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Director’s Summary of Glas G2 Electronic Cigarette Products¹

Executive Summary

Section 910(c)(2)(A) of the Food, Drug and Cosmetics Act requires the Food and Drug Administration (FDA) to determine that marketing a new tobacco product would be **Appropriate for the Protection of the Public Health (APPH)** before granting a marketing authorization for new tobacco products. In assessing whether permitting the marketing of the new products would be APPH, FDA must consider the risks and benefits to the population as a whole, including both users and non-users, taking into account:

- The increased or decreased likelihood that existing tobacco product users will stop using such products and
- The increased or decreased likelihood that non-users will start using tobacco products

FDA has completed a comprehensive review of six new electronic cigarette products from Glas Inc—five e-liquid pods and one rechargeable device. The five e-liquid pods include tobacco, blueberry, mango, and two menthol flavors. The Glas G2 system consists of a rechargeable power unit, which works exclusively with pre-filled e-liquid pods containing 50 mg/mL of nicotine. The rechargeable device has a built-in device access restriction technology that requires, in part, users to verify that they are 21 or older through a smartphone app before the device can be activated.

After scientific evaluation of these applications, FDA found the products to be APPH, subject to specific marketing restrictions and ongoing monitoring requirements.

Central to these decisions was the FDA’s conclusion that the device access restrictions sufficiently mitigate the risk to youth such that the four applications for blueberry, mango and two menthol flavored e-liquid products did not need to demonstrate an added adult benefit relative to tobacco-flavored ENDS.

Furthermore, the applications for the five e-liquid pods demonstrated sufficient potential benefit to adults who smoke combusted cigarettes and completely switch to the new products, or significantly reduce their smoking of combusted cigarettes to outweigh the risks of the products. A more detailed and comprehensive summary of the various findings, considerations and conclusions follow below.

Product Description

The Glas G2 Pod-Based Vaping System includes:

¹ This summary was prepared by the Director of the Office of Science in the Center for Tobacco Products, Dr. Matthew Farrelly.

Device (internal application number: PM0004879.PD8)

- Rechargeable battery-powered unit
- Two preset power settings (ECO and Standard)
- Built-in device access restriction technology that uses smartphone activation requiring age- and identity verification
- Anti-counterfeiting features to prevent use of unauthorized pods (e.g., pod refilling, use of invalid pods)

Five E-liquid Pods:

- Flavored Products: Gold (mango flavor, PM0004879.PD1), Sapphire (blueberry flavor, PM0004879.PD2), Fresh Menthol (PM0004879.PD3), and Classic Menthol (PM0004879.PD4)
- Tobacco-Flavored Product: Blonde Tobacco (PM0004879.PD6)
- All pods contain 1.2 mL of e-liquid with 5% (50 mg/mL) nicotine concentration

Each pod is sealed and designed for single use, preventing users from refilling or tampering with the contents. The products are packaged in child-resistant blister packs.

Device Access Restriction Technology:

A novel feature of these products is the device access restriction system where consumers must:

- Download a smartphone app
- Verify their identity and age (21+) using government-issued ID
- Complete the verification process before the device will function
- Revalidate their identity periodically to continue using the device
- Keep the Glas G2 device within wireless communication range (approximately 10 meters) of the verified smartphone

In addition, the Glas G2 device automatically locks if the verified smartphone is disconnected for a certain period of time described as a proximity grace period (1 hour).

Anti-Counterfeiting Measures:

- Each pod has unique encryption to prevent use of counterfeit products
- The device only works with authentic Glas pods
- The device limits manipulation of device power settings

Scientific Review Findings

To show that the marketing of an ENDS is APPH, an applicant must show that the benefits, including those to adults who use combusted cigarettes, outweigh the risks, including those to youth, resulting in a net benefit to the public health. As the known risks of the product increase or decrease, the burden of

demonstrating a substantial enough benefit likewise increases or decreases. Below we provide summaries of the various considerations in FDA’s review of these applications.

Benefits for Adult Smokers

For flavored ENDS, there is a known and substantial risk of youth initiation and use, whereas for tobacco-flavored ENDS the risk of youth initiation and use is lower. For flavored new products, including menthol products, the marketing of the new flavored products can be APPH only if the applications present (1) reliable and robust evidence that the flavored ENDS have an added benefit relative to a tobacco-flavored ENDS in facilitating the ability of adults who use combusted cigarettes to completely switch or significantly reduce their combusted cigarette use or (2) stringent mitigation measures that mitigate the risk to youth. For the former, to effectively demonstrate this benefit in terms of product use behavior, applications for flavored ENDS generally need to provide product-specific evidence from a randomized controlled trial (RCT) or longitudinal cohort study (LCS), although FDA evaluates other types of evidence on a case-by-case basis to determine whether it is sufficiently reliable and robust to make the necessary showing.

FDA found that while the Glas applications included a product-specific randomized actual use study evaluating complete switching and significant cigarette reduction associated with the blueberry, mango, and two menthol flavored products compared to tobacco-flavored ENDS, the data did not demonstrate statistically significant differences in the rates of complete switching among adult smokers or significant cigarette reduction between the flavored new products compared to tobacco-flavored ENDS. However, CTP concluded that the applicant’s device access restrictions in the device are expected to sufficiently mitigate the risk to youth such that the applications for the four flavored e-liquid products did not need to demonstrate added adult benefit relative to tobacco-flavored ENDS to demonstrate that these non-tobacco flavored e-liquid products are APPH.

Although the applicant did not demonstrate greater switching for the fruit- and menthol-flavored products relative to the tobacco flavors, the overall rate of switching and reduction in cigarettes per day are relative to the APPH determination. The applicant conducted a three-month randomized actual use study among adults 22-64 years old who exclusively smoked more than 10 cigarettes per day and were “open to trying” ENDS but not currently attempting to quit or planning a quit attempt in the next three months. By the end of the study, the applicant demonstrated significant rates of complete switching and reductions in cigarettes per day. By the end of the study:

- **Complete switching:** the past-30 day switching rates across all five flavors (tobacco, mango, blueberry and two menthol flavors) ranged from **12 to 18%**, compared to the rates of smoking cessation from published studies that show that less than 6% of smokers quit after 6 to 12 months with no support or minimal assistance.
- **Reductions in cigarettes per day:** Nearly half of users of the five e-liquid pod products reduced their cigarette consumption by 50-99%.

Abuse Liability Assessment

The findings of FDA's abuse liability (refers to the ability of the product to promote continued use and the development of addiction and dependence) assessment concludes that all five e-liquid pods have lower or similar abuse liability compared to combusted cigarette use in adults who currently smoke combusted cigarettes and experienced ENDS users. This provides additional evidence that the five e-liquid pods could effectively substitute for combusted cigarettes by maintaining nicotine exposures while facilitating complete switching for adults seeking to quit combusted cigarette use. The products pose addiction risk for adult non-tobacco users, but not exceeding that of currently available tobacco products, such as combusted cigarettes.

Youth risks

Data from the 2024 National Youth Tobacco Study demonstrates 88% of youth ENDS users in the past 30 days used a flavored product. The most common flavors among youth are fruit (63%), candy/desserts/sweets (33%), mint (25%), menthol (15%). Experience shows that advertising, promotion, 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 that permitting the marketing of flavored ENDS would be APPH. Rather, for flavored ENDS, only the most stringent mitigation measures, such as device access restrictions, have such mitigation potential.

The age-verification technology in the Glas device addresses FDA's primary concern about flavored e-cigarette products attracting youth users. Traditional marketing restrictions alone have proven insufficient to mitigate the risk to youth for flavored ENDS sufficiently to warrant review of an application that does not include robust and reliable evidence of adult benefit, but the mandatory age-verification system provides a more robust barrier. The applicant submitted studies that FDA reviewed showed that this system was 100% effective at preventing people under 21 (N=43) from activating the device, while 83-96% of adults over 21 (N=120) could successfully complete the verification process. As noted above, FDA concluded that the device access restrictions in the Glas device are expected to be sufficiently effective in preventing youth use such that the applicant does not need to provide reliable and robust evidence that the flavored ENDS have an added benefit relative to a tobacco-flavored ENDS in facilitating the ability of adults who use combusted cigarettes to completely switch or significantly reduce their combusted cigarette use.

However, given the limited sample size of underage youth in the age gating study and the controlled conditions of the study, there may be some residual risk to youth stemming from uncertainty around how the device access restrictions will perform in real-world settings. To address the potential of residual youth risk, FDA required restrictions on advertising, promotion, and sales access to further limit youth exposure to the new products (described below). FDA will rely on complementary surveillance methods to monitor potential instances of youth access to the flavored products.

Toxicological Assessment

ENDS users are potentially exposed to toxic constituents from three distinct sources:

- Thermal degradation or reaction products of e-liquid constituents that transfer to aerosol

- E-liquid ingredients that transfer directly to the aerosol
- Leachables that migrate from ENDS container closure systems and components into the e-liquid and transfer to the aerosol

Risk evaluation of individual products considers both harmful and potentially harmful constituents (HPHCs) on FDA's established list and non-HPHC constituents that may pose substantial health risks.

The main metric of risk characterization for ENDS is a cumulative estimated excess lifetime cancer risks (ELCR), which provides an extrapolated estimate for how many additional cases of cancer would be expected in a population exposed to a given toxicant concentration and intake level for an entire lifetime, based on the toxicant's carcinogenic hazard and potency. The ELCR approach was used as an objective way to consistently estimate cancer risk resulting from individual constituents (e.g., ingredients, HPHCs, and leachables) measured in the new products, and it allows for a robust comparative analysis to other ENDS assessed in the same way. Individual ELCRs for constituents produced by or within a given product were added together to obtain an ELCR which was compared to the ELCR for 1R6F Kentucky research combusted cigarette, which are representative of combusted tobacco products, and compared to the median ELCR of FDA-authorized ENDS marketplace.

The new products have significantly reduced lifetime cancer risks compared to cigarettes. The estimated lifetime cancer risk for the products range from 1.4-10% (approximately 286 – 2000 new cancer cases per 100,000 users over a lifetime) compared to the lifetime cancer risk for cigarettes (10,000 cases per 100,000 users over a lifetime based on the 1R6F Kentucky reference cigarette)². Despite having significantly reduced lifetime cancer risks compared to cigarettes, all of the new products exhibit higher lifetime cancer risk estimates relative to the median estimate (264 estimated cancer cases in 100,000 users) of FDA-authorized ENDS as of July 2025. While there may be a potentially higher cancer risk associated with completely switching from some FDA-authorized ENDS to the new products, the potential benefit of adult smokers switching from combusted cigarettes to the new products is significant and outweighs the potential risk of substituting these new products for some alternative FDA-authorized ENDS.

In the Glas submission, all products show lower cumulative estimated lifetime cancer risk than combusted cigarettes, but vary significantly:

- Four flavored products: 1.4%-10% of combusted cigarette cancer risk (approximately 286-2000 new cancer cases per 100,000 users)
- Blonde Tobacco: 7.7% of combusted cigarettes cancer risk (approximately 1544 new cancer cases per 100,000 users)

Product Characterization and Manufacturing:

Consistent manufacturing, including process controls and quality assurance, is an important consideration for ENDS products as variations in product characteristics can translate into meaningful differences in health risks, nicotine delivery and addictiveness, and consumer satisfaction. FDA concluded that the

² <https://www.fda.gov/media/180610/download>

products demonstrate consistent manufacturing with adequate process controls and quality assurance procedures. The applications contain sufficient engineering, chemistry, and microbiology information to characterize the new products' chemical composition, structural components, and software design including the functionality of the age-gating technology in the Glas G2 device and e-liquid pod anti-counterfeiting technologies in the five pods. The engineering, chemistry, and microbiology information provided by the applicant demonstrate that the new products are manufactured consistently. HPHCs in e-liquids and aerosols of the new products are comparable to marketplace ENDS and lower than combusted cigarettes, and the applicant's e-liquid stability data and leachables testing show minimal compositional changes over the new products' proposed (b) (4) shelf life. These findings indicate low risks for increased toxicant exposure associated with product storage over the proposed (b) (4) shelf life. Based on these findings, FDA concluded that the applications contain sufficient information to characterize the new e-liquid pod products' composition and design and that there are adequate process controls and quality assurance procedures to ensure that these products are manufactured consistently.

Public Health Conclusion

FDA determined that the benefits of these products outweigh the risks when considering the population as a whole. The key factors in this decision were:

1. **Substantial benefit for adult smokers:** High rates of complete switching from cigarettes to the new products among adult users.³
2. **Effective youth protection:** The available data on the device access restrictions indicates that the technology is expected to be effective in preventing underage access.
3. **Lower health risks:** Significantly reduced lifetime cancer risks compared to cigarettes.
4. **Appropriate safeguards:** Marketing restrictions and ongoing monitoring requirements.

Environmental Assessment

FDA examined environmental effects and made a Finding of No Significant Impact (FONSI).

Final Recommendation and Authorization

FDA recommended **marketing granted orders** for the device (PM0004879.PD8), four flavored e-liquid pod products (Gold (mango flavor), PM0004879.PD1), Sapphire (blueberry flavor, PM0004879.PD2), Fresh Menthol (PM0004879.PD3), and Classic Menthol (PM0004879.PD4)) and one tobacco-flavored e-liquid pod product (Blonde Tobacco, PM0004879.PD6). The issuance confirms the applicant met Section 910(c) requirements and authorizes interstate commerce introduction of the products in accordance with marketing order requirements.

³ Although there were high rates of complete switching from cigarettes to the new products among adult users, as noted above, the new flavored products do not have an added benefit compared to tobacco-flavored ENDS in facilitating complete switching or significantly reducing cigarettes per day.