April 7, 2026

Via Overnight Mail and Email

Martin Makary, M.D.
Commissioner

Bret Koplow, Ph.D.
Acting Director
Center for Tobacco Products

David Mednick
Deputy Chief Counsel for Program Review for Devices and Tobacco
Office of Chief Counsel

Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Glas G² PMTA (STN PM0004879) – February 2026 Memo From Sara Brenner, M.D., M.P.H., Principal Deputy Commissioner

Dear Drs. Makary and Koplow and Mr. Mednick:

Glas Inc. (Glas or the Company), a small independent manufacturer of electronic nicotine delivery system (ENDS) products,[1] writes again regarding serious concerns with the FDA's handling of the Glas G² premarket tobacco product application (PMTA) for the Glas G² age-gated ENDS device and e-liquid cartridges (G² PMTA). Specifically, the Company writes regarding a recently released memorandum from Principal Deputy Commissioner Sara Brenner, dated February 18, 2026 (Brenner Memo, Exhibit 1).

Glas is concerned that the Brenner Memo does not fully account for the science and evidence in the record, and that it reaches a conclusion which is difficult to reconcile with both FDA's own review process and the fulsome analysis and recommendations of the Agency's scientific staff, which supported authorization of these products after a comprehensive scientific review. That matters not only for Glas, but for the consistency and credibility of the PMTA process more broadly, particularly for companies that have

[1] Section 900(16) of the Federal Food, Drug, and Cosmetic Act defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees," including the employees of all affiliates.

invested significant time and resources to both deliver innovative solutions and to meet FDA's expectations in good faith.

For years, Glas has worked closely with FDA -- responding to requests, providing the scientific data and results the Agency demanded, and developing a product designed to support harm reduction by helping adult smokers quit or reduce smoking while including strong safeguards to eliminate youth initiation, access and use. Given that record, the Company is requesting that FDA address this arbitrary and capricious conduct, investigate the basis for withholding authorization for the remaining G^2 products, and expeditiously authorize the Glas G^2 ENDS products that remain in regulatory limbo at the Agency.

Given that record, and consistent with Glas's prior correspondence dated February 9, 2026 (Exhibit 2) and March 23, 2026 (Exhibit 3) (among others), Glas remains hopeful that FDA will resolve these issues promptly and without the need for legal action.

I. Background

Glas submitted this bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021. FDA issued a deficiency letter on April 13, 2023, and Glas timely submitted a complete response to the deficiency letter on July 12, 2023. After 386 days of no communication whatsoever, the Agency issued a second deficiency letter to Glas on August 1, 2024. Glas submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the requested 90-day timeframe, and was granted an extension by FDA to produce additional scientific study results on or before April 30, 2025, by which date Glas submitted a complete response.

On December 18, 2025, the FDA Center for Tobacco Products (CTP) Office of Science (OS) recommended authorization of **all G^2 products (8 SKUs in total)**. On February 17, 2026, the Director of CTP-OS recommended authorization of **all but two (Signature Tobacco & Blue Tobacco pods) G^2 products**. However, on March 11, 2026, the Acting CTP Director directed the authorization of **just two G^2 product SKUs (the G^2 device and Blonde Tobacco pod)**, citing the Brenner Memo, which **directed CTP to refrain from issuing MGOs for the flavored ENDS products (4 SKUs in total: Gold, Sapphire, Fresh, and Classic Menthol pods)**. Accordingly, on March 12, 2026, FDA issued a marketing granted order (MGO) letter for **just two G^2 product SKUs (the G^2 device and Blonde tobacco pod)**.

Thus, while OS recommended authorization of all of the G^2 products on December 18, 2025, and the OS Director recommended authorization of all but two of the tobacco-flavored pods, including the two menthol products and two non-tobacco non-menthol products, on February 17, 2026, the Brenner Memo blocked authorization of the flavored G^2 products (Classic Menthol, Fresh Menthol, Gold, and Sapphire pods).

II. Brenner Memo

On April 3, 2026, Glas received a response to a Freedom of Information Act (FOIA) request for a copy of the Brenner Memo. The Brenner Memo reflects a lack of understanding of the data and information included in the G^2 PMTA as well as factual inaccuracies, policy inconsistencies, and inequitable treatment of PMTA applicants.

First, the Brenner Memo references the "Agency's plan to issue guidance communicating FDA's current thinking regarding the evidentiary considerations necessary to demonstrate that marketing flavored ENDS products would be 'appropriate for the protection of the public health' (APPH)" that was "close to being finalized pending review by the Office of Management and Budget." However, FDA issued this guidance prior to issuing the order authorizing only the G^2 device and Blonde Tobacco pod. And, significantly, the PMTA for the flavored G^2 products (Classic Menthol, Fresh Menthol, Gold, and Sapphire pods) meets every concept articulated in the guidance.

The Draft Guidance for Industry: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk, issued on March 9, 2026 (3 days prior to the two Glas Marketing Granted Orders), states:

> *Given the added risk posed by youth appealing flavors and the current lack of real world experience regarding use of [device access restrictions (DAR)] to prevent or sufficiently mitigate the risk of youth use, an applicant whose high youth appealing flavored ENDS purports to rely solely on DAR technology to address risk to youth carries an especially high burden to demonstrate adequate mitigation of such risk based on valid and reliable evidence from robust scientific investigations. In its assessment of whether a product meets the APPH standard for marketing authorization, FDA evaluates the potential for youth initiation and use, especially in the context of youth-appealing flavored ENDS like fruit and candy/dessert/other sweet flavored. As such, DARs submitted for ENDS products with those types of youth-appealing flavors, without adequate and substantial evidence demonstrating sufficient mitigation of youth risk, are insufficient to overcome the heightened concerns associated with these flavor categories.*
>
> *Accordingly, FDA's current thinking is that while such technologies may be a component of a comprehensive youth prevention strategy, they might not, standing alone, satisfy the especially high evidentiary burden to demonstrate adequate risk mitigation of youth use and initiation associated with high youth appealing flavored ENDS (e.g., fruit and candy/dessert/other sweet).*
>
> *FDA's evaluation of flavored ENDS products under the APPH standard is grounded in a risk-proportionate, product-specific evaluation that weighs the potential benefits to adult smokers against the risks of non-user (e.g., youth) initiation and use. Given the well-established and substantial youth*

appeal associated with certain flavor categories, particularly fruit and candy/dessert/other sweet flavors that appeal to youth, applicants bear a heightened evidentiary burden to demonstrate that marketing such products would result in a net benefit to the population as a whole.

The G² PMTA has already fully addressed these issues. Indeed, the August 1, 2024, Deficiency Letter requested that, despite demonstrating in multiple studies that the Glas age-gating technology is 100% effective in preventing underage access and use (see discussion below), the Company also provide "sufficient evidence demonstrating that the new products … facilitate tobacco use behavior that could benefit adult users, including switching among adult [combusted cigarette (CC)] users." The G² PMTA therefore includes the following:

- **A Longitudinal Randomized Experimental Switching Study** to assess adult benefit under the APPH standard. In this three-month longitudinal multi-site randomized study, a total of 400 exclusive heavy smokers were randomly assigned to one of four conditions (Glas age-gated device with Glas flavored, menthol-flavored, or tobacco-flavored pods or an FDA-authorized tobacco-flavored competitor ENDS). Data showed that 13% to 21% of Glas product users completely quit smoking after three months, 45% to 46% of Glas product users reduced their past 30-day cigarettes per day (CPD) by 50%, and 79% to 92% of the Glas users benefited when combining all cigarette reduction. Taken together, these results demonstrate that, while all products contributed to some level of benefit to participants, exclusive heavy smokers showed greatest benefit with Glas menthol and Glas flavored products.
- **A Quantitative Study** to assess actual use of the Glas G² system involving hundreds of subjects (exclusive smokers, dual-users, and ENDS-only users) across three U.S. sites involving three use periods over 35 days that demonstrated that smokers reduced their overall daily cigarette consumption by 40%, that dual users reduced their daily cigarette consumption 28%, and that flavor had a dramatic impact on cigarette consumption (smokers who used Glas Gold pods reduced their daily consumption by 73%, while those who used Glas Sapphire pods reduced their daily consumption by nearly 25%).
- A **Perception Study** including thousands of participants that found that the individuals most interested in the product were smokers who desired to quit within the next 12 months and that youth, former smokers, and never smokers were not interested in the product.
- **Population Health Overview Studies**, including a clinical model that predicted a substantial reduction in the number of estimated deaths and a substantial reduction of years of lives lost by replacement of cigarette smoking with Glas G² products and a supplemental model and study that predicted that the introduction of age-gating technology similar to that in the Glas G² system would have a substantial positive impact on public health, namely an additional 19% increase in deaths avoided and 23% improvement in life years gained compared to the introduction of an ENDS product without age-gating technology.

Thus, Glas has extensively demonstrated that the marketing of the flavored, age-gated G^2 products "would result in a net benefit to the population as a whole."

The Brenner Memo goes on to state: "Given the added risk posed by youth appealing flavors and the current lack of real-world experience demonstrating that use of such technologies prevent or sufficiently mitigate the risk of youth use, the applicant whose high youth appealing flavored ENDS product purports to rely solely on device access restrictions to address risk to youth carries an especially high burden to demonstrate adequate mitigation of such risk based on valid and reliable evidence from robust scientific investigation." First, the G^2 PMTA does not rely solely on device access restrictions, as described above. In addition to demonstrating 100% efficacy of the age-gating technology, increased benefit to adults of the flavored products in terms switching, and lack of interest in the product by youth, Glas has committed to using the following measures to help limit youth exposure, reduce youth appeal, and restrict youth access:

- Not advertising in consumer-facing print publications;
- Restricting point-of-sale advertising to only nicotine licensed major retail outlets;
- Avoiding the use of self-service displays and fuel pump toppers;
- Restricting direct e-mail to only age-verified adults 21+ who have opted-in to receive such communications and avoiding the use of direct mail marketing;
- Requiring users to register and undergo age-verification to access the e-commerce website;
- Employing third-party age- and identity-verification for online/mobile application sales and signature of a 21+ adult upon delivery;
- Requiring retail partners to use similar age-gating restrictions;
- Restricting social media marketing to only Instagram users who are ages 25-54; and
- Restricting digital advertising to only age-gated sites.

Second, the flavored Glas products are not "high youth appealing flavored ENDS product[s]" in that they are not identified as particular fruit or candy flavors but are rather plainly and responsibly labeled as Classic Menthol, Fresh Menthol, Gold, and Sapphire.

And third, and most importantly, the G^2 PMTA demonstrates adequate mitigation of risk based on valid and reliable evidence from robust scientific investigations.

The G^2 PMTA contained multiple studies, including (1) functional testing across a number of subjects in three separate groups ranging in age from 16 to 49 years of age utilizing a tablet with a non-branded version of the Glas application installed across seven different scenarios that identified no scenarios where underage individuals could age verify, (2) age-gating application testing involving participants from around the U.S. of differing sexes and races, ranging in age from 16 to 50+, in which no underage individuals were able to activate the G^2 device and the Glas system accurately detected

invalid pods (counterfeit or re-used) and prevented their use, and (3) a third-party cybersecurity penetration testing that failed to bypass the age-verification process and pod counterfeit protections.

Indeed, the G^2 products utilize a verified and validated embedded technology and software to overcome past industry failures in at least seven ways: (1) a demanding age- and identity-verification process required to initially activate the device before first use after purchase (i.e., underage individuals cannot even turn the product on); (2) required ongoing authentication of the user to continue to use the device, including automatic device locking when the device is out of range of the authenticated smartphone; (3) counterfeit cartridge detection and use prevention; (4) cartridge identification to prevent re-use with unauthorized liquids; (5) continuous secure monitoring of use patterns and behaviors that provides the ability to understand product use in real time; and (6) the ability to roll out live updates or modifications of various use parameters (e.g., an individual product can be remotely deactivated if there is reason to believe that it is defective or being used improperly). Thus, the G^2 products present no risk of youth appeal, uptake, or use.

The Brenner Memo's reference to "the current lack of real-world experience demonstrating that use of such [age-gating] technologies prevent or sufficiently mitigate the risk of youth use" is also incorrect. As noted above, Glas conducted multiple studies that demonstrate that the age-gating technology is 100% effective in preventing underage use. **Moreover, if FDA had any concerns about the efficacy of the technology, it could have requested more data in the second deficiency letter, which it did not.** Indeed, the Technical Project Lead Review Summary states the following:

- "I find that the age-gating technology combined with the marketing restrictions described in section 3.4.1.5, are expected to sufficiently mitigate the risk to youth by preventing youth authorization at the initial user verification stage if users are below the minimum age of sale."
- "This information also supports that the Glas G2 device (PM0004879.PD8) robust integrated DAR/age-gating and e-liquid pod anti-counterfeiting technologies requiring smartphone activation, age-verification, and user revalidation, in addition to marketing restrictions described in section 3.4.1.5, is expected to adequately mitigate youth access and unauthorized pod use."
- "Importantly, the new products' robust DAR/age-gating technology in addition to the marketing restrictions described in section 3.4.1.5 is expected to be an effective approach to mitigating the substantial risk to youth, including youth initiation with flavored ENDS."
- Specifically, in the applicant-provided human factor studies (Age-Gating Studies; see section 3.4.1) conducted under controlled conditions, 100% of youth and young adults below the minimum age of sale failed age-verification … Furthermore, evidence in applicant-provided age-gating studies show that 100% of youth and young adults below minimum age of sale could not revalidate as above 21 years old and use the new Glas G2 PBVS … These results support

> that the DAR/age-gating technology is expected to effectively avert youth initiation of ENDS use with the Glas G2 PBVS new products … or lower these risks to a minimum."

Additionally, if FDA has any lingering concerns about real-world efficacy of the age-gating technology, it could impose a post-marketing requirement to conduct such surveillance as a condition of authorization of the flavored ENDS products. Indeed, in the G^2 PMTA, Glas offered to "work actively with the FDA to construct a comprehensive, effective and cost-efficient postmarket surveillance plan to ensure the marketing of Glas Candidate Products continues to be APPH" and to "leverage the proprietary technology foundation of the Candidate Products to deliver aggregated, anonymized user data in the annual reports submitted to FDA."

III. Conclusion

The Brenner Memo concludes: "The Agency has very little experience evaluating device access restrictions in the context of ENDS and whether a product meets the APPH standard for marketing authorization. That makes it especially important, and more challenging, to ensure our decisions on PMTAs where device access restrictions are material to the decision are carefully thought out and vetted and consistent with the pending guidance. Accordingly, the Agency needs additional time to consider the four non-tobacco products, and I hereby direct you to refrain from issuing MGOs for them to allow for further evaluation."

It is unclear at this juncture – after the G^2 PMTA has been under FDA review for almost five years – what "additional time" could provide, particularly given the current procedural posture of the application. As extensively documented in the Technical Project Lead Review Summary, signed by Dr. Matthew Farrelly on February 17, 2026, the Office of Science has completed its review of the PMTA and has recommended that marketing granted orders be issued for all of the G^2 products. This 94-page document exhaustively analyzes all of the data and information in the G^2 PMTA, ensuring that the decision was "carefully thought out and vetted and consistent with the pending guidance."

In addition to failing to meet the applicable statutory deadline of 180 days, FDA continues to violate the Administrative Procedure Act (APA) by unlawfully withholding and unreasonably delaying action on the remaining Glas products. FDA's failure to act on the G^2 PMTA within a reasonable time (missing the statutorily-imposed deadline by over 1,700 days) and disregard of CTP's scientific expertise warrant judicial intervention to compel the Agency to complete its review.[2] Because FDA has already authorized

[2] *See, e.g.,* Forest Guardians v. Babbitt, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); Biodiversity Legal Found. v. Badgley, 309 F.3d 1166, 1178 (9th Cir. 2002) ("The Service's failure to complete the listing determinations within the mandated time frame compelled the [district] court to grant injunctive relief. . . . The exercise of discretion is foreclosed when statutorily imposed deadlines are not met.").

non-age-gated menthol ENDS products, and has reviewed applications for much larger companies in a much shorter period of time (despite not being in the expedited review queue that the G^2 PMTA was purportedly in), the failure to issue orders for the remaining G^2 ENDS products also represents an unexplained departure from FDA's treatment of similarly situated products and companies in violation of the APA.[3]

Ultimately, in addition to failing to comply with the Federal Food, Drug, and Cosmetic Act's mandates and violating the APA, FDA's continued inaction effectively disincentivizes development of products that directly address important public health concerns long identified by the Agency. Since its first meeting with FDA in March of 2021, Glas has done everything required under the statute and everything the Agency has requested at a cost of tens of millions of dollars, and yet FDA still refuses to act on the G^2 PMTA to the detriment of public health.

By this letter and based on the above, Glas requests that FDA address this arbitrary and capricious conduct, investigate the basis for withholding authorization for the remaining G^2 products, and expeditiously authorize the Glas G^2 ENDS products that remain in regulatory limbo at the Agency. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Robert F. Kennedy Jr.
Sara Brenner
James Blair
Darcie L. Johnston
Ken Callahan
Lowell M. Zeta
Susan Williams
Wendy Vicente
Matthew Farrelly
Cristi Stark
Stacy Ehrlich

[3] *See* Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 27-28 (D.D.C. 1997).

Exhibit 1

U.S. FOOD & DRUG ADMINISTRATION

To: Bret Koplow, Acting Director, CTP

From: Sara Brenner M.D., M.P.H., Principal Deputy Commissioner

Date: February 18, 2026

CONFIDENTIAL / DELIBERATIVE

Subject: Glas PMTAs (PM0004879.PD1- PM0004879.PD4)

These are premarket tobacco product applications (PMTAs) from Glas Inc. for four products (PM0004879.PD1- PM0004879.PD4). You had concurred with the Director of CTP's Office of Science in issuing marketing granted orders (MGOs) for these four products. However, there are ongoing discussions about how to evaluate device access restrictions for non-tobacco-flavored ENDS that could have implications on the overall analysis for determining whether permitting any of these four products to be marketed would be "appropriate for the protection of the public health" (APPH). This is reflected, in part, in the Agency's plan to issue guidance communicating FDA's current thinking regarding the evidentiary considerations necessary to demonstrate that marketing flavored ENDS products would be "appropriate for the protection of the public health" (APPH). That guidance is close to being finalized pending review by the Office of Management and Budget.

As discussed in the guidance, FDA appreciates that ENDS products with flavors other than tobacco may, in certain circumstances, provide benefits to adults who smoke combusted cigarettes, including by facilitating switching away from combusted tobacco products, increasing quit attempts, supporting sustained smoking abstinence, and reducing cigarette consumption among adults who would otherwise continue smoking. However, given the well-established and substantial youth appeal associated with certain flavor categories, particularly fruit, candy, and certain other flavors that appeal to youth, applicants bear a heightened evidentiary burden to demonstrate that marketing such products would result in a net benefit to the population as a whole.

The guidance communicates the FDA's current thinking on the limitations of device access restrictions as a component of a comprehensive youth prevention strategy. Given the added risk posed by youth appealing flavors and the current lack of real-world experience demonstrating that use of such technologies prevent or sufficiently mitigate the risk of youth use, the applicant whose high youth appealing flavored ENDS product purports to rely solely on device access restrictions to address risk to youth carries an especially high burden to demonstrate adequate mitigation of such risk based on valid and reliable evidence from robust scientific investigation. In addition, state law heterogeneity and regulatory loopholes have undermined youth access restrictions; and the agency remains concerned that motivated youth and sellers can easily get

around restrictions through e-commerce exclusions, weak enforcement, alternative delivery methods that circumvent postal rules, and limited penalties.[1,2,3]

In determining whether permitting the marketing of a flavored ENDS product is APPH, the agency considers the potential impact of marketing restrictions and other mitigations measures, including technological measures designed to prevent access and use (device access restrictions). At issue, these four ENDS products purport to rely solely on device access restriction technology to sufficiently mitigate youth access and use. The Agency has very little experience evaluating device access restrictions in the context of ENDS and whether a product meets the APPH standard for marketing authorization. That makes it especially important, and more challenging, to ensure our decisions on PMTAs where device access restrictions are material to the decision are carefully thought out and vetted and consistent with the pending guidance.

Accordingly, the Agency needs additional time to consider the four non-tobacco products, and I hereby direct you to refrain from issuing MGOs for them to allow for further evaluation.

SARA BRENNER -S

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Date: 2026.02.19 09:10:57 -05'00'

/s/

Sara Brenner M.D., M.P.H.
Principal Deputy Commissioner
U.S. Food & Drug Administration

[1] Leas EC, Mejorado T, Harati R, et al. E-commerce licensing loopholes: a case study of online shopping for tobacco products following a statewide sales restriction on flavoured tobacco in California. Tob Control. 2025;34(4):523-526. Published 2025 Jul 31. doi:10.1136/tc-2023-058269

[2] Gottlieb MA. To End Youth Vaping as an On-Ramp to Addiction, Close Legal Loopholes and Rigorously Enforce the Law. Am J Public Health. 2023;113(5):472-473. doi:10.2105/AJPH.2023.307271

[3] Azagba S, Ebling T, Korkmaz A. Social media and e-cigarette use: The mediating role of mental health conditions. J Affect Disord. 2024;344:528-534. doi:10.1016/j.jad.2023.10.053

Exhibit 2

February 9, 2026

Via Overnight Mail and Email

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Glas G^2 Age-Gated ENDS & "Product with Merit" PMTA – FDA Public Health Failure

Dear Mr. Kennedy:

Glas Inc. (Glas), a small independent manufacturer,[1] would like to bring to your attention the Food and Drug Administration's (FDA's) extraordinary delay and arbitrary and capricious conduct in its review of Glas's pending premarket tobacco product application (PMTA) for the Glas G^2 age-gated electronic nicotine delivery system (ENDS) device and e-liquid cartridges (Glas PMTA), which Glas submitted on July 21, 2021.[2] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay also fails to meet the required statutory deadline, violates the Administrative Procedure Act (APA), and raises serious questions about the scientific integrity of the PMTA review process.

Glas has attempted to work collaboratively with FDA multiple times over the past six years, sending numerous letters and meeting requests to various FDA officials. Most recently, Glas sent a letter to FDA Commissioner Martin Makary on January 13, 2026 (enclosed), highlighting the extraordinarily protracted and questionable manner in which the Agency appears to be managing this important "product with merit" application. In the letter, Glas emphasized that this delay is of grave concern and has had a negative impact on public health. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency's (and other stakeholders') long established concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) allow for remote product de-activation in the case of a recall or potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

[1] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."
[2] FDA Submission Tracking Number (STN) PM0004879.

Exhibit 2

We were advised that FDA completed scientific review of the Glas PTMA on October 30, 2025, and the application was sent for "clearance review." On December 17, 2025, FDA contacted Glas to schedule a call to discuss the Glas PMTA. Very early on the morning of the scheduled meeting, however, a Regulatory Health Project Manager (RHPM) sent an email to Glas abruptly canceling that meeting, stating, "Although we had scheduled this teleconference for this time, we are not able to meet." FDA refused any further explanation.

Then, on Saturday, December 20, 2025, FDA posted a PDF document to its website[3] entitled, "E-Cigarettes Authorized by the FDA," which included the following Glas Inc. products: BLONDE TOBACCO 50 MG/ML Pod, CLASSIC MENTHOL 50 MG/ML Pod, FRESH MENTHOL 50 MG/ML Pod, Glas G^2 DEVICE, GOLD 50 MG/ML Pod, AND SAPPHIRE 50 MG/ML Pod (enclosed). The document stated it was "Last Updated: December 2025." When contacted about the FDA post, Acting CTP Director Bret Koplow replied: "The Glas products have not been authorized. The application remains pending. The website is being immediately corrected."

Since that date, Glas has received no further information from FDA and the application remains pending. It goes without saying that creating, and subsequently publishing, a PDF document that states that certain Glas products are "Authorized by the FDA" cannot be an accident; the document was clearly created intentionally. The question is: why did FDA change course so abruptly, cancelling its meeting with Glas mere hours before and qualifying the posting of that document to the FDA website as an "error"?

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that, because of their expected benefit to public health, the G^2 products are considered "products with merit" that were placed (over 4.5 years ago) – first – in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology.[4] Indeed, in May 2025, you yourself emphasized the importance of preventing underage access to vapes and praised U.S. companies' efforts to use age-restrictive technology.[5]

Importantly, Glas has conducted multiple robust studies that support the efficacy and adult benefit of the G^2 technology including a clinical model that predicted a substantial reduction in the number of estimated deaths and a reduction of years of lives lost by replacement of cigarette smoking with Glas G^2 products and a supplemental model and study that predicted that the introduction of age-gating technology similar to that in the Glas G^2 would have a substantial positive impact on public health, namely an additional 19% increase in deaths avoided (69,565 deaths avoided) and 23% improvement in life

[3] The document appeared at https://www.fda.gov/media/190229/download.
[4] See FDA Office of Science Memorandum, Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022 (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue on the Appendix on page 3) (January 21, 2021).
[5] Testimony of HHS Secretary Robert F. Kennedy Jr. before Senate HELP Committee (May 14, 2025), *available at* https://www.youtube.com/watch?v=PjoyMCHZugk (discussion begins at 2:00:53).

years gained (0.957 million life years gained) compared to ENDS introduction without age-gating technology.

Respectfully, in the interest of public health, we request your assistance in securing the immediate authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Darcie L. Johnston
Ken Callahan
Martin Makary, M.D
Bret Koplow, Ph.D.
David Mednick
Lowell M. Zeta
Stacy Ehrlich

Exhibit 2

E-Cigarettes Authorized by the FDA

These are the only e-cigarettes that may be lawfully sold in the United States.

(Last Updated: December 2025)

Manufacturer	Product Name	
Glas Inc.	BLONDE TOBACCO 50 MG/ML Pod	CLASSIC MENTHOL 50 MG/ML Pod
	FRESH MENTHOL 50 MG/ML Pod	Glas G² DEVICE
	GOLD 50 MG/ML Pod	SAPPHIRE 50 MG/ML Pod
JUUL Labs Inc.	JUULpods (Menthol 3.0%)	JUULpods (Menthol 5.0%)
	JUULpods (Virginia Tobacco 3.0%)	JUULpods (Virginia Tobacco 5.0%)
	JUUL Device	
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package	Logic Pro Capsule Tank System (1)
	Logic Vapeleaf Cartridge/Capsule Package	Logic Pro Capsule Tank System (2)
	Logic Vapeleaf Tobacco Vapor System	Logic Power Tobacco e-Liquid Package
	Logic Pro Tobacco e-Liquid Package	Logic Power Rechargeable Kit
NJOY LLC	NJOY DAILY Rich Tobacco 4.5%	NJOY ACE POD Classic Tobacco 2.4%
	NJOY DAILY EXTRA Rich Tobacco 6%	NJOY ACE POD Classic Tobacco 5%
	NJOY DAILY EXTRA Menthol 6%	NJOY ACE POD Rich Tobacco 5%
	NJOY DAILY Menthol 4.5%	NJOY ACE POD Menthol 2.4%
	NJOY ACE Device	NJOY ACE POD Menthol 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)	Vuse Replacement Cartridge Original 4.8% G2
	Vuse Vibe Tank Original 3.0%	Vuse Alto Power Unit
	Vuse Vibe Power Unit (2)	Vuse Alto Pod Golden Tobacco 5%
	Vuse Ciro Power Unit (1)	Vuse Alto Pod Rich Tobacco 5%
	Vuse Ciro Cartridge Original 1.5%	Vuse Alto Pod Golden Tobacco 2.4%
	Vuse Ciro Power Unit (2)	Vuse Alto Pod Rich Tobacco 2.4%
	Vuse Solo Power Unit	Vuse Alto Pod Golden Tobacco 1.8%
	Vuse Replacement Cartridge Original 4.8% G1	Vuse Alto Pod Rich Tobacco 1.8%

For an up-to-date list of authorized e-cigarettes, visit the Searchable Tobacco Products Database.

While these products are authorized to be sold in the United States, it does not mean these products are safe, nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

Exhibit 2

January 13, 2026

Via Overnight Mail and Email

Martin Makary, M.D.
Commissioner

Bret Koplow, Ph.D.
Acting Director
Center for Tobacco Products

David Mednick
Deputy Chief Counsel for Program Review for Devices and Tobacco
Office of Chief Counsel

Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Glas G² PMTA (STN PM0004879) – Failure to Meet Statutory Deadline, Unreasonable Delay, and Arbitrary and Capricious Conduct

Dear Drs. Makary and Koplow and Mr. Mednick:

By this letter, Glas Inc. (Glas or the Company), a small independent manufacturer,[1] would like to bring to your attention the Center for Tobacco Products' (CTP's) extraordinary delay and arbitrary and capricious conduct in its review of Glas's pending premarket tobacco product application (PMTA) for the Glas G² electronic nicotine delivery system (ENDS) device and seven e-liquid cartridges in two nicotine strengths (G² or Glas PMTA).[2] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay also fails to meet the required statutory deadline, violates the Administrative Procedure Act (APA), and raises serious questions about the scientific integrity of the PMTA review process.

[1] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

[2] FDA Submission Tracking Number (STN) PM0004879.

Exhibit 2

I. Introduction

Glas submitted this bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021. FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. After 386 days of no communication whatsoever, the Agency issued a second deficiency letter to Glas on August 1, 2024. Glas submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and was granted an extension by FDA to produce additional scientific study results on or before April 30, 2025, by which date Glas submitted a complete response. Thus, the Glas PMTA was complete (at the very latest) on April 30, 2025, and Glas was informed that the Office of Science completed its scientific review on October 30, 2025, exactly 180 days later.[3] Nevertheless, the Glas PMTA remains pending, 1,637 days (4.5 years) after submission (**over 9 times** the required statutory review period), despite the fact that scientific review was completed more than two months ago.

Recent interaction with FDA has raised further questions about FDA's review of the Glas PMTA. On December 17, 2025, FDA contacted Glas to schedule a call on December 19, 2025, at 11:00am EST to discuss the Glas PMTA. At 4:55am EST on December 19, 2025, however, a Regulatory Health Project Manager (RHPM) sent an email to Glas abruptly canceling that meeting. Both the email from the RHPM and a later one from Cristi Stark, Associate Director of the Office of Science at the Center for Tobacco Products, included the following identical language: "Although we had scheduled this teleconference for this time, we are not able to meet." FDA refused any further explanation.

Then, on Saturday, December 20, 2025, at approximately 2:00pm EST, FDA posted a PDF document to its website[4] entitled, "E-Cigarettes Authorized by the FDA," which included the following Glas Inc. products: BLONDE TOBACCO 50 MG/ML Pod, CLASSIC MENTHOL 50 MG/ML Pod, FRESH MENTHOL 50 MG/ML Pod, Glas G^2 DEVICE, GOLD 50 MG/ML Pod, AND SAPPHIRE 50 MG/ML Pod. See Exhibit A. See also https://www.2firsts.com/news/exclusive-suspected-backend-update-then-withdrawal-suggests-glas-may-be-next-fda-authorized-e-cigarette-brand-after-juul?time=1766303619, a media story summarizing this development that includes an image of the PDF. The document stated it was "Last Updated: December 2025." Interestingly, it did not include all of the SKUs covered by the pending Glas PMTA.

When Glas became aware of the FDA post, it made several attempts to contact multiple individuals at CTP to confirm the products were in fact authorized. When contacted about the FDA post, Dr. Bret Koplow, Acting Director of the Center for Tobacco

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[3] Glas understands that once the Office of Science completes its scientific review, the scientific recommendation then goes through what is known as "clearance review," which can involve review by various federal officials, including the CTP Director, the FDA Commissioner, the FDA Office of Chief Counsel, the Secretary of Health and Human Services, and other members of the Administration.

[4] The document appeared at https://www.fda.gov/media/190229/download.

Products, replied: “The Glas products have not been authorized. The application remains pending. The website is being immediately corrected.” He further advised the following:

> We have further updated the authorized e-cigarette webpage to add the following text: “**This list is up-to-date as of December 21, 2025. There are 39 e-cigarettes authorized by the FDA. These are the only e-cigarettes that may be lawfully sold in the United States. On 12/20/25, FDA experienced a related web error that did not change this list but was corrected the same day.**” *See* https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends-authorized-fda.
>
> I understand the company likely has questions. At this time, we have no additional information to share.

Since that date, Glas has received no further information from FDA and the application remains pending. It goes without saying that creating, and subsequently publishing, a PDF document that states that certain Glas products are “Authorized by the FDA” cannot be an accident; the document was clearly created intentionally. The question is: why did the Agency change course so abruptly, cancelling its meeting with Glas mere hours before and qualifying the posting of that document to the FDA website as an “error”?

The extraordinarily protracted and questionable manner in which the Agency appears to be managing this important “product with merit” application is of grave concern and has had a negative impact on public health. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency’s (and other stakeholders’) long established concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

It is also important to note that, because of these significant public health benefits, the Glas PMTA was placed in a purportedly expedited queue for prioritized review of ENDS products that incorporate age-verification technology, and was in that expedited queue alone for at least two years before any other manufacturer submitted an application for a similar age-gated ENDS product. The extreme delay in FDA’s review of the Glas PMTA has essentially deprived Glas – the only independent company in the expedited review queue – of the benefit of its significant investment in next-generation ENDS products designed to address the youth-access problems and smoking-related disease and death created by the big tobacco companies, who comprise the remainder of the expedited queue.

II. Factual Background

As you are aware, Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." It has now been 1,637 days since Glas submitted the G^2 PMTA, 1504 days since FDA filed the PMTA, 1294 days since the PMTA entered substantive scientific review on June 29, 2022, 258 days since Glas submitted its complete response to the second deficiency letter, and 75 days since the Office of Science completed its substantive review. Still, FDA has failed to take action on the application.[5]

Glas has attempted to work collaboratively with FDA multiple times, sending numerous letters and meeting requests to various FDA officials. For instance, on February 27, 2024, Glas sent a letter to Commissioner Robert Califf, CTP Director Brian King, and others raising serious concerns about the delay in reviewing the Glas PMTA and describing the important public health benefits of the Glas products. See Exhibit B. In response to that letter, FDA offered to meet with Glas, although the meeting was not scheduled until May 13, 2024, and was only with representatives of the Office of Science.

After almost another year of inactivity, Glas sent an additional letter to FDA Commissioner Martin Makary on April 3, 2025, welcoming him to FDA, describing the public health benefits of the Glas products and the lack of action on the Glas PMTA, and requesting a meeting. See Exhibit C. Glas received no response. The following month, Glas sent yet another letter to Dr. Bret Koplow, dated May 27, 2025, congratulating him on his recent appointment as Acting CTP Director, again describing the public health benefits of the Glas products and the lack of action on the Glas PMTA, and requesting a meeting. See Exhibit D. Dr. Koplow did not respond; instead, the Office of Science recommended requesting a formal scientific meeting, which was not at all what the Company requested and would have been denied in any event.

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that, because of their expected benefit to public health, the G^2 products are considered "products with merit" that, as noted above, were placed (over four and a half years ago) – first – in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology.[6]

[5] We also note that FDA completed a PMTA manufacturing inspection of the Glas facility on September 27, 2022, and the Company filed a tobacco product master file update containing all corrective actions from this inspection on December 6, 2022.

[6] See FDA Office of Science Memorandum, Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022 (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue on the Appendix on page 3) (January 21, 2021).

III. Public Health Benefits of the Glas Products

Bringing this disruptive and standard-setting technology to the U.S. market as soon as possible would maximize the benefits to public health by providing adult smokers who will not or cannot cease using nicotine a compelling reduced-risk alternative that completely mitigates any youth-access or -use or counterfeit concerns associated with the ENDS category.

Indeed, in May 2025, Department of Health and Human Services Secretary Robert F. Kennedy Jr. emphasized the importance of preventing underage access to vapes and praised U.S. companies' efforts to use age-restrictive technology.[7] Likewise, Dr. Koplow stated at an October 2025 Food and Drug Law Institute conference: "One area that holds particular promise is effective age-gating and access-restriction technology to help mitigate risk to youth for products that could be beneficial to adults who smoke. I think it's a potential game changer. We want to encourage development of innovative technology that can prevent youth use. This includes effective age-gating technology that can verify adult users in the context of nicotine pouch products."[8]

The Glas G^2 products, which include embedded age-gating and counterfeit-detection technology, have the potential to reshape the way ENDS products are sold and used to successfully move adult smokers down the continuum of risk while eliminating youth access and use. Glas believes that its G^2 products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health. In fact, at least three big tobacco companies filed PMTAs with FDA for age-gated ENDS products, years after Glas filed its application.

The G^2 products utilize a verified and validated embedded technology and software to overcome past industry failures in at least seven ways: (1) a demanding age- and identity-verification process required to initially activate the device before first use after purchase (i.e., underage individuals cannot even turn the product on); (2) required ongoing authentication of the user to continue to use the device, including automatic device locking when the device is out of range of the authenticated smartphone; (3) counterfeit cartridge detection and use prevention; (4) cartridge identification to prevent re-use with unauthorized liquids; (5) continuous secure monitoring of use patterns and behaviors that provides the ability to understand product use in real time; (6) the ability to roll out live updates or modifications of various use parameters (e.g., an individual product can be remotely deactivated if there is reason to believe that it is defective or

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[7] Testimony of HHS Secretary Robert F. Kennedy Jr. before Senate HELP Committee (May 14, 2025), *available at* https://www.youtube.com/watch?v=PjoyMCHZugk (discussion begins at 2:00:53). Secretary Kennedy also emphasized the need to clear counterfeit and illicit products from the market, which is consistent with GLAS's G^2 anti-counterfeiting technology. *Id.*; *see also* HHS Makes Push to Stop Youth Vaping (Sept. 15, 2025), *available at* https://www.hhs.gov/press-room/hhs-youth-vaping-resource-guide-illegal-vapes.html.

[8] *See* Acting CTP Director Offers 'Groundbreaking' Views at FDLI, *available at* https://tobaccoreporter.com/2025/10/29/acting-ctp-director-offers-groundbreaking-views-at-fdli/.

being used improperly); and (7) the ability for users to monitor their own product use and potentially self-select limits on such use.

The Company believes that the G^2 products provide the most tailored solution for adult smokers to access flavored ENDS products that will help them fully transition away from smoking while preventing any youth access or use. Indeed, FDA has stated the following:

> Experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, *for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential*.[9]

The G^2 device's access restrictions allow for the effective control and monitoring of both the youth "on ramp" and the adult "off ramp" through age-verified activation and authentication and real-time market surveillance and use-data capture. As described in detail in Exhibits B, C, and D, Glas has conducted multiple robust studies that support the efficacy and adult benefit of the G^2 technology:

- A **Longitudinal Randomized Experimental Switching Study** to assess adult benefit under APPH standard. In this three-month longitudinal multi-site randomized study, a total of 400 exclusive heavy smokers were randomly assigned to one of four conditions (Glas age-gated device with Glas flavored, menthol-flavored, or tobacco-flavored pods or an FDA-authorized tobacco-flavored competitor ENDS). Data showed that 13% to 21% of Glas product users completely quit smoking after three months, 45% to 46% of Glas product users reduced their past 30-day cigarettes per day (CPD) by 50%, and 79% to 92% of the Glas users benefited when combining all cigarette reduction. Taken together, these results demonstrate that while all products contributed to some level of benefit to participants, exclusive heavy smokers showed greatest benefit with Glas menthol and Glas flavored products.
- A **Quantitative Study** to assess actual use of the Glas G^2 involving hundreds of subjects (exclusive smokers, dual-users and vape-only users) across 3 sites in U.S. involving three use periods over 35 days that demonstrated that smokers reduced their overall daily cigarette consumption 40% while dual users reduced their daily cigarette consumption 28%, and that flavor had a dramatic impact on cigarette consumption (smokers who used Glas Gold reduced their daily consumption by 73% while those who used Glas Sapphire reduced daily consumption by nearly 25%).
- **Age-gating Studies** to assess the risk to youth under APPH standard. Multiple studies, including (1) functional testing across a number of subjects in three

[9] See, e.g., Technical Project Lead (TPL) Review of Logic Technology Development LLC PMTAs (PM0000529-31, PM0000535-37, PM0000540-41) at 5 (August 19, 2019) (emphasis added).

separate groups ranging in age from 16 to 49 years of age utilizing a tablet with a non-branded version of the Glas application installed across seven different scenarios that identified no scenarios where underage individuals could age verify, (2) age-gating application testing involving participants from around the U.S. of differing sex and race, ranging in age from 16 to 50+, in which no underage individuals were able to activate the G2 device and the Glas system accurately detected invalid pods (counterfeit or re-used) and prevented their continuous use, and (3) a third-party cybersecurity penetration testing that failed to bypass the age-verification process and pod counterfeit protections.

- A **Perception Study** including thousands of participants that found that the main individuals interested in the product were smokers who desired to quit within the next 12 months and that youth, former smokers and never smokers were not interested in the product.
- **Population Health Overview Studies**, including a clinical model that predicted a substantial reduction in the number of estimated deaths and a reduction of years of lives lost by replacement of cigarette smoking with Glas G2 products and a supplemental model and study that predicted that the introduction of age-gating technology similar to that in the Glas G2 would have a substantial positive impact on public health, namely an additional 19% increase in deaths avoided and 23% improvement in life years gained compared to ENDS introduction without age-gating technology.

Thus, the G^2 products present no risk of youth appeal, uptake, or use and lead to a significant reduction in combustible cigarette consumption in adult dual users and cigarette smokers.

IV. Failure to Meet Statutory Deadline, Unreasonable Delay, and Arbitrary and Capricious Conduct

As noted above, Section 910(c)(1) of the FFDCA requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." In the preamble to the final PMTA rule, FDA clarified that the 180-day review clock begins "on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples)" and that "[w]hile FDA will restart the 180-day review period after the receipt of a major amendment, the Agency intends to promptly act on an amended application, which might take fewer than 180 days."[10]

Glas submitted a complete response to CTP's second deficiency letter on April 30, 2025, which we understand FDA considers to be a major amendment. However, contrary to its commitment in the preamble, CTP has not acted "promptly" on Glas's amended application. Rather, despite the fact that Glas filed the second amendment over 250 days ago, and that scientific review was completed over two months ago, CTP

[10] Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed.Reg. 55300, 55374, 55382 (October 5, 2021).

has not acted on the Glas PMTA. Importantly, the lackadaisical and inconsistent manner with which the Agency is managing this "product with merit" application is not in the best interests of public health, particularly adult smokers who continue to die at a rate of over 450,000 per year.

In addition to failing to meet the applicable statutory deadline, FDA has violated the Administrative Procedure Act (APA) by unlawfully withholding and unreasonably delaying Agency action. This failure to act on the G^2 PMTA within a reasonable time, particularly when also failing to meet a statutorily-imposed deadline, warrants judicial intervention to compel the Agency to complete its review. See, e.g.*, Forest Guardians v. Babbitt*, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1178 (9th Cir. 2002) ("The Service's failure to complete the listing determinations within the mandated time frame compelled the [district] court to grant injunctive relief. . . . The exercise of discretion is foreclosed when statutorily imposed deadlines are not met.").

Ultimately, in addition to failing to comply with the FFDCA's mandates and violating the APA, CTP is negatively skewing incentives by permitting the continued marketing of illegal products while delaying authorization for companies like Glas that have invested high eight figures to follow the rules and develop products that directly address important public health concerns, but are unable to launch their products because the Agency has not completed its review of applications that have been pending for years. Since its first meeting with FDA in March of 2021, Glas has done everything required under the statute and everything the Agency has requested and yet FDA still refuses to act on the Glas PMTA to the detriment of public health.

V. Conclusion

By this letter and based on the above, we request immediate authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Matthew Farrelly, Ph.D.
Cristi Stark
Stacy Ehrlich

Exhibit 2

E-Cigarettes Authorized by the FDA

These are the only e-cigarettes that may be lawfully sold in the United States.

(Last Updated: December 2025)

Manufacturer	Product Name	
Glas Inc.	BLONDE TOBACCO 50 MG/ML Pod	CLASSIC MENTHOL 50 MG/ML Pod
	FRESH MENTHOL 50 MG/ML Pod	Glas G² DEVICE
	GOLD 50 MG/ML Pod	SAPPHIRE 50 MG/ML Pod
JUUL Labs Inc.	JUULpods (Menthol 3.0%)	JUULpods (Menthol 5.0%)
	JUULpods (Virginia Tobacco 3.0%)	JUULpods (Virginia Tobacco 5.0%)
	JUUL Device	
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package	Logic Pro Capsule Tank System (1)
	Logic Vapeleaf Cartridge/Capsule Package	Logic Pro Capsule Tank System (2)
	Logic Vapeleaf Tobacco Vapor System	Logic Power Tobacco e-Liquid Package
	Logic Pro Tobacco e-Liquid Package	Logic Power Rechargeable Kit
NJOY LLC	NJOY DAILY Rich Tobacco 4.5%	NJOY ACE POD Classic Tobacco 2.4%
	NJOY DAILY EXTRA Rich Tobacco 6%	NJOY ACE POD Classic Tobacco 5%
	NJOY DAILY EXTRA Menthol 6%	NJOY ACE POD Rich Tobacco 5%
	NJOY DAILY Menthol 4.5%	NJOY ACE POD Menthol 2.4%
	NJOY ACE Device	NJOY ACE POD Menthol 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)	Vuse Replacement Cartridge Original 4.8% G2
	Vuse Vibe Tank Original 3.0%	Vuse Alto Power Unit
	Vuse Vibe Power Unit (2)	Vuse Alto Pod Golden Tobacco 5%
	Vuse Ciro Power Unit (1)	Vuse Alto Pod Rich Tobacco 5%
	Vuse Ciro Cartridge Original 1.5%	Vuse Alto Pod Golden Tobacco 2.4%
	Vuse Ciro Power Unit (2)	Vuse Alto Pod Rich Tobacco 2.4%
	Vuse Solo Power Unit	Vuse Alto Pod Golden Tobacco 1.8%
	Vuse Replacement Cartridge Original 4.8% G1	Vuse Alto Pod Rich Tobacco 1.8%

For an up-to-date list of authorized e-cigarettes, visit the Searchable Tobacco Products Database.

While these products are authorized to be sold in the United States, it does not mean these products are safe, nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

Exhibit 2

February 27, 2024

Via Overnight Mail and Email

Robert M. Califf, M.D., MACC
Commissioner

Brian King, Ph.D., M.P.H.
Director
Center for Tobacco Products

David Mednick
Deputy Chief Counsel for Program Review for Devices and Tobacco
Office of Chief Counsel

Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Glas G² PMTA (STN PM0004879) – Failure to Meet Statutory Deadline and Unreasonable Delay

Dear Drs. Califf and King and Mr. Mednick:

By this letter, Glas Inc. (Glas or the Company) would like to bring to your attention the Center for Tobacco Products' (CTP's) delay in issuing a decision with respect to Glas's pending premarket tobacco product application (PMTA) for the Glas G² electronic nicotine delivery system (ENDS) device and seven e-liquid cartridges in two nicotine strengths (G² PMTA).[1] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay both fails to meet the statutory deadline and violates the Administrative Procedure Act (APA).

Glas submitted this bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021. FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. The G² PMTA was therefore complete at least seven months ago, and we understand that a decision on the application is not expected to be issued for at least another several months. Thus, although the required statutory deadline for PMTA review is 180 days, it appears that a

[1] FDA Submission Tracking Number (STN) PM0004879.

decision will not be forthcoming for a minimum of 425 days, more than twice the time the statute permits for such decision-making.

The sluggish manner in which the Agency appears to be managing this important "product with merit" application is of grave concern. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

I. Introduction

As you are aware, Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." It has now been over 950 days since Glas submitted the G^2 PMTA, 815 days since FDA filed the PMTA, 605 days since the PMTA entered substantive scientific review on June 29, 2022, and 225 days since Glas submitted its response to the deficiency letter, and Glas has not received any substantive correspondence from the Office of Science.[2]

For a small tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, this delay is existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the G^2 products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that the G^2 products are considered "products with merit" that were placed in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology. Bringing this disruptive and standard-setting technology to the U.S. market as soon as possible would maximize the benefits to public health by providing adult smokers who will not or cannot cease using nicotine a compelling reduced-risk alternative that completely mitigates any youth-access or -use concerns associated with the ENDS category. As Dr. Califf has observed:

[2] We also note that FDA completed a PMTA manufacturing inspection of the Glas facility on September 27, 2022, and the Company filed a tobacco product master file update containing all corrective actions from this inspection on December 6. 2022.

[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

> This work is particularly critical as we focus on preventing initiation, while also helping people quit, especially the deadliest form of tobacco use, combustible tobacco products. Despite meaningful declines in cigarette use over the past several decades, nearly 500,000 Americans still die every year from cigarette smoking. Additionally, with more than 3 million youth reporting current use of a tobacco product in 2022, and e-cigarettes being the most used product, we risk another generation becoming addicted to these products.[4]

The Glas G^2 products, which include embedded age-gating and counterfeit detection technology, have the potential to re-shape the way ENDS products are sold and used to successfully move adult smokers down the continuum of risk while eliminating youth access and use. Glas believes that its G^2 products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

Specifically, in addition to age-verification at point of sale (whether at retail or online), the G^2 products utilize a verified and validated embedded technology and software to overcome past industry failures in at least seven ways: (1) a demanding age- and identity-verification process required to initially activate the device before first use after purchase (i.e., underage individuals cannot even turn the product on); (2) required ongoing authentication of the user to continue to use the device, including automatic device locking when the device is out of range of the authenticated smartphone; (3) counterfeit cartridge detection and use prevention; (4) cartridge identification to prevent re-use with unauthorized liquids; (5) continuous secure monitoring of use patterns and behaviors that provides the ability to understand product use in real time; (6) the ability to roll out live updates or modifications of various use parameters (e.g., an individual product can be remotely deactivated if there is reason to believe that it is defective or being used improperly); and (7) the ability for users to monitor their own product use and potentially self-select limits on such use.

The Company believes that the G^2 products provide the most tailored solution for adult smokers to access flavored ENDS products that will help them fully transition away from smoking while preventing any youth access or use. Indeed, FDA has stated the following:

> Experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, *for flavored ENDS, only the most stringent*

[4] Statement from FDA Commissioner Califf, FDA Provides Update on External Evaluation to Strengthen Agency's Tobacco Program (December 19, 2022), accessed at https://www.fda.gov/news-events/press-announcements/fda-provides-update-external-evaluation-strengthen-agencys-tobacco-program.

> *mitigation measures – specifically device access restrictions – have such mitigation potential*.[5]

The G^2 device's access restrictions allow for the effective control and monitoring of both the youth "on ramp" and the adult "off ramp" through age-verified activation and authentication and real-time market surveillance and use-data capture.

Importantly, authorizing the flavored G^2 products (Classic Menthol, Fresh Menthol, Gold, and Sapphire) as soon as possible will give FDA the strongest response to arguments made in court and administrative appeals of marketing denial orders (MDOs) that FDA's so-called "fatal flaw" memo[6] (which FDA has now applied to menthol-flavored ENDS products as well[7]) established a de facto product standard prohibiting flavored ENDS products without observing the required notice-and-comment rulemaking process.[8]

Because, as demonstrated in the Glas PMTA, the G^2 products do not present any risk of youth appeal, access, or use whatsoever, FDA can authorize the flavored G^2 products without a need to demonstrate a benefit over the tobacco-flavored variants. In any event, however, as described below, the Glas studies demonstrate that the flavored

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[5] See, e.g., Technical Project Lead (TPL) Review of Logic Technology Development LLC PMTAs (PM0000529-31, PM0000535-37, PM0000540-41) at 5 (August 19, 2019) (emphasis added).

[6] FDA memorandum, "ENDS Containing Non-Tobacco Flavored E-Liquid: Approach to PMTAs not in Substantive Scientific Review (Phase III)" (July 9, 2021) (announcing a policy of requiring evidence from a randomized controlled trial or longitudinal cohort study demonstrating that a non-tobacco flavored product provides an incremental benefit to adult smokers relative to a tobacco-flavored product based on "the known and substantial risk of flavored ENDS with respect to youth appeal, uptake, and use").

[7] We note that, in light of FDA's intention to implement a product standard prohibiting menthol as a characterizing flavor in cigarettes, it is essential that FDA authorize lower-risk alternative menthol options, such as the G^2 menthol products, to which adults smokers can switch following the effective date of any such product standard.

[8] *See, e.g.*, *Breeze Smoke, LLC v. FDA*, No. 21-3902 (6th Cir.), Corrected Opening Brief of Petitioner (Nov. 16, 2021) at 45 ("The new evidentiary requirement that FDA applied to all flavored ENDS pursuant to its Fatal Flaw Review process is a new 'tobacco product standard' in every relevant sense … Under the TCA, FDA was required to provide notice of its proposed standard for flavored ENDS and to give affected manufacturers an opportunity to comment."); Reply Brief in Support of Emergency Application for Stay to the Supreme Court of the United States by Breeze Smoke, LLC (December 7, 2021) at 8 ("…[T]o the extent FDA has now concluded, after its final PMTA guidance, that flavored e-cigarettes should be categorically banned or subject to more demanding evidentiary standards than tobacco-flavored products, the agency has the tools to impose such restrictions in a manner that provides fair notice and respects reliance—it can issue new tobacco product standards for all flavored e-cigarette products, after undergoing notice and comment. See 21 U.S.C. §§ 387g(c), (d)(1); id. § 387g(a)(1)(A) (prohibiting flavored cigarettes as a 'tobacco product standard'). What the agency cannot do is take a shortcut by providing certain review standards in industry guidelines, but then imposing a different, behind-the-scenes standard that leads it to reject all of the millions of product applications that companies filed."); R.J. Reynolds Vapor Company Petition for Stay of Action (Jan. 27, 2023) at 4 ("FDA's orders are unlawful because FDA adopted a policy that no non-tobacco-flavored ENDS will be authorized. In so doing, FDA has created a 'tobacco product standard' in violation of the Tobacco Control Act.").

G^2 products (i.e., Sapphire, Gold) have an added benefit relative to that of tobacco-flavored products in facilitating smokers' significantly reducing their cigarette use.

II. Data Supporting the G^2 PMTA

The Glas studies demonstrate the effectiveness of the advanced age-gating technology embedded in the G^2 products in eliminating youth access. The results from a study of both underage and legal age users throughout the United States show strong effectiveness of the G^2 products in preventing youth access. No underage individuals were able to activate the device. Data from a perception and intention study additionally demonstrate that youth are not interested in trying or using the G^2 products. Thus, the G^2 products present no risk of youth appeal, uptake, or use. Moreover, the Company's actual use study's results demonstrate that use of the G^2 products, particularly the flavored G^2 products (i.e., Sapphire, Gold), causes a significant reduction in combustible cigarette consumption in dual users and cigarette smokers.

A. G^2 Age-Gating Technology

The user age-verification feature authenticates that the user is at least 21 years of age before the device can be activated for use. The user is required to scan his or her state-issued driver's license or ID document. The ID information is extracted and compared to public ID records to verify that the information is correct. The user is also required to capture a short selfie video to further verify his or her authenticity. The system compares the short selfie video against the image on the ID document to verify that they belong to the same person. The system uses the ID information along with the user's selfie video to verify that the user is above the legal vaping age.[9] User cases that do not pass the verification protocol are forwarded to customer service for manual review and, if appropriate, approval. During an onboarding period, the user is periodically asked to record another selfie video. The new video is compared against the original user's video to ensure that the authenticated smartphone is still in the eligible user's possession and has not been given to another user (including to a minor). This prevents, among other things, a minor from using an adult's smartphone to activate the device.

The G^2 device is automatically locked if the smartphone is disconnected from the G^2 device for more than 60 minutes to ensure that the G^2 device remains in the possession of the original authenticated user. This prevents a minor from surreptitiously using an adult's smartphone to activate the device. This feature also enables the authenticated user to lock the G^2 device through the mobile application while the G^2 device is not in use, further preventing potential unauthorized use by minors. All of these features also prevent unauthorized use of the G^2 product if it is lost or stolen.

[9] To add an additional margin of safety, the system is designed to scrutinize individuals physically appearing under the age of 25.

The Company conducted two age-verification, user-based studies and a third-party G^2 product ecosystem security assessment, which involved, among other things, penetration testing.[10] The first age-gating testing study (Functionality Testing of the Age-Gating Smartphone Application) evaluated the theoretical functionality of the software by using test scenarios on a tablet device with the age-verification software installed. The study identified no scenarios where underage study participants could inadvertently age verify, and no underage individuals were able to age verify. The second study (Qualitative Functionality Testing of the Age-gating Smartphone Application) used actual underage individuals as well as adults, smartphones with the Glas application installed, and the G^2 products. This was a full test of all aspects of the age-gating application, the Glas website, and the G^2 products. The study required participants to go to the actual Glas website and register the G^2 device. **No underage individuals were able to activate the G^2 device. Age, gender, and ethnicity had no effect on the accuracy of the age verification application.** The adult participants who were able to age verify and unlock the device were asked to puff on a series of non-nicotine-containing Glas pods. Various valid and invalid pods were tested. **The system accurately detected invalid pods (counterfeit or re-used) and prevented their use.**

Glas engaged a nationally recognized cybersecurity firm to conduct third-party penetration testing and an internet of things (IoT) product ecosystem security assessment of the G^2 products. The firm designed the tests to provide Glas with an independent, point-in-time assessment of the security posture of the G^2 products from the perspective of a malicious actor. The firm's testing and vulnerability threat rankings were aligned to industry-proven NIST 800-30 threat rankings methodology, and Glas ranked low in threat likelihood, impact, and level of risk across all findings. Specific select results from the months-long testing included that the firm was unable to bypass the age verification process (age verification testing) and unable to bypass the counterfeit protections in place (counterfeit protection testing).

B. Adult Product Use

The Company conducted two user-based studies informed by its March 22, 2021, meeting with FDA and subsequent correspondence. The first, an actual use study (Quantitative Study to Assess the Actual Use of the Glas G^2 Pod-Based Vaping System Among US Adults Tobacco/Nicotine Product Users or AUS), was designed to assess the effect the G^2 products may have on tobacco/nicotine use behavior among current tobacco/nicotine consumers. In particular, the purpose of the study was to investigate how adult exclusive conventional cigarette smokers, dual users, and ENDS users actually use the G^2 products over an "actual use" period in a real-life/naturalistic environment. Participants self-reported via an eDiary on a daily basis ad libitum use of

[10] Penetration testing is a simulated cyber-attack against the device operation system and cloud architecture to check for exploitable vulnerabilities.

the G^2 products[11] as well as any other tobacco/nicotine products typically consumed. All participants initially documented their baseline product use during a one-week period. Exclusive cigarette smokers and dual users were then provided the G^2 products for two 14-day use periods.[12] Subjects had the opportunity to try the products and pick their desired flavor and nicotine strength (30 mg/ml or 50 mg/ml).

In the initial G^2 product use period, the subjects were provided either a tobacco or menthol product based on their normal tobacco product flavor preference. In the second G^2 product use period, the subjects were allowed to taste and choose among the seven flavors and two nicotine strengths. Over 50% of dual users and exclusive smokers choose the products that were not tobacco or menthol flavors (i.e., Gold and Sapphire). A total of 67% of the ENDS users switched to the same flavors. During the baseline period, smokers recorded using 10.7 cigarettes per day and dual users 8.5 cigarettes per day; ENDS users recorded using 3.6 pods per week and dual users 4 pods per week.

In this study, use of the G^2 products by smokers and dual users caused a noticeable reduction in other tobacco/nicotine use, including combustible cigarettes. By the end of the two 14-day use periods, the smokers reduced their overall cigarette consumption 40% from 10.7 to 6.5 cigarettes per day. Dual users reduced their cigarette consumption 28% from 7.0 to 5.0 cigarettes per day. These are remarkable reductions in such a short period of time. Importantly, the smokers were not forced to switch to the G^2 products; the reduction was of their own free will.

Furthermore, flavor had an impact on cigarette consumption. Overwhelmingly, the subjects preferred the Gold or Sapphire flavors during the final 14-day use period when they could choose their preferred flavor. Smokers who used Gold flavored pods during the second use period reduced their cigarette consumption from a baseline of 12.3 cigarettes per day to 3.3, **a 73% reduction**. Among those who used Sapphire flavored pods, cigarette consumption was reduced to 7.0 from a baseline of 9.0 cigarettes per day. By the end of the final use period, the likelihood of future use of the G^2 products was higher among dual users and exclusive cigarette smokers compared to primary ENDS users. The demographic and smoking/vaping profiles of those most likely to use G^2 products in the future did not exhibit any notable skews compared to the complete study population.

C. Effects on the Population as a Whole

The G^2 PMTA also contains two population models. In the first, the Company evaluated the impact of introducing an ENDS product on population health. As expected, there was a population benefit. The Company performed an additional study (Technology Population Health Overview) using the same approach and assumptions as the original

[11] The device also recorded each puff, its duration, and time of day, and location.

[12] The smokers and dual users were provided the products but not required to switch or use them.

population model (e.g., estimating the population health impact of introducing ENDS in general, and the G^2 products in particular, into the U.S. population) comparing the population health impacts of introducing traditional ENDS products and a novel type of ENDS product that prohibited youth use into the U.S. population. **The study results suggest that introduction of the G^2 age-gating technology could reduce cigarette smoking-related deaths by an additional 19% and reduce the life years lost by an additional 23%.** The age-gating technology has the potential to amplify the positive public health benefits of ENDS by eliminating youth initiation and usage.

III. Failure to Meet Statutory Deadline and Unreasonable Delay

As noted above, Section 910(c)(1) of the FFDCA requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." In the preamble to the final PMTA rule, FDA clarified that the 180-day review clock begins "on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples)" and that "[w]hile FDA will restart the 180-day review period after the receipt of a major amendment, the Agency intends to promptly act on an amended application, which might take fewer than 180 days."[13]

Glas submitted a complete response to CTP's deficiency letter on July 12, 2023, which we understand FDA considers to be a major amendment. However, contrary to its commitment in the preamble, CTP has not acted "promptly" on Glas's amended application. Rather, despite the fact that Glas filed the amendment over 225 days ago, we understand that CTP does not expect to issue an order for at least another several months, which would bring the total to over 425 days.

Surprisingly, Glas understands that although the Glas PMTA is in a separate prioritized review queue for "products with merit" (e.g., those with embedded age-verification technology), and all of the primary scientific disciplines have completed their review of the G^2 application, CTP is nonetheless prioritizing the applications filed by September 2020 (for products that are currently on the market) for its clearance review and is now estimating that it may not issue a decision on the G^2 PMTA until late 2024. In the meantime, because Glas cannot sell the G^2 products until CTP authorizes them, the Company is facing serious economic consequences each day it waits for CTP to complete its review. Most importantly, the lackadaisical manner with which the Agency is managing this "product with merit" application is not in the best interests of public health, particularly adult smokers who continue to die at a rate of over 450,000 per year.

In addition to failing to meet the applicable statutory deadline, FDA has violated the Administrative Procedure Act (APA) by unlawfully withholding and unreasonably delaying Agency action. This failure to act on the G^2 PMTA within a reasonable time, particularly when also failing to meet a statutorily-imposed deadline, warrants judicial

[13] Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed.Reg. 55300, 55374, 55382 (October 5, 2021).

intervention to compel the Agency to complete its review. *See, e.g.*, *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1178 (9th Cir. 2002) ("The Service's failure to complete the listing determinations within the mandated time frame compelled the [district] court to grant injunctive relief. . . . The exercise of discretion is foreclosed when statutorily imposed deadlines are not met.").

Ultimately, in addition to failing to comply with the FFDCA's mandates and violating the APA, CTP is negatively skewing incentives by permitting the continued marketing of illegal products while delaying authorization for companies that have invested millions of dollars to follow the rules and develop products that directly address important public health concerns, but are unable to launch their products because the Agency has not completed its review of applications that have been pending for years.

IV. Conclusion

By this letter and based on the above, we request timely authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Matthew Farrelly, Ph.D.
William Loy
Eshael Johnson
Stacy Ehrlich

Exhibit 2

April 3, 2025

Via Overnight Mail and Email

Martin A. Makary, M.D., MPH
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Welcome & Glas Introduction

Dear Dr. Makary:

Congratulations on your recent appointment and U.S. Senate confirmation as Commissioner of the U.S. Food and Drug Administration (FDA). The team at Glas Inc. (Glas or the Company) has worked closely with the Center for Tobacco Products (CTP) over the past several years with respect to the Company's pending premarket tobacco product applications (PMTAs) for the Glas next-generation device and pods (Glas G^2 ENDS), accepted by FDA on August 3, 2021, and filed by FDA on December 1, 2021.

I look forward to meeting with you in the near future and working with you closely as we continue our tireless efforts to bring the Glas G^2 "product with merit"[1] to market as we believe this technology will re-shape the way electronic nicotine delivery system (ENDS) products are sold and used, successfully eliminating youth access and use while moving adult smokers down the continuum of harm. Glas believes that its products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

The Glas G^2 ENDS products that are the subject of Glas's PMTAs are embedded with robust, continuous age-verification technology and are groundbreaking and directly address FDA's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product uptake and use by minors; (2) prevent

[1] "Product with merit" is an internal CTP designation that provides for prioritized consideration and review of certain PMTAs, based on certain product attributes that FDA views as more likely to support the statutory standard of "appropriate for the protection of public health" (APPH). FDA has indicated that specific examples of such attributes include technology that provides for age-verification and -gating of users of the ENDS device and anti-counterfeiting and anti-cloning of pods. These applications are in a separate queue from all other PMTAs. We understand that the Glas PMTA is first in that separate expedited queue. Significantly, FDA has stated in multiple PMTA orders that "[e]xperience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential."

cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health. I have attached our current executive summary for your convenience and reference.

Glas submitted a bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021 (over 1,200 days ago). FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. After 386 days, over twice the time period the Federal Food, Drug, and Cosmetic Act (FFDCA) permits for FDA's review of PMTAs,[2] the Agency issued a second deficiency letter on August 1, 2024. Although some of the information requested in the second deficiency letter appears to be related to issues raised in the previous deficiency letter, a number of the requests appear to "move the goalposts" from where FDA had previously set them, both for Glas and for other similarly situated applicants. Despite this fact we submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and were granted an extension by FDA to produce additional scientific study results on or before April 30, 2025. I understand the CTP Office of Science has substantially completed scientific review of the Glas PMTA and the application has reached the so-called "clearance review" level at the Agency, which I believe involves oversight by the CTP Director, FDA's Office of Chief Counsel and others, notably political appointees.

For a small tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, FDA's repeated review delays have been existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the Glas G^2 products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

I founded Glas from a deeply personal foundation - my own struggles as a teen smoker. I formed Glas and have designed innovative, tech-enabled products to help other smokers quit, pure and simple. Over the last four years, Glas has sought to effectively collaborate with FDA in bringing this disruptive and standard-setting technology to the U.S. market as soon as possible to maximize the benefits to public health. Again, I look forward to you and your colleagues at FDA working closely with us to achieve the Glas mission to eliminate product access and use by minors, prevent cartridge counterfeiting, and help adult smokers successfully move away from combustible cigarettes.

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[2] Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application."

[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

Exhibit 2

Thank you in advance for your time and consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas Inc.

cc: Benjamin Apelberg, Ph.D.
Cristi Stark
William Loy
Eshael Johnson
Fatima Sow
Stacy Ehrlich

Exhibit 2

glas

Executive Summary

Authorization of Glas' premarket tobacco product application ("PMTA") will protect American youth, further MAHA goals, and help U.S. businesses in the fight against illicit Chinese products.

Why vaping? A way to move adult smokers down the continuum of harm away from combustible cigarettes.[1] Smoking kills more than 480,000 Americans each year, causing 30% of all U.S. cancer deaths and 80% of lung cancer deaths. Vaping provides smokers with an offramp that promotes successfully switching away from smoking -- especially with flavored products. The CDC acknowledges that "more frequent use of e-cigarettes is associated with greater smoking cessation." In 2024, a comprehensive review of 88 vaping studies published in the Cochrane Library concluded that vaping with or without nicotine increases smoking cessation.

The vaping opportunity. An essential growth vector for global tobacco & nicotine.[2] Cigarette consumption is declining at about 3-4% per annum. Smoking prevalence is falling in almost every market worldwide due to the increased awareness of the long-term health implications of smoking. New categories of reduced risk products are helping smokers transition away from combustibles while creating new revenue opportunities. The total non-combustible market is estimated at $68 billion as of 2023, with vaping expected to grow 4x from ~$20 billion to $74 billion by 2035.

The youth vaping crisis and Trump's response. [3] While the availability of flavored products is a key demand driver for e-cigarettes, flavors also present undeniable underage usage concerns. In early 2020 during the first Trump administration, the FDA reasonably banned the sale of flavored cartridge-based e-cigarettes other than tobacco and menthol due to the appeal of fruit and mint flavors amongst underage users. The FDA has since been adamant that flavored PMTAs will be rejected without sufficient underage risk prevention, while welcoming age-gating technology to unlock access.

The Glas technology solution. Following the ban, Glas recognized the need for technology-based controls to better manage access to vapor offerings. The company developed age-verification/gating and anticounterfeiting technology that provides a reduced-risk alternative for adult smokers, while eliminating youth access. Glas devices connect to a smartphone app that requires ID age-verification and restricts use to within close proximity of the user's phone for a limited duration, while also safeguarding against use of unregulated counterfeit products through micro-chip authentication of Glas pods.

Critical, patented, and FDA-validated features of Glas' technology that unlock approval of flavored ENDS products.

Glas devices connect to a smartphone app that requires ID age-verification and restricts use to within close proximity of the registered user's phone for a limited duration, thereby preventing underage access. Micro-chip authentication of Glas pods further safeguards against unregulated counterfeit products.

1 **Device Control**
Age-verification/gating

- Proprietary firmware and software enabling continuous communication and control from Glas mobile app.
- Smartphone registration and authentication, user age-verification, access security and control, and counterfeit pod detection.

2 **Pod Security**
Anticounterfeiting

- Pod ID, authentication, tracking and history.
- EPROM (erasable programmable read-only memory) embedded in each pod with unique IDs cryptographically signed during the Glas e-liquid filling process in the U.S..

The new problem: no FDA-approved alternatives and the rise of China's illegal imports. [4] Under the Biden administration, the FDA failed to crack down on the sale of unauthorized flavored products targeted at teens. New unauthorized disposable vapes from China have flooded the market and are estimated to represent over half of the e-cigarette market today. The FDA's response has simultaneously penalized businesses in compliance with regulations by failing to offer legal alternatives.[5] As of March 2024, 27 million PMTAs had been submitted since 2021, and the FDA had refused to accept 20 million (74%) applications outright.

The path forward is here today. The FDA must authorize an age-gating verification system. Glas' novel age-verification/gating and anti-counterfeiting technology is awaiting authorization, has already been vetted by the FDA, and is a win-win solution to improve America's health and economy. However, Glas' PMTA submission is now 1,200 days outstanding with no transparency from the FDA – despite receiving a "product with merit" designation. Meanwhile, the FDA's inaction is enabling an illicit, dangerous market. A prompt authorization of Glas would help solve the youth vaping crisis, crack down on illicit Chinese imports, and give millions of adult smokers the legitimate, effective alternative they need.

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[1] Nicotine & Tobacco Research, MUSC via ScienceDirect, Royal College of Physicians, NHS, CDC, Cochrane. cancer.org.
[2] Source: BAT & Deutsche Bank Research.
[3] Nicotine & Tobacco Research, FDA. Dr. Brian King (FDA Director, Center for Tobacco Products, keynote address at Global Tobacco and Nicotine Forum 2024 in Athens Sep-2024).
[4] University of Rochester Medical Center, Tobacco Control, CDC, FDA Premarket Tobacco Product Marketing Granted Orders, Associated Press, FDA PMTA, FDA Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, CSP and Nielsen via Statista, CDC Foundation.
[5] Sources: FDA-Vuse, FDA-blu. In October 2023, the FDA denied marking of six flavored Vuse Alto e-cigarette products, stating that the application rationale was not "sufficient to outweigh the known risks to youth." In February 2024, the FDA issued denial orders for five of Imperial's blu e-cigarette products on the same rationale – noting specifically that "among youth who currently used e-cigarettes, 6% reported using blu brand e-cigarettes."

Exhibit 2

May 27, 2025

Via Overnight Mail and Email

Bret Koplow Ph.D., J.D.
Acting Director
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Re: Welcome & Glas Introduction

Dear Dr. Koplow:

Congratulations on your recent appointment as Acting Director of the Center for Tobacco Products (CTP). The team at Glas Inc. (Glas or the Company) has worked closely with CTP over the past several years with respect to the Company's pending premarket tobacco product applications (PMTAs) for the Glas next-generation device and pods (Glas G^2 ENDS), submitted to FDA on July 21, 2021, filed by FDA on December 1, 2021, and which moved into the Phase 3 substantive scientific review process on June 29, 2022.

We look forward to meeting with you in the near future and working with you as we continue our tireless efforts to bring the Glas G^2 "product with merit"[1] to market as we believe this effective age-gating technology will re-shape the way electronic nicotine delivery system (ENDS) products are sold and used, successfully eliminating youth access and use while moving adult smokers down the continuum of harm. Glas believes

[1] "Product with merit" is an internal CTP designation that provides for prioritized consideration and review of certain PMTAs, based on certain product attributes that FDA views as more likely to support the statutory standard of "appropriate for the protection of public health" (APPH). See FDA Office of Science Memorandum, "Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022" (January 21, 2021) (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue in the Appendix on page 3).

FDA has indicated that specific examples of such attributes include technology that provides for age-verification and -gating of users of the ENDS device and anti-counterfeiting and anti-cloning of pods. These applications are in a separate queue from all other PMTAs. We understand that the Glas PMTA is first in that separate expedited queue. Significantly, FDA has stated in multiple PMTA orders that "[e]xperience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential."

that its products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

Frankly, I was very encouraged by the recent testimony of U.S. Health and Human Services Secretary Robert F. Kennedy Jr. before the Senate HELP Committee on May 14, 2025, as he referenced how FDA can do better in addressing its application backlog and U.S. vape market: "absolutely, and we are looking at it right now… During the Biden Administration the FDA slow-walked the approvals for U.S. vaping companies and the U.S. vaping companies in my view they were acting very responsible. They were putting chips in their vapes that would make sure that young people could not use them… they really went out of their way not to make it attractive to children."

The Glas G^2 ENDS products that are the subject of Glas's PMTAs are embedded with robust, continuous age-verification technology and are groundbreaking and directly address FDA's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product uptake and use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health. I have attached our current executive summary for your convenience and reference.

Glas submitted a bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021 (over 1,400 days ago). FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. After 386 days, over twice the time period the Federal Food, Drug, and Cosmetic Act (FFDCA) permits for FDA's review of PMTAs,[2] the Agency issued a second deficiency letter on August 1, 2024. Although some of the information requested in the second deficiency letter appeared to be related to issues raised in the previous deficiency letter, a number of the requests appeared to "move the goalposts" from where FDA had previously set them, both for Glas and for other similarly situated applicants.

Despite this fact, Glas submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and were granted an extension by FDA to produce additional scientific study results on or before April 30, 2025, which we met and submitted a complete response by that date. I understand the CTP Office of Science had, prior to the issuance of the second deficiency letter, substantially completed scientific review of the Glas PMTA and the application reached the so-called "clearance review" level at the Agency, which I believe involves oversight by the CTP Director, FDA's Office of Chief Counsel and others, notably political appointees.

[2] Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application."

Exhibit 2

For a small U.S.-based tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, FDA's repeated review delays have been existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the Glas G[2] products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

I founded Glas from a deeply personal foundation - my own struggles as a teen smoker. I formed Glas and have designed innovative, tech-enabled products to help other smokers switch, pure and simple. Over the last four years, Glas has sought to effectively collaborate with FDA in bringing this disruptive and standard-setting technology to the U.S. market as soon as possible to maximize the benefits to public health. Again, I look forward to you and your colleagues at FDA working closely with us to achieve the Glas mission to eliminate product access and use by minors, prevent cartridge counterfeiting, and help adult smokers successfully move away from combustible cigarettes. By this letter, I request a meeting to introduce our company and technology.

Thank you in advance for your time and consideration.

Sincerely,

Sean Greenbaum
Founder & Chief Executive Officer
Glas Inc.

cc: Todd L. Cecil, Ph.D.
Benjamin Apelberg, Ph.D.
Cristi Stark
William Loy
Eshael Johnson
Fatima Sow
Stacy Ehrlich

[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

Exhibit 3

March 23, 2026

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Glas G² Age-Gated ENDS – Public Health Failure and APA Violation

Dear Mr. Kennedy:

Glas Inc. (Glas), a small independent manufacturer,[1] would like to bring to your attention the Food and Drug Administration's (FDA's) continued extraordinary delay and arbitrary and capricious conduct[2] in its review of Glas's pending premarket tobacco product application (PMTA) for the Glas G² age-gated electronic nicotine delivery system (ENDS) device and e-liquid cartridges (G² PMTA), which Glas submitted on July 21, 2021.[3]

On March 18, 2026, Glas received a response to its FOIA request for documents relating to the G² PMTA. Those documents clearly show that there was high-level interference with the scientific process in authorizing the G² products. In particular, the FDA Center for Tobacco Products (CTP) Office of Science (OS) recommended authorization of **all G² products (8 SKUs in total)** on December 18, 2025. Further, on February 17, 2026, the Director of CTP-OS recommended authorization of **all but two (Signature Tobacco & Blue Tobacco) G² products**. However, on March 11, 2026, the Acting CTP Director directed the authorization of **just two G² product SKUs (the G² device and Blonde Tobacco)**, citing an internal FDA memorandum signed February 19, 2026, by Principal Deputy Commissioner, Sara Brenner, which **directed CTP to refrain from issuing MGOs for the flavored ENDS products (4 SKUs in total: Gold, Sapphire, Fresh & Classic Menthol)**.[4] Accordingly, on March 12, 2026, FDA issued an marketing granted order (MGO) letter for **just two G² product SKUs (the G² device and Blonde tobacco)**.

Thus, while OS recommended authorization of all of the G² products on December 18, 2025, and the OS Director, recommended authorization of all but two of the tobacco-flavored pods on February 17, 2026, a February 19, 2026, memo from the Commissioner's Office blocked authorization of the flavored G² products (Classic Menthol, Fresh Menthol, Gold, and Sapphire pods).

[1] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

[2] For more background, see Glas's previous letter to Secretary Kennedy, dated February 9, 2026, enclosed as Exhibit 1.

[3] FDA Submission Tracking Number (STN) PM0004879.

[4] See Exhibit 2, enclosed.

Exhibit 3

As described below, FDA's continued arbitrary and capricious conduct in its review of the G² PMTA is contrary to the interests of public health, fails to meet the required statutory deadline, violates the Administrative Procedure Act (APA), and raises serious questions about the scientific integrity of the PMTA review process. Because the G² products are groundbreaking and directly address the Agency's (and other stakeholders') long-established concerns regarding the current ENDS marketplace in that they prevent product access, initiation and use by minors, FDA designated the G² PMTA as a "product with merit" and placed the application first in a purportedly expedited queue for prioritized review of ENDS products that incorporate age-verification technology. Nonetheless, as detailed in the timeline below, FDA's review of the G² PMTA has been marked by delay and procedural defects.

Over four years after Glas submitted the G² PTMA,[5] FDA completed scientific review on October 30, 2025. On December 17, 2025, FDA contacted Glas to schedule a teleconference on December 19, 2025. On December 18, 2025, the Technical Project Lead (TPL), Selvin H. Edwards, signed the Technical Project Lead Review Decision Summary for the G² PMTA, recommending that FDA "[i]ssue marketing granted orders" for all products covered by the G² PMTA. Very early the next morning, FDA abruptly canceled the scheduled meeting with Glas.

On Saturday, December 20, 2025, FDA posted a PDF document to its website entitled, "E-Cigarettes Authorized by the FDA," which included the following Glas Inc. products: BLONDE TOBACCO 50 MG/ML Pod, CLASSIC MENTHOL 50 MG/ML Pod, FRESH MENTHOL 50 MG/ML Pod, Glas G² DEVICE, GOLD 50 MG/ML Pod, AND SAPPHIRE 50 MG/ML Pod (enclosed). When contacted about the FDA post, Acting CTP Director Bret Koplow replied: "The Glas products have not been authorized. The application remains pending. The website is being immediately corrected."

After months of no communication from FDA, OS reached out to schedule a teleconference with Glas for February 17, 2026, during which Cristi Stark, OS Associate Director, apologized for the cancellation of the December 19, 2025 meeting and advised that FDA would issue decisions in the next few weeks.

We now know through a response to our Freedom of Information Act request that later that same day, Dr. Matthew Farrelly, OS Director, signed the Decision Summary for the G² PMTA, "[c]oncur[ring] with the TPL's recommendation" to issue marketing granted orders (MGOs) for all products in the PMTA, with the exception of Blue Tobacco and Signature Tobacco flavors, which required further consideration (these flavors were also the two SKUs not included in the "accidental" PDF that was posted to the FDA website on December 20,

[5] Glas's review has taken approximately 4.7 years (July 2021 to March 2026) thus far. By comparison, NJOY's review took approximately 2 years, R.J. Reynolds approximately 1.5 years, and Logic Technology approximately 2 years. Only JUUL's review was comparably lengthy (~5 years), and JUUL's delay was at least partly due to a prior denial that was judicially reversed. None of these applications were placed in the expedited queue for "products with merit," like the G² PMTA. The extended review timeline for Glas raises questions about whether smaller companies face structural disadvantages in FDA's review process.

2025). The Decision Summary concluded that "permitting the marketing of the new products … is appropriate for the protection of the public health [and] [m]arketing granted orders should be issued for the new products that are the subject of this review."

On February 19, 2026, two days after FDA's final scientific determination to grant MGOs for the Glas G^2 device as well as the Blonde Tobacco, Classic Menthol, Fresh Menthol, Gold, and Sapphire Pods, Principal Deputy Commissioner Sara Brenner issued a memo which "directed CTP to refrain from issuing MGOs for the flavored ENDS products [Classic Menthol, Fresh Menthol, Gold, and Sapphire pods]." Glas has not been provided access to this memo and is not aware of the basis for this directive. Thus, for reasons the company does not understand, and therefore cannot address, FDA has blocked authorization of the Classic Menthol, Fresh Menthol, Gold, and Sapphire pods. Accordingly, at the current time, Glas is in regulatory limbo, and FDA continues to delay authorization of the products for which an age-gated device is most appropriate.

This is the case despite the fact that FDA has already authorized non-age-gated menthol ENDS products and that the data in the G^2 PMTA (including those showing 100% effective age-gating technology plus robust added switching benefit of the G^2 flavored products to adult smokers) fully satisfies, and likely helped inform, the standards outlined in the FDA's draft guidance for authorization of flavored ENDS released on March 9, 2026. FDA, Draft Guidance for Industry: Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications – Considerations Related to Youth Risk (March 2026).

On March 12, 2026, FDA issued an MGO letter for only the Glas G^2 device and Blonde Tobacco pod. FDA has not posted the Decision Summary on the FDA website, as is customary, presumably because the Decision Summary includes authorization of Glas G^2 device and Blonde Tobacco, Classic Menthol, Fresh Menthol, Gold, and Sapphire Pods, not just Glas G^2 device and Blonde Tobacco pod.

In sum, FDA scientists recommended authorizing all of Glas's age-gated products, concluding that they meet the public health standard, but senior political leadership overrode that science and blocked authorization of the flavored products without explanation, leaving the products in regulatory limbo. As a result, in addition to failing to meet the applicable statutory deadline of 180 days for PMTA review, FDA has violated the Administrative Procedure Act (APA) by failing to follow the statute and its own regulations and by unlawfully withholding and unreasonably delaying Agency action. *See, e.g.*, *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, (1983) ("An agency decision may be deemed arbitrary and capricious: if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

Exhibit 3

Respectfully, in the interest of public health, we request your assistance in securing the immediate authorization of the remainder of the Glas G^2 products, consistent with FDA's final scientific determination. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: James Blair
Darcie L. Johnston
Ken Callahan
Martin Makary, M.D
Bret Koplow, Ph.D.
David Mednick
Lowell M. Zeta
Stacy Ehrlich

Exhibit 3

U.S. FOOD & DRUG ADMINISTRATION

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

From: Bret Koplow, Ph.D, J.D.
Acting Director
Center for Tobacco Products

Bret Koplow -S Digitally signed by Bret Koplow -S Date: 2026.03.11 09:06:50 -04'00'

Company: Glas Inc.

Subject: Glas PMTAs (PM0004879.PD1- PM0004879.PD8)

On December 18, 2025, a Technical Project Lead (TPL) review for premarket tobacco product applications (PMTAs) from Glas Inc for eight products[1] was signed by Selvin Edwards. The review recommends issuing marketing granted orders (MGOs) for all products.

On February 17, 2026, the Office of Science Director, Matthew Farrelly, concurred with issuing the marketing granted orders (MGOs) for all the products except for PM0004879.PD5 and PM0004879.PD7.[2] Recognizing Dr. Farrelly's findings that the new products PM0004879.PD5 and PM0004879.PD7 have excess lifetime cancer risk (ELCRc) values significantly higher than the FDA-authorized ENDS median,[3] I agreed that it was appropriate to take additional time to consider the implications for the overall APPH analysis of these two products (i.e., PM0004879.PD5 and PM0004879.PD7) and issue MGOs for the remaining six products: the device (PM0004879.PD8), flavored (PM0004879.PD1-PM0004879.PD4) and Blonde tobacco-flavored (PM0004879.PD6).

In a memo signed February 19, 2026, the Principal Deputy Commissioner, Sara Brenner, directed CTP to refrain from issuing MGOs for the flavored ENDS products (PM0004879.PD1-PM0004879.PD4).[4] Accordingly, no marketing order is being issued at this time with respect to PM0004879.PD1-PM0004879.PD4.

CTP will issue MGOs for the device (PM0004879.PD8) and Blonde tobacco-flavored (PM0004879.PD6) new products from Glas Inc.

[1] PM0004879.PD1-PM0004879.PD8

[2] Memorandum: Decision on Glas PMTAs (PM0004879.PD1-PM0004879.PD4, PM0004879.PD6, and PM0004879.PD8), dated February 17, 2026.

[3] *Id.*

[4] Memorandum: Glas PMTAs (PM0004879.PD1- PM0004879.PD4), signed February 19, 2026.

Appendix A[5,6,7]

Tobacco Products Subject of This Review

Common Attributes[8]	
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, Closed E-cigarette
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

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

[6] Product name is brand/sub-brand or other commercial name used in commercial distribution.

[7] 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.

[8] 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)[9]	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[10]
Battery capacity	350 mAh
E-liquid volume	N/A
Nicotine concentration	None
PG/VG ratio	N/A

[9] 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”.

[10] 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[11]	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

[11] This amendment applies to all the STNs subject of this review.

Exhibit 2

Exhibit 3

February 9, 2026

Via Overnight Mail and Email

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Glas G^2 Age-Gated ENDS & "Product with Merit" PMTA – FDA Public Health Failure

Dear Mr. Kennedy:

Glas Inc. (Glas), a small independent manufacturer,[1] would like to bring to your attention the Food and Drug Administration's (FDA's) extraordinary delay and arbitrary and capricious conduct in its review of Glas's pending premarket tobacco product application (PMTA) for the Glas G^2 age-gated electronic nicotine delivery system (ENDS) device and e-liquid cartridges (Glas PMTA), which Glas submitted on July 21, 2021.[2] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay also fails to meet the required statutory deadline, violates the Administrative Procedure Act (APA), and raises serious questions about the scientific integrity of the PMTA review process.

Glas has attempted to work collaboratively with FDA multiple times over the past six years, sending numerous letters and meeting requests to various FDA officials. Most recently, Glas sent a letter to FDA Commissioner Martin Makary on January 13, 2026 (enclosed), highlighting the extraordinarily protracted and questionable manner in which the Agency appears to be managing this important "product with merit" application. In the letter, Glas emphasized that this delay is of grave concern and has had a negative impact on public health. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency's (and other stakeholders') long established concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) allow for remote product de-activation in the case of a recall or potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

[1] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."
[2] FDA Submission Tracking Number (STN) PM0004879.

We were advised that FDA completed scientific review of the Glas PTMA on October 30, 2025, and the application was sent for "clearance review." On December 17, 2025, FDA contacted Glas to schedule a call to discuss the Glas PMTA. Very early on the morning of the scheduled meeting, however, a Regulatory Health Project Manager (RHPM) sent an email to Glas abruptly canceling that meeting, stating, "Although we had scheduled this teleconference for this time, we are not able to meet." FDA refused any further explanation.

Then, on Saturday, December 20, 2025, FDA posted a PDF document to its website[3] entitled, "E-Cigarettes Authorized by the FDA," which included the following Glas Inc. products: BLONDE TOBACCO 50 MG/ML Pod, CLASSIC MENTHOL 50 MG/ML Pod, FRESH MENTHOL 50 MG/ML Pod, Glas G^2 DEVICE, GOLD 50 MG/ML Pod, AND SAPPHIRE 50 MG/ML Pod (enclosed). The document stated it was "Last Updated: December 2025." When contacted about the FDA post, Acting CTP Director Bret Koplow replied: "The Glas products have not been authorized. The application remains pending. The website is being immediately corrected."

Since that date, Glas has received no further information from FDA and the application remains pending. It goes without saying that creating, and subsequently publishing, a PDF document that states that certain Glas products are "Authorized by the FDA" cannot be an accident; the document was clearly created intentionally. The question is: why did FDA change course so abruptly, cancelling its meeting with Glas mere hours before and qualifying the posting of that document to the FDA website as an "error"?

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that, because of their expected benefit to public health, the G^2 products are considered "products with merit" that were placed (over 4.5 years ago) – first – in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology.[4] Indeed, in May 2025, you yourself emphasized the importance of preventing underage access to vapes and praised U.S. companies' efforts to use age-restrictive technology.[5]

Importantly, Glas has conducted multiple robust studies that support the efficacy and adult benefit of the G^2 technology including a clinical model that predicted a substantial reduction in the number of estimated deaths and a reduction of years of lives lost by replacement of cigarette smoking with Glas G^2 products and a supplemental model and study that predicted that the introduction of age-gating technology similar to that in the Glas G^2 would have a substantial positive impact on public health, namely an additional 19% increase in deaths avoided (69,565 deaths avoided) and 23% improvement in life

[3] The document appeared at https://www.fda.gov/media/190229/download.
[4] See FDA Office of Science Memorandum, Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022 (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue on the Appendix on page 3) (January 21, 2021).
[5] Testimony of HHS Secretary Robert F. Kennedy Jr. before Senate HELP Committee (May 14, 2025), *available at* https://www.youtube.com/watch?v=PjoyMCHZugk (discussion begins at 2:00:53).

years gained (0.957 million life years gained) compared to ENDS introduction without age-gating technology.

Respectfully, in the interest of public health, we request your assistance in securing the immediate authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Darcie L. Johnston
Ken Callahan
Martin Makary, M.D
Bret Koplow, Ph.D.
David Mednick
Lowell M. Zeta
Stacy Ehrlich

Exhibit 3

E-Cigarettes Authorized by the FDA

These are the only e-cigarettes that may be lawfully sold in the United States.

(Last Updated: December 2025)

Manufacturer	Product Name	
Glas Inc.	BLONDE TOBACCO 50 MG/ML Pod	CLASSIC MENTHOL 50 MG/ML Pod
	FRESH MENTHOL 50 MG/ML Pod	Glas G² DEVICE
	GOLD 50 MG/ML Pod	SAPPHIRE 50 MG/ML Pod
JUUL Labs Inc.	JUULpods (Menthol 3.0%)	JUULpods (Menthol 5.0%)
	JUULpods (Virginia Tobacco 3.0%)	JUULpods (Virginia Tobacco 5.0%)
	JUUL Device	
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package	Logic Pro Capsule Tank System (1)
	Logic Vapeleaf Cartridge/Capsule Package	Logic Pro Capsule Tank System (2)
	Logic Vapeleaf Tobacco Vapor System	Logic Power Tobacco e-Liquid Package
	Logic Pro Tobacco e-Liquid Package	Logic Power Rechargeable Kit
NJOY LLC	NJOY DAILY Rich Tobacco 4.5%	NJOY ACE POD Classic Tobacco 2.4%
	NJOY DAILY EXTRA Rich Tobacco 6%	NJOY ACE POD Classic Tobacco 5%
	NJOY DAILY EXTRA Menthol 6%	NJOY ACE POD Rich Tobacco 5%
	NJOY DAILY Menthol 4.5%	NJOY ACE POD Menthol 2.4%
	NJOY ACE Device	NJOY ACE POD Menthol 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)	Vuse Replacement Cartridge Original 4.8% G2
	Vuse Vibe Tank Original 3.0%	Vuse Alto Power Unit
	Vuse Vibe Power Unit (2)	Vuse Alto Pod Golden Tobacco 5%
	Vuse Ciro Power Unit (1)	Vuse Alto Pod Rich Tobacco 5%
	Vuse Ciro Cartridge Original 1.5%	Vuse Alto Pod Golden Tobacco 2.4%
	Vuse Ciro Power Unit (2)	Vuse Alto Pod Rich Tobacco 2.4%
	Vuse Solo Power Unit	Vuse Alto Pod Golden Tobacco 1.8%
	Vuse Replacement Cartridge Original 4.8% G1	Vuse Alto Pod Rich Tobacco 1.8%

For an up-to-date list of authorized e-cigarettes, visit the Searchable Tobacco Products Database.

While these products are authorized to be sold in the United States, it does not mean these products are safe, nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

Exhibit 3

January 13, 2026

Via Overnight Mail and Email

Martin Makary, M.D.
Commissioner

Bret Koplow, Ph.D.
Acting Director
Center for Tobacco Products

David Mednick
Deputy Chief Counsel for Program Review for Devices and Tobacco
Office of Chief Counsel

Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Glas G² PMTA (STN PM0004879) – Failure to Meet Statutory Deadline, Unreasonable Delay, and Arbitrary and Capricious Conduct

Dear Drs. Makary and Koplow and Mr. Mednick:

By this letter, Glas Inc. (Glas or the Company), a small independent manufacturer,[1] would like to bring to your attention the Center for Tobacco Products' (CTP's) extraordinary delay and arbitrary and capricious conduct in its review of Glas's pending premarket tobacco product application (PMTA) for the Glas G² electronic nicotine delivery system (ENDS) device and seven e-liquid cartridges in two nicotine strengths (G² or Glas PMTA).[2] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay also fails to meet the required statutory deadline, violates the Administrative Procedure Act (APA), and raises serious questions about the scientific integrity of the PMTA review process.

[1] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

[2] FDA Submission Tracking Number (STN) PM0004879.

Exhibit 3

I. Introduction

Glas submitted this bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021. FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. After 386 days of no communication whatsoever, the Agency issued a second deficiency letter to Glas on August 1, 2024. Glas submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and was granted an extension by FDA to produce additional scientific study results on or before April 30, 2025, by which date Glas submitted a complete response. Thus, the Glas PMTA was complete (at the very latest) on April 30, 2025, and Glas was informed that the Office of Science completed its scientific review on October 30, 2025, exactly 180 days later.[3] Nevertheless, the Glas PMTA remains pending, 1,637 days (4.5 years) after submission (**over 9 times** the required statutory review period), despite the fact that scientific review was completed more than two months ago.

Recent interaction with FDA has raised further questions about FDA's review of the Glas PMTA. On December 17, 2025, FDA contacted Glas to schedule a call on December 19, 2025, at 11:00am EST to discuss the Glas PMTA. At 4:55am EST on December 19, 2025, however, a Regulatory Health Project Manager (RHPM) sent an email to Glas abruptly canceling that meeting. Both the email from the RHPM and a later one from Cristi Stark, Associate Director of the Office of Science at the Center for Tobacco Products, included the following identical language: "Although we had scheduled this teleconference for this time, we are not able to meet." FDA refused any further explanation.

Then, on Saturday, December 20, 2025, at approximately 2:00pm EST, FDA posted a PDF document to its website[4] entitled, "E-Cigarettes Authorized by the FDA," which included the following Glas Inc. products: BLONDE TOBACCO 50 MG/ML Pod, CLASSIC MENTHOL 50 MG/ML Pod, FRESH MENTHOL 50 MG/ML Pod, Glas G^2 DEVICE, GOLD 50 MG/ML Pod, AND SAPPHIRE 50 MG/ML Pod. See Exhibit A. See also https://www.2firsts.com/news/exclusive-suspected-backend-update-then-withdrawal-suggests-glas-may-be-next-fda-authorized-e-cigarette-brand-after-juul?time=1766303619, a media story summarizing this development that includes an image of the PDF. The document stated it was "Last Updated: December 2025." Interestingly, it did not include all of the SKUs covered by the pending Glas PMTA.

When Glas became aware of the FDA post, it made several attempts to contact multiple individuals at CTP to confirm the products were in fact authorized. When contacted about the FDA post, Dr. Bret Koplow, Acting Director of the Center for Tobacco

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[3] Glas understands that once the Office of Science completes its scientific review, the scientific recommendation then goes through what is known as "clearance review," which can involve review by various federal officials, including the CTP Director, the FDA Commissioner, the FDA Office of Chief Counsel, the Secretary of Health and Human Services, and other members of the Administration.

[4] The document appeared at https://www.fda.gov/media/190229/download.

Products, replied: “The Glas products have not been authorized. The application remains pending. The website is being immediately corrected.” He further advised the following:

> We have further updated the authorized e-cigarette webpage to add the following text: “**This list is up-to-date as of December 21, 2025. There are 39 e-cigarettes authorized by the FDA. These are the only e-cigarettes that may be lawfully sold in the United States. On 12/20/25, FDA experienced a related web error that did not change this list but was corrected the same day.**” *See* https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends-authorized-fda.
>
> I understand the company likely has questions. At this time, we have no additional information to share.

Since that date, Glas has received no further information from FDA and the application remains pending. It goes without saying that creating, and subsequently publishing, a PDF document that states that certain Glas products are “Authorized by the FDA” cannot be an accident; the document was clearly created intentionally. The question is: why did the Agency change course so abruptly, cancelling its meeting with Glas mere hours before and qualifying the posting of that document to the FDA website as an “error”?

The extraordinarily protracted and questionable manner in which the Agency appears to be managing this important “product with merit” application is of grave concern and has had a negative impact on public health. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency’s (and other stakeholders’) long established concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

It is also important to note that, because of these significant public health benefits, the Glas PMTA was placed in a purportedly expedited queue for prioritized review of ENDS products that incorporate age-verification technology, and was in that expedited queue alone for at least two years before any other manufacturer submitted an application for a similar age-gated ENDS product. The extreme delay in FDA’s review of the Glas PMTA has essentially deprived Glas – the only independent company in the expedited review queue – of the benefit of its significant investment in next-generation ENDS products designed to address the youth-access problems and smoking-related disease and death created by the big tobacco companies, who comprise the remainder of the expedited queue.

II. Factual Background

As you are aware, Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." It has now been 1,637 days since Glas submitted the G^2 PMTA, 1504 days since FDA filed the PMTA, 1294 days since the PMTA entered substantive scientific review on June 29, 2022, 258 days since Glas submitted its complete response to the second deficiency letter, and 75 days since the Office of Science completed its substantive review. Still, FDA has failed to take action on the application.[5]

Glas has attempted to work collaboratively with FDA multiple times, sending numerous letters and meeting requests to various FDA officials. For instance, on February 27, 2024, Glas sent a letter to Commissioner Robert Califf, CTP Director Brian King, and others raising serious concerns about the delay in reviewing the Glas PMTA and describing the important public health benefits of the Glas products. See Exhibit B. In response to that letter, FDA offered to meet with Glas, although the meeting was not scheduled until May 13, 2024, and was only with representatives of the Office of Science.

After almost another year of inactivity, Glas sent an additional letter to FDA Commissioner Martin Makary on April 3, 2025, welcoming him to FDA, describing the public health benefits of the Glas products and the lack of action on the Glas PMTA, and requesting a meeting. See Exhibit C. Glas received no response. The following month, Glas sent yet another letter to Dr. Bret Koplow, dated May 27, 2025, congratulating him on his recent appointment as Acting CTP Director, again describing the public health benefits of the Glas products and the lack of action on the Glas PMTA, and requesting a meeting. See Exhibit D. Dr. Koplow did not respond; instead, the Office of Science recommended requesting a formal scientific meeting, which was not at all what the Company requested and would have been denied in any event.

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that, because of their expected benefit to public health, the G^2 products are considered "products with merit" that, as noted above, were placed (over four and a half years ago) – first – in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology.[6]

[5] We also note that FDA completed a PMTA manufacturing inspection of the Glas facility on September 27, 2022, and the Company filed a tobacco product master file update containing all corrective actions from this inspection on December 6, 2022.

[6] See FDA Office of Science Memorandum, Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022 (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue on the Appendix on page 3) (January 21, 2021).

III. Public Health Benefits of the Glas Products

Bringing this disruptive and standard-setting technology to the U.S. market as soon as possible would maximize the benefits to public health by providing adult smokers who will not or cannot cease using nicotine a compelling reduced-risk alternative that completely mitigates any youth-access or -use or counterfeit concerns associated with the ENDS category.

Indeed, in May 2025, Department of Health and Human Services Secretary Robert F. Kennedy Jr. emphasized the importance of preventing underage access to vapes and praised U.S. companies' efforts to use age-restrictive technology.[7] Likewise, Dr. Koplow stated at an October 2025 Food and Drug Law Institute conference: "One area that holds particular promise is effective age-gating and access-restriction technology to help mitigate risk to youth for products that could be beneficial to adults who smoke. I think it's a potential game changer. We want to encourage development of innovative technology that can prevent youth use. This includes effective age-gating technology that can verify adult users in the context of nicotine pouch products."[8]

The Glas G^2 products, which include embedded age-gating and counterfeit-detection technology, have the potential to reshape the way ENDS products are sold and used to successfully move adult smokers down the continuum of risk while eliminating youth access and use. Glas believes that its G^2 products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health. In fact, at least three big tobacco companies filed PMTAs with FDA for age-gated ENDS products, years after Glas filed its application.

The G^2 products utilize a verified and validated embedded technology and software to overcome past industry failures in at least seven ways: (1) a demanding age- and identity-verification process required to initially activate the device before first use after purchase (i.e., underage individuals cannot even turn the product on); (2) required ongoing authentication of the user to continue to use the device, including automatic device locking when the device is out of range of the authenticated smartphone; (3) counterfeit cartridge detection and use prevention; (4) cartridge identification to prevent re-use with unauthorized liquids; (5) continuous secure monitoring of use patterns and behaviors that provides the ability to understand product use in real time; (6) the ability to roll out live updates or modifications of various use parameters (e.g., an individual product can be remotely deactivated if there is reason to believe that it is defective or

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[7] Testimony of HHS Secretary Robert F. Kennedy Jr. before Senate HELP Committee (May 14, 2025), *available at* https://www.youtube.com/watch?v=PjoyMCHZugk (discussion begins at 2:00:53). Secretary Kennedy also emphasized the need to clear counterfeit and illicit products from the market, which is consistent with GLAS's G^2 anti-counterfeiting technology. *Id.*; *see also* HHS Makes Push to Stop Youth Vaping (Sept. 15, 2025), *available at* https://www.hhs.gov/press-room/hhs-youth-vaping-resource-guide-illegal-vapes.html.

[8] *See* Acting CTP Director Offers 'Groundbreaking' Views at FDLI, *available at* https://tobaccoreporter.com/2025/10/29/acting-ctp-director-offers-groundbreaking-views-at-fdli/.

being used improperly); and (7) the ability for users to monitor their own product use and potentially self-select limits on such use.

The Company believes that the G^2 products provide the most tailored solution for adult smokers to access flavored ENDS products that will help them fully transition away from smoking while preventing any youth access or use. Indeed, FDA has stated the following:

> Experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, *for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential*.[9]

The G^2 device's access restrictions allow for the effective control and monitoring of both the youth "on ramp" and the adult "off ramp" through age-verified activation and authentication and real-time market surveillance and use-data capture. As described in detail in Exhibits B, C, and D, Glas has conducted multiple robust studies that support the efficacy and adult benefit of the G^2 technology:

- A **Longitudinal Randomized Experimental Switching Study** to assess adult benefit under APPH standard. In this three-month longitudinal multi-site randomized study, a total of 400 exclusive heavy smokers were randomly assigned to one of four conditions (Glas age-gated device with Glas flavored, menthol-flavored, or tobacco-flavored pods or an FDA-authorized tobacco-flavored competitor ENDS). Data showed that 13% to 21% of Glas product users completely quit smoking after three months, 45% to 46% of Glas product users reduced their past 30-day cigarettes per day (CPD) by 50%, and 79% to 92% of the Glas users benefited when combining all cigarette reduction. Taken together, these results demonstrate that while all products contributed to some level of benefit to participants, exclusive heavy smokers showed greatest benefit with Glas menthol and Glas flavored products.
- A **Quantitative Study** to assess actual use of the Glas G^2 involving hundreds of subjects (exclusive smokers, dual-users and vape-only users) across 3 sites in U.S. involving three use periods over 35 days that demonstrated that smokers reduced their overall daily cigarette consumption 40% while dual users reduced their daily cigarette consumption 28%, and that flavor had a dramatic impact on cigarette consumption (smokers who used Glas Gold reduced their daily consumption by 73% while those who used Glas Sapphire reduced daily consumption by nearly 25%).
- **Age-gating Studies** to assess the risk to youth under APPH standard. Multiple studies, including (1) functional testing across a number of subjects in three

[9] See, e.g., Technical Project Lead (TPL) Review of Logic Technology Development LLC PMTAs (PM0000529-31, PM0000535-37, PM0000540-41) at 5 (August 19, 2019) (emphasis added).

separate groups ranging in age from 16 to 49 years of age utilizing a tablet with a non-branded version of the Glas application installed across seven different scenarios that identified no scenarios where underage individuals could age verify, (2) age-gating application testing involving participants from around the U.S. of differing sex and race, ranging in age from 16 to 50+, in which no underage individuals were able to activate the G2 device and the Glas system accurately detected invalid pods (counterfeit or re-used) and prevented their continuous use, and (3) a third-party cybersecurity penetration testing that failed to bypass the age-verification process and pod counterfeit protections.

- A **Perception Study** including thousands of participants that found that the main individuals interested in the product were smokers who desired to quit within the next 12 months and that youth, former smokers and never smokers were not interested in the product.
- **Population Health Overview Studies**, including a clinical model that predicted a substantial reduction in the number of estimated deaths and a reduction of years of lives lost by replacement of cigarette smoking with Glas G2 products and a supplemental model and study that predicted that the introduction of age-gating technology similar to that in the Glas G2 would have a substantial positive impact on public health, namely an additional 19% increase in deaths avoided and 23% improvement in life years gained compared to ENDS introduction without age-gating technology.

Thus, the G^2 products present no risk of youth appeal, uptake, or use and lead to a significant reduction in combustible cigarette consumption in adult dual users and cigarette smokers.

IV. Failure to Meet Statutory Deadline, Unreasonable Delay, and Arbitrary and Capricious Conduct

As noted above, Section 910(c)(1) of the FFDCA requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." In the preamble to the final PMTA rule, FDA clarified that the 180-day review clock begins "on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples)" and that "[w]hile FDA will restart the 180-day review period after the receipt of a major amendment, the Agency intends to promptly act on an amended application, which might take fewer than 180 days."[10]

Glas submitted a complete response to CTP's second deficiency letter on April 30, 2025, which we understand FDA considers to be a major amendment. However, contrary to its commitment in the preamble, CTP has not acted "promptly" on Glas's amended application. Rather, despite the fact that Glas filed the second amendment over 250 days ago, and that scientific review was completed over two months ago, CTP

[10] Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed.Reg. 55300, 55374, 55382 (October 5, 2021).

has not acted on the Glas PMTA. Importantly, the lackadaisical and inconsistent manner with which the Agency is managing this "product with merit" application is not in the best interests of public health, particularly adult smokers who continue to die at a rate of over 450,000 per year.

In addition to failing to meet the applicable statutory deadline, FDA has violated the Administrative Procedure Act (APA) by unlawfully withholding and unreasonably delaying Agency action. This failure to act on the G^2 PMTA within a reasonable time, particularly when also failing to meet a statutorily-imposed deadline, warrants judicial intervention to compel the Agency to complete its review. See, e.g.*, Forest Guardians v. Babbitt*, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1178 (9th Cir. 2002) ("The Service's failure to complete the listing determinations within the mandated time frame compelled the [district] court to grant injunctive relief. . . . The exercise of discretion is foreclosed when statutorily imposed deadlines are not met.").

Ultimately, in addition to failing to comply with the FFDCA's mandates and violating the APA, CTP is negatively skewing incentives by permitting the continued marketing of illegal products while delaying authorization for companies like Glas that have invested high eight figures to follow the rules and develop products that directly address important public health concerns, but are unable to launch their products because the Agency has not completed its review of applications that have been pending for years. Since its first meeting with FDA in March of 2021, Glas has done everything required under the statute and everything the Agency has requested and yet FDA still refuses to act on the Glas PMTA to the detriment of public health.

V. Conclusion

By this letter and based on the above, we request immediate authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Matthew Farrelly, Ph.D.
Cristi Stark
Stacy Ehrlich

Exhibit 3

E-Cigarettes Authorized by the FDA

These are the only e-cigarettes that may be lawfully sold in the United States.

(Last Updated: December 2025)

Manufacturer	Product Name	
Glas Inc.	BLONDE TOBACCO 50 MG/ML Pod	CLASSIC MENTHOL 50 MG/ML Pod
	FRESH MENTHOL 50 MG/ML Pod	Glas G² DEVICE
	GOLD 50 MG/ML Pod	SAPPHIRE 50 MG/ML Pod
JUUL Labs Inc.	JUULpods (Menthol 3.0%)	JUULpods (Menthol 5.0%)
	JUULpods (Virginia Tobacco 3.0%)	JUULpods (Virginia Tobacco 5.0%)
	JUUL Device	
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package	Logic Pro Capsule Tank System (1)
	Logic Vapeleaf Cartridge/Capsule Package	Logic Pro Capsule Tank System (2)
	Logic Vapeleaf Tobacco Vapor System	Logic Power Tobacco e-Liquid Package
	Logic Pro Tobacco e-Liquid Package	Logic Power Rechargeable Kit
NJOY LLC	NJOY DAILY Rich Tobacco 4.5%	NJOY ACE POD Classic Tobacco 2.4%
	NJOY DAILY EXTRA Rich Tobacco 6%	NJOY ACE POD Classic Tobacco 5%
	NJOY DAILY EXTRA Menthol 6%	NJOY ACE POD Rich Tobacco 5%
	NJOY DAILY Menthol 4.5%	NJOY ACE POD Menthol 2.4%
	NJOY ACE Device	NJOY ACE POD Menthol 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)	Vuse Replacement Cartridge Original 4.8% G2
	Vuse Vibe Tank Original 3.0%	Vuse Alto Power Unit
	Vuse Vibe Power Unit (2)	Vuse Alto Pod Golden Tobacco 5%
	Vuse Ciro Power Unit (1)	Vuse Alto Pod Rich Tobacco 5%
	Vuse Ciro Cartridge Original 1.5%	Vuse Alto Pod Golden Tobacco 2.4%
	Vuse Ciro Power Unit (2)	Vuse Alto Pod Rich Tobacco 2.4%
	Vuse Solo Power Unit	Vuse Alto Pod Golden Tobacco 1.8%
	Vuse Replacement Cartridge Original 4.8% G1	Vuse Alto Pod Rich Tobacco 1.8%

For an up-to-date list of authorized e-cigarettes, visit the Searchable Tobacco Products Database.

While these products are authorized to be sold in the United States, it does not mean these products are safe, nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

Exhibit 3

February 27, 2024

Via Overnight Mail and Email

Robert M. Califf, M.D., MACC
Commissioner

Brian King, Ph.D., M.P.H.
Director
Center for Tobacco Products

David Mednick
Deputy Chief Counsel for Program Review for Devices and Tobacco
Office of Chief Counsel

Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Glas G² PMTA (STN PM0004879) – Failure to Meet Statutory Deadline and Unreasonable Delay

Dear Drs. Califf and King and Mr. Mednick:

By this letter, Glas Inc. (Glas or the Company) would like to bring to your attention the Center for Tobacco Products' (CTP's) delay in issuing a decision with respect to Glas's pending premarket tobacco product application (PMTA) for the Glas G² electronic nicotine delivery system (ENDS) device and seven e-liquid cartridges in two nicotine strengths (G² PMTA).[1] As explained below, in addition to the fact that it is contrary to the interests of public health, this delay both fails to meet the statutory deadline and violates the Administrative Procedure Act (APA).

Glas submitted this bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021. FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. The G² PMTA was therefore complete at least seven months ago, and we understand that a decision on the application is not expected to be issued for at least another several months. Thus, although the required statutory deadline for PMTA review is 180 days, it appears that a

[1] FDA Submission Tracking Number (STN) PM0004879.

decision will not be forthcoming for a minimum of 425 days, more than twice the time the statute permits for such decision-making.

The sluggish manner in which the Agency appears to be managing this important "product with merit" application is of grave concern. Significantly, the next-generation G^2 products that are the subject of this PMTA are groundbreaking and directly address the Agency's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health.

I. Introduction

As you are aware, Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." It has now been over 950 days since Glas submitted the G^2 PMTA, 815 days since FDA filed the PMTA, 605 days since the PMTA entered substantive scientific review on June 29, 2022, and 225 days since Glas submitted its response to the deficiency letter, and Glas has not received any substantive correspondence from the Office of Science.[2]

For a small tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, this delay is existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the G^2 products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

This situation is especially frustrating in light of the fact that Glas has been advised on multiple occasions that the G^2 products are considered "products with merit" that were placed in an expedited queue for prioritized review of ENDS products that incorporate age-verification technology. Bringing this disruptive and standard-setting technology to the U.S. market as soon as possible would maximize the benefits to public health by providing adult smokers who will not or cannot cease using nicotine a compelling reduced-risk alternative that completely mitigates any youth-access or -use concerns associated with the ENDS category. As Dr. Califf has observed:

[2] We also note that FDA completed a PMTA manufacturing inspection of the Glas facility on September 27, 2022, and the Company filed a tobacco product master file update containing all corrective actions from this inspection on December 6. 2022.

[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

> This work is particularly critical as we focus on preventing initiation, while also helping people quit, especially the deadliest form of tobacco use, combustible tobacco products. Despite meaningful declines in cigarette use over the past several decades, nearly 500,000 Americans still die every year from cigarette smoking. Additionally, with more than 3 million youth reporting current use of a tobacco product in 2022, and e-cigarettes being the most used product, we risk another generation becoming addicted to these products.[4]

The Glas G^2 products, which include embedded age-gating and counterfeit detection technology, have the potential to re-shape the way ENDS products are sold and used to successfully move adult smokers down the continuum of risk while eliminating youth access and use. Glas believes that its G^2 products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

Specifically, in addition to age-verification at point of sale (whether at retail or online), the G^2 products utilize a verified and validated embedded technology and software to overcome past industry failures in at least seven ways: (1) a demanding age- and identity-verification process required to initially activate the device before first use after purchase (i.e., underage individuals cannot even turn the product on); (2) required ongoing authentication of the user to continue to use the device, including automatic device locking when the device is out of range of the authenticated smartphone; (3) counterfeit cartridge detection and use prevention; (4) cartridge identification to prevent re-use with unauthorized liquids; (5) continuous secure monitoring of use patterns and behaviors that provides the ability to understand product use in real time; (6) the ability to roll out live updates or modifications of various use parameters (e.g., an individual product can be remotely deactivated if there is reason to believe that it is defective or being used improperly); and (7) the ability for users to monitor their own product use and potentially self-select limits on such use.

The Company believes that the G^2 products provide the most tailored solution for adult smokers to access flavored ENDS products that will help them fully transition away from smoking while preventing any youth access or use. Indeed, FDA has stated the following:

> Experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, *for flavored ENDS, only the most stringent*

[4] Statement from FDA Commissioner Califf, FDA Provides Update on External Evaluation to Strengthen Agency's Tobacco Program (December 19, 2022), accessed at https://www.fda.gov/news-events/press-announcements/fda-provides-update-external-evaluation-strengthen-agencys-tobacco-program.

> *mitigation measures – specifically device access restrictions – have such mitigation potential*.[5]

The G^2 device's access restrictions allow for the effective control and monitoring of both the youth "on ramp" and the adult "off ramp" through age-verified activation and authentication and real-time market surveillance and use-data capture.

Importantly, authorizing the flavored G^2 products (Classic Menthol, Fresh Menthol, Gold, and Sapphire) as soon as possible will give FDA the strongest response to arguments made in court and administrative appeals of marketing denial orders (MDOs) that FDA's so-called "fatal flaw" memo[6] (which FDA has now applied to menthol-flavored ENDS products as well[7]) established a de facto product standard prohibiting flavored ENDS products without observing the required notice-and-comment rulemaking process.[8]

Because, as demonstrated in the Glas PMTA, the G^2 products do not present any risk of youth appeal, access, or use whatsoever, FDA can authorize the flavored G^2 products without a need to demonstrate a benefit over the tobacco-flavored variants. In any event, however, as described below, the Glas studies demonstrate that the flavored

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[5] See, e.g., Technical Project Lead (TPL) Review of Logic Technology Development LLC PMTAs (PM0000529-31, PM0000535-37, PM0000540-41) at 5 (August 19, 2019) (emphasis added).

[6] FDA memorandum, "ENDS Containing Non-Tobacco Flavored E-Liquid: Approach to PMTAs not in Substantive Scientific Review (Phase III)" (July 9, 2021) (announcing a policy of requiring evidence from a randomized controlled trial or longitudinal cohort study demonstrating that a non-tobacco flavored product provides an incremental benefit to adult smokers relative to a tobacco-flavored product based on "the known and substantial risk of flavored ENDS with respect to youth appeal, uptake, and use").

[7] We note that, in light of FDA's intention to implement a product standard prohibiting menthol as a characterizing flavor in cigarettes, it is essential that FDA authorize lower-risk alternative menthol options, such as the G^2 menthol products, to which adults smokers can switch following the effective date of any such product standard.

[8] *See, e.g.*, *Breeze Smoke, LLC v. FDA*, No. 21-3902 (6th Cir.), Corrected Opening Brief of Petitioner (Nov. 16, 2021) at 45 ("The new evidentiary requirement that FDA applied to all flavored ENDS pursuant to its Fatal Flaw Review process is a new 'tobacco product standard' in every relevant sense … Under the TCA, FDA was required to provide notice of its proposed standard for flavored ENDS and to give affected manufacturers an opportunity to comment."); Reply Brief in Support of Emergency Application for Stay to the Supreme Court of the United States by Breeze Smoke, LLC (December 7, 2021) at 8 ("…[T]o the extent FDA has now concluded, after its final PMTA guidance, that flavored e-cigarettes should be categorically banned or subject to more demanding evidentiary standards than tobacco-flavored products, the agency has the tools to impose such restrictions in a manner that provides fair notice and respects reliance—it can issue new tobacco product standards for all flavored e-cigarette products, after undergoing notice and comment. See 21 U.S.C. §§ 387g(c), (d)(1); id. § 387g(a)(1)(A) (prohibiting flavored cigarettes as a 'tobacco product standard'). What the agency cannot do is take a shortcut by providing certain review standards in industry guidelines, but then imposing a different, behind-the-scenes standard that leads it to reject all of the millions of product applications that companies filed."); R.J. Reynolds Vapor Company Petition for Stay of Action (Jan. 27, 2023) at 4 ("FDA's orders are unlawful because FDA adopted a policy that no non-tobacco-flavored ENDS will be authorized. In so doing, FDA has created a 'tobacco product standard' in violation of the Tobacco Control Act.").

G^2 products (i.e., Sapphire, Gold) have an added benefit relative to that of tobacco-flavored products in facilitating smokers' significantly reducing their cigarette use.

II. Data Supporting the G^2 PMTA

The Glas studies demonstrate the effectiveness of the advanced age-gating technology embedded in the G^2 products in eliminating youth access. The results from a study of both underage and legal age users throughout the United States show strong effectiveness of the G^2 products in preventing youth access. No underage individuals were able to activate the device. Data from a perception and intention study additionally demonstrate that youth are not interested in trying or using the G^2 products. Thus, the G^2 products present no risk of youth appeal, uptake, or use. Moreover, the Company's actual use study's results demonstrate that use of the G^2 products, particularly the flavored G^2 products (i.e., Sapphire, Gold), causes a significant reduction in combustible cigarette consumption in dual users and cigarette smokers.

A. G^2 Age-Gating Technology

The user age-verification feature authenticates that the user is at least 21 years of age before the device can be activated for use. The user is required to scan his or her state-issued driver's license or ID document. The ID information is extracted and compared to public ID records to verify that the information is correct. The user is also required to capture a short selfie video to further verify his or her authenticity. The system compares the short selfie video against the image on the ID document to verify that they belong to the same person. The system uses the ID information along with the user's selfie video to verify that the user is above the legal vaping age.[9] User cases that do not pass the verification protocol are forwarded to customer service for manual review and, if appropriate, approval. During an onboarding period, the user is periodically asked to record another selfie video. The new video is compared against the original user's video to ensure that the authenticated smartphone is still in the eligible user's possession and has not been given to another user (including to a minor). This prevents, among other things, a minor from using an adult's smartphone to activate the device.

The G^2 device is automatically locked if the smartphone is disconnected from the G^2 device for more than 60 minutes to ensure that the G^2 device remains in the possession of the original authenticated user. This prevents a minor from surreptitiously using an adult's smartphone to activate the device. This feature also enables the authenticated user to lock the G^2 device through the mobile application while the G^2 device is not in use, further preventing potential unauthorized use by minors. All of these features also prevent unauthorized use of the G^2 product if it is lost or stolen.

[9] To add an additional margin of safety, the system is designed to scrutinize individuals physically appearing under the age of 25.

The Company conducted two age-verification, user-based studies and a third-party G^2 product ecosystem security assessment, which involved, among other things, penetration testing.[10] The first age-gating testing study (Functionality Testing of the Age-Gating Smartphone Application) evaluated the theoretical functionality of the software by using test scenarios on a tablet device with the age-verification software installed. The study identified no scenarios where underage study participants could inadvertently age verify, and no underage individuals were able to age verify. The second study (Qualitative Functionality Testing of the Age-gating Smartphone Application) used actual underage individuals as well as adults, smartphones with the Glas application installed, and the G^2 products. This was a full test of all aspects of the age-gating application, the Glas website, and the G^2 products. The study required participants to go to the actual Glas website and register the G^2 device. **No underage individuals were able to activate the G^2 device. Age, gender, and ethnicity had no effect on the accuracy of the age verification application.** The adult participants who were able to age verify and unlock the device were asked to puff on a series of non-nicotine-containing Glas pods. Various valid and invalid pods were tested. **The system accurately detected invalid pods (counterfeit or re-used) and prevented their use.**

Glas engaged a nationally recognized cybersecurity firm to conduct third-party penetration testing and an internet of things (IoT) product ecosystem security assessment of the G^2 products. The firm designed the tests to provide Glas with an independent, point-in-time assessment of the security posture of the G^2 products from the perspective of a malicious actor. The firm's testing and vulnerability threat rankings were aligned to industry-proven NIST 800-30 threat rankings methodology, and Glas ranked low in threat likelihood, impact, and level of risk across all findings. Specific select results from the months-long testing included that the firm was unable to bypass the age verification process (age verification testing) and unable to bypass the counterfeit protections in place (counterfeit protection testing).

B. Adult Product Use

The Company conducted two user-based studies informed by its March 22, 2021, meeting with FDA and subsequent correspondence. The first, an actual use study (Quantitative Study to Assess the Actual Use of the Glas G^2 Pod-Based Vaping System Among US Adults Tobacco/Nicotine Product Users or AUS), was designed to assess the effect the G^2 products may have on tobacco/nicotine use behavior among current tobacco/nicotine consumers. In particular, the purpose of the study was to investigate how adult exclusive conventional cigarette smokers, dual users, and ENDS users actually use the G^2 products over an "actual use" period in a real-life/naturalistic environment. Participants self-reported via an eDiary on a daily basis ad libitum use of

[10] Penetration testing is a simulated cyber-attack against the device operation system and cloud architecture to check for exploitable vulnerabilities.

the G^2 products[11] as well as any other tobacco/nicotine products typically consumed. All participants initially documented their baseline product use during a one-week period. Exclusive cigarette smokers and dual users were then provided the G^2 products for two 14-day use periods.[12] Subjects had the opportunity to try the products and pick their desired flavor and nicotine strength (30 mg/ml or 50 mg/ml).

In the initial G^2 product use period, the subjects were provided either a tobacco or menthol product based on their normal tobacco product flavor preference. In the second G^2 product use period, the subjects were allowed to taste and choose among the seven flavors and two nicotine strengths. Over 50% of dual users and exclusive smokers choose the products that were not tobacco or menthol flavors (i.e., Gold and Sapphire). A total of 67% of the ENDS users switched to the same flavors. During the baseline period, smokers recorded using 10.7 cigarettes per day and dual users 8.5 cigarettes per day; ENDS users recorded using 3.6 pods per week and dual users 4 pods per week.

In this study, use of the G^2 products by smokers and dual users caused a noticeable reduction in other tobacco/nicotine use, including combustible cigarettes. By the end of the two 14-day use periods, the smokers reduced their overall cigarette consumption 40% from 10.7 to 6.5 cigarettes per day. Dual users reduced their cigarette consumption 28% from 7.0 to 5.0 cigarettes per day. These are remarkable reductions in such a short period of time. Importantly, the smokers were not forced to switch to the G^2 products; the reduction was of their own free will.

Furthermore, flavor had an impact on cigarette consumption. Overwhelmingly, the subjects preferred the Gold or Sapphire flavors during the final 14-day use period when they could choose their preferred flavor. Smokers who used Gold flavored pods during the second use period reduced their cigarette consumption from a baseline of 12.3 cigarettes per day to 3.3, **a 73% reduction**. Among those who used Sapphire flavored pods, cigarette consumption was reduced to 7.0 from a baseline of 9.0 cigarettes per day. By the end of the final use period, the likelihood of future use of the G^2 products was higher among dual users and exclusive cigarette smokers compared to primary ENDS users. The demographic and smoking/vaping profiles of those most likely to use G^2 products in the future did not exhibit any notable skews compared to the complete study population.

C. Effects on the Population as a Whole

The G^2 PMTA also contains two population models. In the first, the Company evaluated the impact of introducing an ENDS product on population health. As expected, there was a population benefit. The Company performed an additional study (Technology Population Health Overview) using the same approach and assumptions as the original

[11] The device also recorded each puff, its duration, and time of day, and location.

[12] The smokers and dual users were provided the products but not required to switch or use them.

population model (e.g., estimating the population health impact of introducing ENDS in general, and the G^2 products in particular, into the U.S. population) comparing the population health impacts of introducing traditional ENDS products and a novel type of ENDS product that prohibited youth use into the U.S. population. **The study results suggest that introduction of the G^2 age-gating technology could reduce cigarette smoking-related deaths by an additional 19% and reduce the life years lost by an additional 23%.** The age-gating technology has the potential to amplify the positive public health benefits of ENDS by eliminating youth initiation and usage.

III. Failure to Meet Statutory Deadline and Unreasonable Delay

As noted above, Section 910(c)(1) of the FFDCA requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application." In the preamble to the final PMTA rule, FDA clarified that the 180-day review clock begins "on the date the last piece of information necessary to complete the submission is received by CTP's Document Control Center or the FDA laboratory (for product samples)" and that "[w]hile FDA will restart the 180-day review period after the receipt of a major amendment, the Agency intends to promptly act on an amended application, which might take fewer than 180 days."[13]

Glas submitted a complete response to CTP's deficiency letter on July 12, 2023, which we understand FDA considers to be a major amendment. However, contrary to its commitment in the preamble, CTP has not acted "promptly" on Glas's amended application. Rather, despite the fact that Glas filed the amendment over 225 days ago, we understand that CTP does not expect to issue an order for at least another several months, which would bring the total to over 425 days.

Surprisingly, Glas understands that although the Glas PMTA is in a separate prioritized review queue for "products with merit" (e.g., those with embedded age-verification technology), and all of the primary scientific disciplines have completed their review of the G^2 application, CTP is nonetheless prioritizing the applications filed by September 2020 (for products that are currently on the market) for its clearance review and is now estimating that it may not issue a decision on the G^2 PMTA until late 2024. In the meantime, because Glas cannot sell the G^2 products until CTP authorizes them, the Company is facing serious economic consequences each day it waits for CTP to complete its review. Most importantly, the lackadaisical manner with which the Agency is managing this "product with merit" application is not in the best interests of public health, particularly adult smokers who continue to die at a rate of over 450,000 per year.

In addition to failing to meet the applicable statutory deadline, FDA has violated the Administrative Procedure Act (APA) by unlawfully withholding and unreasonably delaying Agency action. This failure to act on the G^2 PMTA within a reasonable time, particularly when also failing to meet a statutorily-imposed deadline, warrants judicial

[13] Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed.Reg. 55300, 55374, 55382 (October 5, 2021).

intervention to compel the Agency to complete its review. *See, e.g.*, *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1191 (10th Cir. 1999) ("When an entity governed by the APA fails to comply with a statutorily imposed absolute deadline, it has unlawfully withheld agency action and courts, upon proper application, must compel the agency to act."); *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166, 1178 (9th Cir. 2002) ("The Service's failure to complete the listing determinations within the mandated time frame compelled the [district] court to grant injunctive relief. . . . The exercise of discretion is foreclosed when statutorily imposed deadlines are not met.").

Ultimately, in addition to failing to comply with the FFDCA's mandates and violating the APA, CTP is negatively skewing incentives by permitting the continued marketing of illegal products while delaying authorization for companies that have invested millions of dollars to follow the rules and develop products that directly address important public health concerns, but are unable to launch their products because the Agency has not completed its review of applications that have been pending for years.

IV. Conclusion

By this letter and based on the above, we request timely authorization of the Glas G^2 products. Thank you for your consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas, Inc.

cc: Matthew Farrelly, Ph.D.
William Loy
Eshael Johnson
Stacy Ehrlich

Exhibit 3

April 3, 2025

Via Overnight Mail and Email

Martin A. Makary, M.D., MPH
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Welcome & Glas Introduction

Dear Dr. Makary:

Congratulations on your recent appointment and U.S. Senate confirmation as Commissioner of the U.S. Food and Drug Administration (FDA). The team at Glas Inc. (Glas or the Company) has worked closely with the Center for Tobacco Products (CTP) over the past several years with respect to the Company's pending premarket tobacco product applications (PMTAs) for the Glas next-generation device and pods (Glas G^2 ENDS), accepted by FDA on August 3, 2021, and filed by FDA on December 1, 2021.

I look forward to meeting with you in the near future and working with you closely as we continue our tireless efforts to bring the Glas G^2 "product with merit"[1] to market as we believe this technology will re-shape the way electronic nicotine delivery system (ENDS) products are sold and used, successfully eliminating youth access and use while moving adult smokers down the continuum of harm. Glas believes that its products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

The Glas G^2 ENDS products that are the subject of Glas's PMTAs are embedded with robust, continuous age-verification technology and are groundbreaking and directly address FDA's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product uptake and use by minors; (2) prevent

[1] "Product with merit" is an internal CTP designation that provides for prioritized consideration and review of certain PMTAs, based on certain product attributes that FDA views as more likely to support the statutory standard of "appropriate for the protection of public health" (APPH). FDA has indicated that specific examples of such attributes include technology that provides for age-verification and -gating of users of the ENDS device and anti-counterfeiting and anti-cloning of pods. These applications are in a separate queue from all other PMTAs. We understand that the Glas PMTA is first in that separate expedited queue. Significantly, FDA has stated in multiple PMTA orders that "[e]xperience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential."

cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health. I have attached our current executive summary for your convenience and reference.

Glas submitted a bundled PMTA on July 21, 2021, and FDA filed it on December 1, 2021 (over 1,200 days ago). FDA issued a deficiency letter on April 13, 2023, and Glas filed a fulsome timely response to the deficiency letter on July 12, 2023. After 386 days, over twice the time period the Federal Food, Drug, and Cosmetic Act (FFDCA) permits for FDA's review of PMTAs,[2] the Agency issued a second deficiency letter on August 1, 2024. Although some of the information requested in the second deficiency letter appears to be related to issues raised in the previous deficiency letter, a number of the requests appear to "move the goalposts" from where FDA had previously set them, both for Glas and for other similarly situated applicants. Despite this fact we submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and were granted an extension by FDA to produce additional scientific study results on or before April 30, 2025. I understand the CTP Office of Science has substantially completed scientific review of the Glas PMTA and the application has reached the so-called "clearance review" level at the Agency, which I believe involves oversight by the CTP Director, FDA's Office of Chief Counsel and others, notably political appointees.

For a small tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, FDA's repeated review delays have been existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the Glas G^2 products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

I founded Glas from a deeply personal foundation - my own struggles as a teen smoker. I formed Glas and have designed innovative, tech-enabled products to help other smokers quit, pure and simple. Over the last four years, Glas has sought to effectively collaborate with FDA in bringing this disruptive and standard-setting technology to the U.S. market as soon as possible to maximize the benefits to public health. Again, I look forward to you and your colleagues at FDA working closely with us to achieve the Glas mission to eliminate product access and use by minors, prevent cartridge counterfeiting, and help adult smokers successfully move away from combustible cigarettes.

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[2] Section 910(c)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that FDA issue an order stating whether a product that is the subject of a PMTA may be introduced into interstate commerce "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application."

[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."

Exhibit 3

Thank you in advance for your time and consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas Inc.

cc: Benjamin Apelberg, Ph.D.
Cristi Stark
William Loy
Eshael Johnson
Fatima Sow
Stacy Ehrlich

Exhibit 3

glas

Executive Summary

Authorization of Glas' premarket tobacco product application ("PMTA") will protect American youth, further MAHA goals, and help U.S. businesses in the fight against illicit Chinese products.

Why vaping? A way to move adult smokers down the continuum of harm away from combustible cigarettes.[1] Smoking kills more than 480,000 Americans each year, causing 30% of all U.S. cancer deaths and 80% of lung cancer deaths. Vaping provides smokers with an offramp that promotes successfully switching away from smoking -- especially with flavored products. The CDC acknowledges that "more frequent use of e-cigarettes is associated with greater smoking cessation." In 2024, a comprehensive review of 88 vaping studies published in the Cochrane Library concluded that vaping with or without nicotine increases smoking cessation.

The vaping opportunity. An essential growth vector for global tobacco & nicotine.[2] Cigarette consumption is declining at about 3-4% per annum. Smoking prevalence is falling in almost every market worldwide due to the increased awareness of the long-term health implications of smoking. New categories of reduced risk products are helping smokers transition away from combustibles while creating new revenue opportunities. The total non-combustible market is estimated at $68 billion as of 2023, with vaping expected to grow 4x from ~$20 billion to $74 billion by 2035.

The youth vaping crisis and Trump's response. [3] While the availability of flavored products is a key demand driver for e-cigarettes, flavors also present undeniable underage usage concerns. In early 2020 during the first Trump administration, the FDA reasonably banned the sale of flavored cartridge-based e-cigarettes other than tobacco and menthol due to the appeal of fruit and mint flavors amongst underage users. The FDA has since been adamant that flavored PMTAs will be rejected without sufficient underage risk prevention, while welcoming age-gating technology to unlock access.

The Glas technology solution. Following the ban, Glas recognized the need for technology-based controls to better manage access to vapor offerings. The company developed age-verification/gating and anticounterfeiting technology that provides a reduced-risk alternative for adult smokers, while eliminating youth access. Glas devices connect to a smartphone app that requires ID age-verification and restricts use to within close proximity of the user's phone for a limited duration, while also safeguarding against use of unregulated counterfeit products through micro-chip authentication of Glas pods.

Critical, patented, and FDA-validated features of Glas' technology that unlock approval of flavored ENDS products.

Glas devices connect to a smartphone app that requires ID age-verification and restricts use to within close proximity of the registered user's phone for a limited duration, thereby preventing underage access. Micro-chip authentication of Glas pods further safeguards against unregulated counterfeit products.

1 **Device Control**
Age-verification/gating

- Proprietary firmware and software enabling continuous communication and control from Glas mobile app.
- Smartphone registration and authentication, user age-verification, access security and control, and counterfeit pod detection.

2 **Pod Security**
Anticounterfeiting

- Pod ID, authentication, tracking and history.
- EPROM (erasable programmable read-only memory) embedded in each pod with unique IDs cryptographically signed during the Glas e-liquid filling process in the U.S..

The new problem: no FDA-approved alternatives and the rise of China's illegal imports. [4] Under the Biden administration, the FDA failed to crack down on the sale of unauthorized flavored products targeted at teens. New unauthorized disposable vapes from China have flooded the market and are estimated to represent over half of the e-cigarette market today. The FDA's response has simultaneously penalized businesses in compliance with regulations by failing to offer legal alternatives.[5] As of March 2024, 27 million PMTAs had been submitted since 2021, and the FDA had refused to accept 20 million (74%) applications outright.

The path forward is here today. The FDA must authorize an age-gating verification system. Glas' novel age-verification/gating and anti-counterfeiting technology is awaiting authorization, has already been vetted by the FDA, and is a win-win solution to improve America's health and economy. However, Glas' PMTA submission is now 1,200 days outstanding with no transparency from the FDA – despite receiving a "product with merit" designation. Meanwhile, the FDA's inaction is enabling an illicit, dangerous market. A prompt authorization of Glas would help solve the youth vaping crisis, crack down on illicit Chinese imports, and give millions of adult smokers the legitimate, effective alternative they need.

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[1] Nicotine & Tobacco Research, MUSC via ScienceDirect, Royal College of Physicians, NHS, CDC, Cochrane. cancer.org.
[2] Source: BAT & Deutsche Bank Research.
[3] Nicotine & Tobacco Research, FDA. Dr. Brian King (FDA Director, Center for Tobacco Products, keynote address at Global Tobacco and Nicotine Forum 2024 in Athens Sep-2024).
[4] University of Rochester Medical Center, Tobacco Control, CDC, FDA Premarket Tobacco Product Marketing Granted Orders, Associated Press, FDA PMTA, FDA Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products, CSP and Nielsen via Statista, CDC Foundation.
[5] Sources: FDA-Vuse, FDA-blu. In October 2023, the FDA denied marking of six flavored Vuse Alto e-cigarette products, stating that the application rationale was not "sufficient to outweigh the known risks to youth." In February 2024, the FDA issued denial orders for five of Imperial's blu e-cigarette products on the same rationale – noting specifically that "among youth who currently used e-cigarettes, 6% reported using blu brand e-cigarettes."

Exhibit 3

May 27, 2025

Via Overnight Mail and Email

Bret Koplow Ph.D., J.D.
Acting Director
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Re: Welcome & Glas Introduction

Dear Dr. Koplow:

Congratulations on your recent appointment as Acting Director of the Center for Tobacco Products (CTP). The team at Glas Inc. (Glas or the Company) has worked closely with CTP over the past several years with respect to the Company's pending premarket tobacco product applications (PMTAs) for the Glas next-generation device and pods (Glas G^2 ENDS), submitted to FDA on July 21, 2021, filed by FDA on December 1, 2021, and which moved into the Phase 3 substantive scientific review process on June 29, 2022.

We look forward to meeting with you in the near future and working with you as we continue our tireless efforts to bring the Glas G^2 "product with merit"[1] to market as we believe this effective age-gating technology will re-shape the way electronic nicotine delivery system (ENDS) products are sold and used, successfully eliminating youth access and use while moving adult smokers down the continuum of harm. Glas believes

[1] "Product with merit" is an internal CTP designation that provides for prioritized consideration and review of certain PMTAs, based on certain product attributes that FDA views as more likely to support the statutory standard of "appropriate for the protection of public health" (APPH). See FDA Office of Science Memorandum, "Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2022" (January 21, 2021) (On page 2, Glas is the redacted (b)(4) which was also bumped to #1 in the queue in the Appendix on page 3).

FDA has indicated that specific examples of such attributes include technology that provides for age-verification and -gating of users of the ENDS device and anti-counterfeiting and anti-cloning of pods. These applications are in a separate queue from all other PMTAs. We understand that the Glas PMTA is first in that separate expedited queue. Significantly, FDA has stated in multiple PMTA orders that "[e]xperience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures – specifically device access restrictions – have such mitigation potential."

that its products will also be a catalyst to drive other industry players to focus on the same objectives in the best interest of public health.

Frankly, I was very encouraged by the recent testimony of U.S. Health and Human Services Secretary Robert F. Kennedy Jr. before the Senate HELP Committee on May 14, 2025, as he referenced how FDA can do better in addressing its application backlog and U.S. vape market: "absolutely, and we are looking at it right now… During the Biden Administration the FDA slow-walked the approvals for U.S. vaping companies and the U.S. vaping companies in my view they were acting very responsible. They were putting chips in their vapes that would make sure that young people could not use them… they really went out of their way not to make it attractive to children."

The Glas G^2 ENDS products that are the subject of Glas's PMTAs are embedded with robust, continuous age-verification technology and are groundbreaking and directly address FDA's (and other stakeholders') concerns regarding the current ENDS marketplace in that they (1) prevent product uptake and use by minors; (2) prevent cartridge counterfeiting; (3) enable effective market surveillance; and (4) even allow for remote product de-activation in the case of a recall or other potential safety issue. Thus, allowing Glas to introduce the G^2 products to the U.S. market would be an important contribution to public health. I have attached our current executive summary for your convenience and reference.

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Despite this fact, Glas submitted initial materials responding to the second deficiency letter on October 30, 2024, again within the 90 days required, and were granted an extension by FDA to produce additional scientific study results on or before April 30, 2025, which we met and submitted a complete response by that date. I understand the CTP Office of Science had, prior to the issuance of the second deficiency letter, substantially completed scientific review of the Glas PMTA and the application reached the so-called "clearance review" level at the Agency, which I believe involves oversight by the CTP Director, FDA's Office of Chief Counsel and others, notably political appointees.

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Exhibit 3

For a small U.S.-based tobacco product manufacturer[3] investing significant resources in complying with the law and developing cutting-edge technology to address significant public health concerns, FDA's repeated review delays have been existential, particularly because – unlike the applications filed by September 9, 2020, where the subject products have been on the market since August 2016 and continue to generate revenue and cash for their applicants – the Glas G[2] products may not be introduced to the U.S. market until FDA issues a marketing granted order (MGO) for the products.

I founded Glas from a deeply personal foundation - my own struggles as a teen smoker. I formed Glas and have designed innovative, tech-enabled products to help other smokers switch, pure and simple. Over the last four years, Glas has sought to effectively collaborate with FDA in bringing this disruptive and standard-setting technology to the U.S. market as soon as possible to maximize the benefits to public health. Again, I look forward to you and your colleagues at FDA working closely with us to achieve the Glas mission to eliminate product access and use by minors, prevent cartridge counterfeiting, and help adult smokers successfully move away from combustible cigarettes. By this letter, I request a meeting to introduce our company and technology.

Thank you in advance for your time and consideration.

Sincerely,

Sean Greenbaum

Sean Greenbaum
Founder & Chief Executive Officer
Glas Inc.

cc: Todd L. Cecil, Ph.D.
Benjamin Apelberg, Ph.D.
Cristi Stark
William Loy
Eshael Johnson
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[3] Section 900(16) of the FFDCA defines a small tobacco product manufacturer as "a tobacco product manufacturer that employs fewer than 350 employees."