Juul Labs®

Parker D. Kasmer
Senior Director
Regulatory Engagement

October 5, 2020

Electronic Submission

EO 12866 Meeting
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
Washington, D.C. 20503
Oira_submission@omb.eop.gov

Re: RIN 0910-AI51; Prohibition of the Sale of Tobacco Products to Persons Younger Than 21 Years of Age

To whom it may concern,

On behalf of Juul Labs, Inc. (JLI or the Company),[1] I write to express JLI's strong support for the swift implementation of federal legislation that raises the minimum-purchasing age for all tobacco products, including electronic nicotine delivery systems (ENDS), from 18 to 21 years of age (Tobacco 21 legislation).[2]

Tobacco 21 legislation serves as a central component in an evidence-based tobacco-control strategy to restrict underage access to tobacco products and ultimately reduce underage use.[3] A leading contributor of underage use has been social sourcing — when a purchaser of legal age provides a tobacco product to an underage user. Recent data published by the Centers for Disease Control and Prevention (CDC) and others indicate that social sourcing accounts for approximately 70–80% of underage ENDS use.[4] Based on the

[1] JLI is the manufacturer of the JUUL System, a closed, cartridge-based product that utilizes proprietary heating technology to aerosolize and deliver nicotine without combustion. The JUUL System is composed of the JUUL Device and JUULpods. JUULpods are pre-filled with a nicotine-containing e-liquid formulation, which varies by tobacco or menthol flavor and nicotine concentration. The JUUL System is marketed as an alternative for adult smokers to transition and completely switch them from combustible cigarettes.

[2] *See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, Div. N, tit. I, §§ 603-04 (Dec. 20, 2019).

[3] *See, e.g.,* Institute of Medicine of the National Academies, Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products (2015).

[4] *See, e.g.*, M.R. Creamer, et al., "Tobacco Product Use Among High School Students — Youth Risk Behavior Survey, United States, 2019," 69 Morbidity and Mortality Weekly Report 56 (Aug. 21, 2020) (finding that the usual sources of ENDS products for 76.8% of respondents under 18 years of age were "Gave someone else money to buy them for me," "Borrowed them from someone else," "A person who can legally buy these products gave them to me," or "Took them from a store or another person"); *see also* We Card, Where Do Kids

2019 National Youth Tobacco Survey (NYTS), over 80% of youth ENDS users obtained the product from a social source, with approximately 63% of respondents obtaining the product from a friend.[5] By raising the minimum-purchasing age, Tobacco 21 legislation prevents teenagers from lawfully accessing tobacco products, while significantly reducing access to those underage through social sourcing from legal-aged individuals.

With the Food and Drug Administration's (FDA or the Agency) final rule pending regulatory review with the Office of Information and Regulatory Affairs (OIRA), JLI writes to express its full support of the updated regulations on the new, national minimum-purchasing age for tobacco products consistent with the Tobacco 21 legislation, as well as continued enforcement of these legal requirements. We also take this opportunity to offer insights to better ensure the implementation of Tobacco 21 across the country and additional tools to further restrict underage access. As part of a comprehensive tobacco-control strategy — built on restricting access, limiting appeal, and enforcement — Tobacco 21 has the potential to significantly reduce underage use of all tobacco products, including ENDS.

Communicate Tobacco 21 as the Law of the Land and Facilitate Adoption and Compliance Nationwide

Shortly after its enactment, FDA appropriately highlighted the self-executing nature of the Tobacco 21 legislation and informed stakeholders, including retailers, that "[i]t is now illegal for a retailer to sell any tobacco product — including cigarettes, cigars and e-cigarettes — to anyone under 21."[6] At the time, nineteen states and Washington, D.C. already had passed legislation raising the minimum-purchasing age for tobacco products to 21 years of age. Since then, an additional eleven states have passed Tobacco 21 legislation, with varying effective dates into the future. Regardless, 21 is the national minimum-purchasing age for tobacco products and has been since December 2019.

Yet with twenty states currently having minimum-purchasing ages lower than 21 years, there remains uncertainty among some stakeholders on the preemptive effect of the federal legislation. Retailers in these "non-Tobacco 21 states" — especially small, independently-owned local businesses — may not know that Tobacco 21 even applies to them. Or worse yet, they may not be enforcing against the federal legal requirement in light of conflicting laws and information from states where local Tobacco 21 laws have not been enacted or taken effect.

Get Tobacco & Vapor Products (May 2020), https://www.wecard.org/where-do-kids-get-tobacco-vapor-products.

[5] *See* Centers for Disease Control and Prevention (CDC), National Youth Tobacco Survey (2019).

[6] FDA, Selling Tobacco Products in Retail Stores, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores. ("On December 20, 2019, the President signed legislation to amend the [FDCA], and raise the federal minimum age of sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21. FDA will provide additional details on this issue as they become available.").

To clarify any ambiguity on the immediate and nationwide effect of Tobacco 21, JLI believes FDA can undertake a number of actions in updating its regulations under 21 C.F.R. part 1140 currently under OIRA review or in tandem with this update:

First, FDA should ensure the preemptive effect of the new, national minimum-purchasing age in its final rule is made clear and further communicate this preemptive effect to state authorities through supplemental measures.

Whether through FDA's Division of Federal-State relations or some other means, such as letters directly to state officials, FDA can convey that Tobacco 21 applies immediately and in all jurisdictions throughout the United States, regardless of whether a sale occurs online or at brick-and-mortar retail or whether a state or local law includes a lower age limit (e.g., 18 years of age). By way of precedent, after amendments to the Agriculture Marketing Act were enacted in 2016 which, among other things, required a national uniform standard for certain food disclosures, the United States Department of Agriculture (USDA) issued letters to governors of all U.S. states and territories informing them of the self-executing nature of the law as well as its preemptive effect.[7] USDA also made these letters available on its website.[8]

The Department of Health and Human Services (HHS), likewise, in the past has issued letters addressed to state governors discussing federal policy changes and initiatives, seeking collaboration with state governments to achieve successful implementation.[9] To better assure compliance with the Tobacco 21 legislation, JLI encourages FDA to take similar action by issuing letters to state governors notifying them of the immediate and preemptive effect of the Tobacco 21 legislation.

Second, FDA should further amplify its own communications and educational tools for retailers to ensure age-verification compliance with Tobacco 21.

JLI understands that FDA already has updated its website to explain the changes in the law and how retailers must comply;[10] developed a webinar to help retailers comply

---

[7] *See* Letters from E. Avalos, Undersec'y, Mktg. and Regulatory Programs, USDA, to Hon. B. Walker, Governor of Alaska, et al. (Aug. 1, 2016), available at https://www.ams.usda.gov/sites/default/files/media/GMOExemptionLettersto50Governors.pdf.

[8] *See id.*

[9] *See, e.g.,* Letter from K. Sebelius, Sec'y of Health and Hum. Servs., and A. Duncan, Sec'y of Education, to State Governors (Apr. 12, 2011), available at https://www.cms.gov/CCIIO/Resources/Technical-Implementation-Letters/Downloads/exchange-blueprint-letter.pdf; Letter from K. Sebelius, Sec'y of Health and Hum. Servs., to State Governors (Nov. 9, 2012), available at https://www.cms.gov/CCIIO/Resources/Technical-Implementation-Letters/Downloads/exchange-blueprint-letter.pdf

[10] *See* FDA, Tobacco 21, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/tobacco-21 (last accessed on Oct. 2, 2020); FDA, Selling Tobacco Products in Retail Stores, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/selling-tobacco-products-retail-stores (last accessed Oct. 2, 2020).

with Tobacco 21;[11] provided free resources to retailers to help assist in calculating the age of customers;[12] and a "Tobacco 21" fact sheet available for order or download.[13] In addition, the Agency should consider utilizing other communication channels, such as retailer trade association newsletters and trade publications, that may have a more expansive reach to regional and local convenience stores, independent outlets, and specialty tobacco shops. Moreover, any retailer communication or educational program should emphasize the preemptive effect of the Tobacco 21 legislation and, once finalized, FDA's minimum-purchasing age regulations, regardless of what the state minimum-purchasing age is for a retailer of tobacco products.

Incorporate Additional Access Controls to Further Restrict Underage Access and Drive Down Underage Use

Raising the minimum-purchasing age for tobacco products, particularly ENDS, may have the most significant impact of any one policy to reduce underage use enacted to date. For example, results from the recently released 2020 NYTS show a significant year-over-year decline in underage use of ENDS products: In 2020, 19.6% of high-school students reported use in the past-30 days, compared to 27.5% in 2019. For middle-school students, 4.7% reported use in the past-30 days, compared to 10.5% in 2019.[14] Given the timing of the survey, fielded between January and March 2020 following the passage of the federal legislation, Tobacco 21 was likely a significant driver in the reduction of ENDS use among youth.

Such results are encouraging. But JLI believes more can and should be done to accelerate the decline in underage use of ENDS products, and a rapidly evolving marketplace, driven by new technology, presents an opportunity to shift the paradigm on how age-restricted products like ENDS are sold at retail.

Even with federal age-verification requirements, data suggest that retailers still fail to prevent underage access to tobacco products. In 2018, based on FDA's retailer compliance-check inspection database, there were approximately 17,000 violations for

---

[11] *See* FDA, FDA Tobacco Compliance Webinars, "Recent Changes That Impact the Sale of Tobacco Products in Retail Establishments," available at https://www.fda.gov/tobacco-products/compliance-enforcement-training/fda-tobacco-compliance-webinars (last accessed Oct. 2, 2020).

[12] *See* FDA, This Is Our Watch, https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch (last accessed Oct. 2, 2020).

[13] Center for Tobacco Products Exchange Lab, FDA's Tobacco Education Resources, "Raising the Federal Minimum Age of Sale of Tobacco Products to 21," available at https://digitalmedia.hhs.gov/tobacco/print_materials/RE-30.

[14] *See* T.W. Wang, et al., "E-Cigarette Use Among Middle and High School Students — United States, 2020," 69 Morbidity and Mortality Weekly Report 1310 (Sept. 18, 2020).

age-verification non-compliance.[15] In 2019, there were approximately 18,000 violations.[16] And in 2020, although FDA suspended inspections in March 2020 because of COVID-19, there have been approximately 3,800 violations to date.[17] The historical non-compliance rate in inspections across categories of tobacco product retailers, including convenience stores and specialty shops, has been between approximately 10–20%. While Tobacco 21 will have a significant effect, particularly on social sourcing, ensuring compliance with age-verification requirements is critical to effectively address underage use.

Technologically-based solutions may provide the answer. Over the past few years, stakeholders across industry have been deploying new technologies to better control and restrict access to certain products, including ENDS. For example, brick-and-mortar retailers now can use barcode-scanning technology to automatically verify the purchaser's age and validity of their identification (ID). Physical scanners or other software-based technologies can pull information from the barcode on a government-issued ID and determine whether the purchaser is of legal age and whether the ID has expired. The same technology can extract information from the purchaser's ID and temporarily display that information on the point-of-sale screen, enabling the retail clerk to verify that it matches what is presented on the physical ID to reduce potential fraud. Sales systems also can identify a certain product as "restricted" — e.g., tobacco, alcohol, lottery tickets — and require that age- and identity-verification requirements be met before the transaction can be completed. Additionally, point-of-sale systems can be embedded with automated controls that limit the amount of product that can be purchased, thus restricting bulk purchases and further reducing the potential for social sourcing.

These types of additional access controls at the point-of-sale can inform a comprehensive tobacco-control strategy. But in concert with the implementation of Tobacco 21 legislation, their adoption category-wide — whether for ENDS or all tobacco products — will accelerate a decline in underage use.

With its implementation of the Tobacco 21 legislation, JLI encourages FDA to facilitate the adoption of technologically-based access controls across industry. This may take the form of Guidance for Industry or retailer and trade communications to encourage the adoption of these technologies; industry meetings or public hearings to explore new tools to restrict underage access; and the consideration of such controls as sales and distribution restrictions for new tobacco products through premarket-review process.

As part of the September 9, 2020, submission deadline for deemed new tobacco products that were on the market in the U.S. as of August 8, 2016, JLI assumes that ENDS and other manufacturers have proposed various sales and distribution restrictions for the marketing of their products post-authorization. Under § 910(c)(1)(B) of the Federal Food,

---

[15] *See* FDA, Compliance Check Inspections of Tobacco Product Retailers (through 8/31/2020), https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

[16] *See id.*

[17] *See id.*

Drug, and Cosmetic Act (as amended by the Family Smoking Prevention and Tobacco Control Act), as part of a marketing order for a new tobacco product subject to a PMTA, FDA "may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d)."[18] Section 906(d), in turn, states in relevant part that FDA may "by regulation require restrictions on the sale and distribution of a tobacco product . . . if [FDA] determines that such regulation would be appropriate for the protection of public health."[19] And under FDA's proposed rule for "Premarket Tobacco Product Applications and Recordkeeping Requirements," manufacturers also may propose sales and distribution for the new tobacco product "to help support a showing that the marketing of the product is appropriate for the protection of public health (e.g., a restriction that decreases the likelihood that those who do not currently use tobacco products will initiate tobacco product use with the new tobacco product)."[20]

Rather than solely adopting such restrictions in piecemeal as part of individual marketing orders, FDA should consider a category-wide application that builds upon the types of additional access controls being developed and implemented in the marketplace to restrict these products to age-verified adults.

***

The Tobacco 21 legislation is a centerpiece of what can become the comprehensive implementation of evidence-based tobacco-control strategies to address underage use, particularly of newer products like ENDS. Beyond nationwide implementation, ensuring effective enforcement with the new minimum-purchasing age will be imperative. And given advancements in the retail marketplace for the sale of age-restricted products, we believe FDA and other stakeholders can fundamentally change how products like ENDS are sold to further restrict underage access and accelerate the decline in underage use.

These measures, while significant, are only part of potential solutions. Through the science-based PMTA review process, manufacturers must demonstrate that their new tobacco products are appropriate for the protection of public health. This necessarily requires controls to ensure nonusers, particularly those who are underage, will not likely start using the product. Such controls should encompass how the products will be marketed (to limit appeal) and how they will be sold (to restrict access), in addition to broad enforcement to clear the market of illegal and black-market products.

---

[18] 21 U.S.C. § 387j(c)(1)(B). Section 906(d), in relevant part, limits FDA from adopting restrictions that "prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets."

[19] 21 U.S.C. § 387j(c)(1)(B).

[20] 84 Fed. Reg. 50566, 50580 (Sept. 25, 2019).

Regards,