false or misleading. Each new product has its own unique balance of risks and benefits; thus, it is important to consider each product independently when determining what is appropriate for the protection of public health (APPH).

Given that products PM0004879.PD5 and PM0004879.PD7 have ELCRc values significantly higher than the FDA-authorized ENDS median, I want additional time to consider the impacts on the overall APPH analysis. While we consider further, I do not want to hold up authorizations for the other products.

¹ PM0004879.PD1-PM0004879.PD8

Table 1. Summary of cancer risk characterization tier 1-4C (ELCR_c 1 in 10⁵)

New Products STN (flavor)	ELCR _c	% 1R6F ELCR _c ^a	% above FDA-authorized ENDS median ^b
PM0004879.PD2 (Sapphire)	406	2.0	54
PM0004879.PD4 (Classic Menthol)	286	1.4	8.3
PM0004879.PD3 (Fresh Menthol)	289	1.4	9.5
PM0004879.PD6 (Blonde Tobacco)	1544	7.7	485
PM0004879.PD1 (Gold)	1999	10	657
PM0004879.PD7 (Signature Tobacco)	6547	32.8	2380
PM0004879.PD5 (Blue Tobacco)	7602	38.1	2780

- a. Compared to ELCR_c for Kentucky 1R6F reference CC
- b. Relative to the median ELCR_c from the FDA-authorized ENDS that make up the current ENDS marketplace as of July 2025

Additionally, I wanted to clarify that although the tobacco-flavored ENDS (PM0004879.PD7 used with PM0004879.PD8) has device access restrictions, the potential to further mitigate the risk to youth via employing device access restrictions was not necessary in determining that this tobacco-flavored product is APPH because the randomized, actual use study LRESS-GLAS01-2024 showed significant complete switching rates.

CONCLUSION AND RECOMMENDATION

Based on my review of the TPL review, OS will issue MGOs for the device (PM0004879.PD8), flavored (PM0004879.PD1-PM0004879.PD4) and Blonde tobacco-flavored (PM0004879.PD6) new products from Glas Inc. Additionally, OS will split out the Blue Tobacco (PM0004879.PD5) and Signature Tobacco (PM0004879.PD7) new products for further consideration regarding whether permitting marketing would be APPH.

Appendix A^{2,3,4}
Tobacco Products Subject of This Review

Common Attributes⁵	
Submit date	July 21, 2021
Receipt date	July 21, 2021
Applicant	Glas Inc.
Product manufacturer	Glas Inc.
Product category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product subcategory	Closed E-liquid ² , Closed E-cigarette ³
Attributes	New Tobacco Product
STN	PM0004879.PD1
Product name	GOLD 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Mango
E-liquid volume	1.2 milliliters (mL)
Nicotine concentration	50 mg/mL (milligrams/milliliters)
PG/VG ratio	44/56
STN	PM0004879.PD2
Product name	SAPPHIRE 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF)	Flavored
Flavored CF, as identified	Blueberry
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	59/41
STN	PM0004879.PD3
Product name	FRESH MENTHOL 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF)	Menthol
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	58/42
STN	PM0004879.PD4
Product name	CLASSIC MENTHOL 50 MG/ML Pod
Package type	Blister Pack

² We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

³ Product name is brand/sub-brand or other commercial name used in commercial distribution.

⁴ Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

⁵ Attributes in Appendix A may display converted values.

Product quantity	1 Cartridge
Characterizing flavor (CF)	Menthol
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	60/40
STN	PM0004879.PD5
Product name	BLUE TOBACCO 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF) ⁶	Tobacco
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	58/42
STN	PM0004879.PD6
Product name	BLONDE TOBACCO 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF)	Tobacco
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	69/31
STN	PM0004879.PD7
Product name	SIGNATURE TOBACCO 50 MG/ML Pod
Package type	Blister Pack
Product quantity	1 Cartridge
Characterizing flavor (CF)	Tobacco
E-liquid volume	1.2 mL
Nicotine concentration	50 mg/mL
PG/VG ratio	44/56
STN	PM0004879.PD8
Product name	Glas G ² DEVICE
Package type	Box
Product quantity	1 E-Cigarette
Characterizing flavor (CF)	Unflavored
Length	88.67 mm
Diameter	21.21 mm
Wattage	6 or 8 W ⁷
Battery capacity	350 mAh
E-liquid volume	N/A
Nicotine concentration	None
PG/VG ratio	N/A

⁶ For PM0004879.PD5 (Blue Tobacco 50 mg/mL) new product does not contain menthol nor any other ingredient with a mint flavor profile. Therefore, FDA considers the characterizing flavor as “tobacco” instead of “menthol”.

⁷ Subject ENDS has two user-controlled power settings: ECO and STD. ECO mode: 8 W for the first 0.5 s and then at 6 W for the rest of the puff duration. STD mode: 10 W for the first 0.3 s and then at 8 W for the rest of the puff duration.

Appendix B

Amendments and Additional Submissions Received for This Applicant

Amendment(s) Received for These Applications

Submit Date	Receipt Date	Applications being amended ⁸	Brief Description
March 8, 2022	March 8, 2022	All	Correction or clarification to original submission; amend multiple sections of PMTA submission
September 21, 2022	September 21, 2022	All	Response to August 16, 2022, OCE Information Request
July 12, 2023	July 12, 2023	All	Response to April 13, 2023, Deficiency Letter
July 31, 2023	July 31, 2023	All	Response to April 13, 2023, Deficiency Letter
July 31, 2023	July 31, 2023	All	Response to April 13, 2023, Deficiency Letter
October 29, 2024	October 29, 2024	All	Request for extension to August 1, 2024, Deficiency Letter
October 30, 2024	October 30, 2024	All	Response to the August 1, 2024, Deficiency Letter
January 14, 2025	January 14, 2025	All	Response to the August 1, 2024, Deficiency Letter
April 30, 2025	April 30, 2025	All	Response to the August 1, 2024, Deficiency Letter

Additional Submissions Received for This Applicant

Submit Date	Receipt Date	Reviewed	Brief Description
August 4, 2021	August 4, 2021	Yes	Updated contact information
August 12, 2021	August 12, 2021	Yes	Product with Merit Request
February 10, 2022	February 10, 2022	Yes	OS Meeting Request
August 22, 2022	August 22, 2022	Yes	Updated corporate mailing address
January 13, 2026	January 15, 2026	Yes	Unreasonable delay in review decision

⁸ This amendment applies to all the STNs subject of this review.