Jose Luis Murillo
Chief Regulatory Officer

January 31, 2020

By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-0661; Comment on Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry

To whom it may concern,

JUUL Labs, Inc. (JLI or Company) appreciates the opportunity to comment on the FDA's recently-published final guidance document outlining the Agency's enforcement priorities for electronic nicotine delivery system (ENDS) products and other deemed tobacco products currently on the market without premarket authorization.[1]

JLI applauds this measure as a broader and critical reset of the ENDS category to address the reported increases in underage use of these products. The Enforcement Priorities Guidance, along with implementation of the recently-enacted legislation raising the federal minimum-purchasing age for tobacco products, including ENDS, from 18 to 21 (T21 legislation),[2] serve as a major step toward restricting access, appeal, and ultimately use of ENDS products among those underage.

To strengthen the overall impact of these efforts, JLI urges FDA to take prompt action to address potential gaps or ambiguities relating to the Guidance as well as the immediate effect of the T21 legislation. For example, we encourage FDA to clarify how it defines "cartridge-based ENDS products" to address misconceptions about potential loopholes, particularly for products that may be gaining popularity among minors. We also hope that the Agency will elaborate on its enforcement priorities for products that have

[1] FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization (Jan. 2020), available at http://bit.ly/36xpplv ("Enforcement Priorities Guidance" or "Guidance").

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

never been subject to an FDA compliance period: products first marketed after the August 8, 2016 effective date of the Deeming Rule[3] and illicit or "black market" counterfeit and compatible products.[4] Moreover, we urge the Agency to move forward with rulemaking on age-verification measures for remote (e.g., online) sales, in concert with its implementation of the T21 legislation, to ensure that e-commerce channels do not remain an open source for underage access.

The Company believes addressing these outstanding issues will help ensure robust enforcement and advance the important cause of curbing underage use of ENDS and other tobacco products, while preserving legitimate ENDS products as a potentially less harmful alternative for adult smokers.

I. ENSURING A ROBUST APPLICATION OF THE ENFORCEMENT PRIORITIES GUIDANCE

A. Encouraging Industry Support to Further Facilitate FDA's Enforcement of the Guidance

JLI welcomes the Enforcement Priorities Guidance as a critical step to reset the ENDS category today and into the near future, through the PMTA submission deadline for currently marketed deemed products. It has become increasingly clear that the harm-reduction potential of ENDS and other alternative products for adult smokers could be at risk until the trend in underage use is addressed. That is, in part, why the Company suspended the sale of all flavored JUUL products other than tobacco and menthol in November 2019, following the release of national youth survey data on ENDS use and JUUL use specifically.[5]

We also believe that industry, including JLI, can support FDA's enforcement of the Guidance in other material ways to ensure robust compliance. For example, JLI and other manufacturers have the tools and resources to follow commercial trends and alert the Agency of the introduction and proliferation of illicit, black market products. We suggest that ENDS manufacturers support FDA's enforcement efforts against these illegal products and provide relevant market information to the Agency for it to consider as part of its enforcement efforts.

Manufacturers can and should work with retailers to improve age-verification compliance and deploy additional measures to restrict product access from those

---

[3] 81 Fed. Reg. 28973, 29011 (May 10, 2016) (stating that the compliance periods in the Deeming Rule apply to "those newly deemed products that were on the market on the effective date of this final rule, but that were not on the market on February 15, 2007").

[4] *See* Enforcement Priorities Guidance at 28-29 (discussing FDA's enforcement policies for illicit, "black market" products).

[5] *See* A. Leventhal et al., Research Letter, "Flavors of e-Cigarettes Used by Youths in the United States," 322 J. AM. MED. ASS'N 2132 (2019).

underage. As the Company has previously commented, point-of-sale (POS) technology has changed significantly over the last several years.[6] Retailers can now incorporate electronic scanning of government-issued IDs to verify age and ID validity automatically, before completing purchases with consumers. Similar technology also can be used to impose automated limits on the amount of product that can be purchased to restrict social sourcing. We recommend that industry continue to develop new technologies that enable retailers to better ensure ENDS products are restricted to legal-aged purchasers.

The Enforcement Priorities Guidance makes it clear that manufacturers, along with other stakeholders, must play an active role to restrict access and limit appeal of ENDS products among those underage. JLI supports this category-wide approach and will continue to focus its underage prevention programs on limiting the availability and sale of JUUL products to adult smokers as an alternative to combustible cigarettes.

B. Applying Principles in Enforcement Priorities Guidance to Single-Use, Disposable Products

JLI supports FDA's decision to focus its enforcement resources on non-tobacco and non-menthol flavored, cartridge-based ENDS products. We are concerned, however, that other manufacturers are taking advantage of a purported loophole in the Enforcement Priorities Guidance relating to "self-contained, disposable products." The Company believes this "exemption" is being interpreted incorrectly, but more importantly, FDA already has articulated that such products, regardless of type or flavor, will be subject to its enforcement authorities because they are otherwise illegal or are marketed directly to minors.

The Guidance defines "cartridge-based ENDS product" as "a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system."[7] In an accompanying footnote, however, the Guidance states that: "An example of products that would *not* be captured by this definition include completely self-contained, disposable products."[8]

We believe the footnote is being read incorrectly to exclude from FDA's enforcement policy self-contained, single-use ENDS products that otherwise meet the "cartridge-based ENDS product" definition or are functional equivalents, except for the minor fact that the

[6] JUUL Labs, Inc., Comment on Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance for Industry (Docket No. FDA-2019-D-0661).

[7] *See* Enforcement Priorities Guidance at 9.

[8] *Id.* at 9 n.20 (emphasis added).

products are disposable.[9] Such products include those like Puff Bar, STIG, and Eonsmoke, which are single-use products that, among other things, contain e-liquids in "pod devices" and have been marketed explicitly for their discreteness.[10] For example, according to STIGpods.com: "The future of vaping is here as we introduce a cutting edge disposable, all in one, pod device we call the STIG. It is small, extremely easy to use straight out of the box and can be utilized discreetly by all types of vapers."[11]

Syndicated market data — which tracks the sale of various tobacco products, including ENDS, through limited channels (e.g., convenience stores, grocery) — show a steady increase over the last several weeks of these disposable, pod-based products in the U.S. market. For example, based on weekly syndicated sell-through data from the market research company IRI, Puff Bar device volume grew 194.6% from December 8 to December 15, 2019, and, more recently, 70.4% from January 12 to January 19, 2020. For STIG, device volume grew 29.0% from January 12 to January 19, 2020.

The below chart, based on IRI syndicated data, reflects the recent growth by product sales of Puff Bar, STIG, and Eonsmoke disposable products against the total disposable market and "legacy products"[12]:

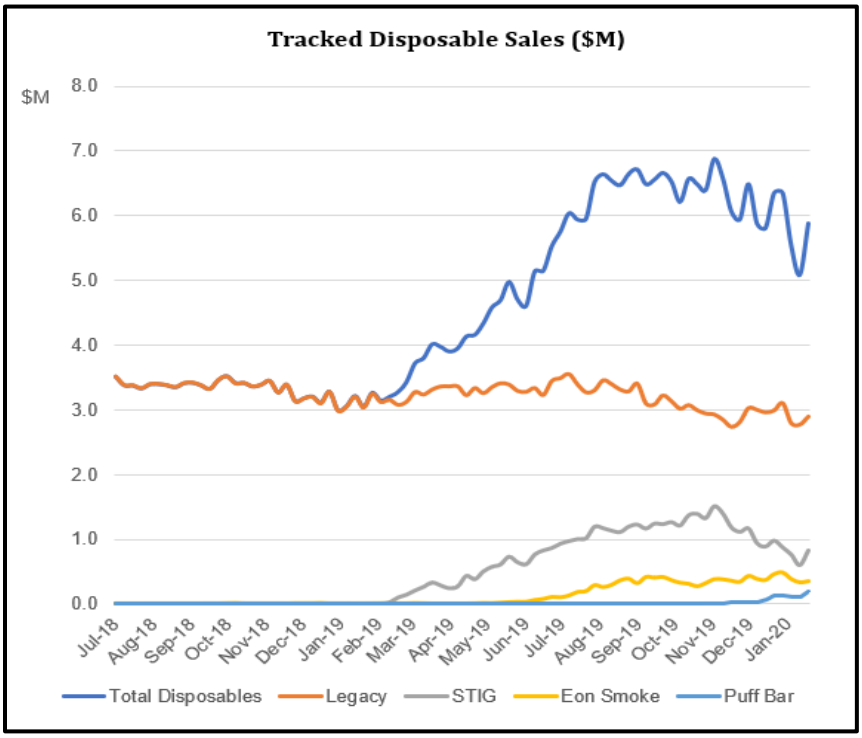
---

[9] *See, e.g.*, Gerald Porter, Jr., Some Vaping Flavors Banned as FDA Seeks to Curb Teen Use, Bloomberg (Jan. 2, 2020), available at https://www.bloomberg.com/news/articles/2020-01-02/flavored-vaping-products-barred-under-strict-fda-curbs, ("Along with Suorin, disposable vape brands like Puff Bar and Stig could pose an enforcement hurdle.").

[10] *See, e.g.*, STIG, "Disposable Pod Device," https://stigpods.com/ (last accessed Jan. 30, 2020); Puff, "Puff Bars Disposable," https://www.puffsalt.com/collections/puff-bars (last accessed Jan. 30, 2020); Eonsmoke, "Eonsmoke Disposables," https://www.eonsmoke.com/product-category/disposables/ (last accessed Jan. 30, 2020).

[11] *See* STIG, "Disposable Pod Device," https://stigpods.com/ (last accessed Jan. 30, 2020).

[12] "Legacy products" refer to previously marketed ENDS products that, although self-contained and disposable, typically were cylindrical in shape (i.e., cig-a-likes).



It is important to keep in mind that the syndicated market data is only a snapshot of the ENDS market and does not capture specialty stores, including vape shops, where these types of products are typically carried and sold or online.[13]

One recent report shows that consumers are "turning to Puff Bars, a nearly identical product [to JUUL products] that skirts the new rules by fusing the liquid-filled cartridge to the pen-sized stem."[14] Based on a review of an online site that sells Puff Bar, flavors include "Lush Ice," "Mango," "Blue Razz," "Pink Lemonade," and "O.M.G." (Orange, Mango, Grapefruit) in 5% and 2% nicotine concentrations in 1.3 mL of nicotine-containing e-liquid.[15] Critically, it is unclear where these products are manufactured, what the ingredients are, and whether any quality controls, manufacturing standards, and product testing are in place as part of production and the commercial-release process.

---

[13] *See, e.g.*, PuffEcig.com, https://puffecig.com/puff-bar-disposable-device/ (last accessed Jan. 30, 2020); Element Vape, https://www.elementvape.com/puff-bar (last accessed Jan. 30, 2020); LA Vaporz Wholesale, https://www.lavaporz.com/products/puff-bar-disposable-pod-device (last accessed Jan. 30, 2020); and Alternative Pods, https://www.alternativepods.com/products/puff-bar-disposables.html (last accessed Jan. 30, 2020).

[14] "After FDA Crackdown on Juul, Disposable Knockoffs Take Over," Dallas Observer (Jan. 21, 2020), available at https://www.dallasobserver.com/news/after-fda-crackdown-on-juul-disposable-knockoffs-take-over-11851152.

[15] *See* PuffECig.com, https://puffecig.com/puff-bar-disposable-device/ (last accessed Jan. 30, 2020).

Any reading of the footnote that excludes these products is misplaced because FDA's reasoning for prioritizing its enforcement efforts on non-single-use flavored, cartridge-based ENDS products (other than tobacco and menthol flavors) applies directly to self-contained, single-use ENDS products such as these that are cartridge- or pod-based and can be easily hidden or discretely used. The fact that such products are self-contained, single-use, and disposable does not mitigate or otherwise address the Agency's concerns outlined in the Guidance relating to underage appeal and access. Indeed, the single-use and disposable nature of such products, if anything, could make them even more "easy to conceal" and "use[ ] discreetly."[16] As such, we encourage FDA to clarify that its enforcement policy extends to all cartridge-based ENDS products that are not tobacco- or menthol-flavored ENDS products, regardless of whether they are self-contained, disposable or may be reused.

More critically, the Enforcement Priorities Guidance made it explicitly clear that it — and the footnote on self-contained, disposable products — does not apply to products that came to the market after August 8, 2016, and lack premarket authorization.[17] For some of these self-contained, disposable products, particularly Puff Bar, STIG, and Eonsmoke, we believe they are being marketed outside of FDA's compliance policy for deemed products and thus are illegal and subject to enforcement immediately — regardless of product type or flavor.

Finally, regardless of any confusion as to whether certain self-contained, disposable products come within FDA's enforcement priority for cartridge-based ENDS products (other than tobacco and menthol flavors), such products fall squarely within FDA's enforcement focus to address underage access and appeal broadly. Recent reports have highlighted the ability of those underage to access these self-contained products and their preference for fruity and kid-friendly favors like "Banana Ice."[18] It is not clear that these manufacturers have adequate measures in place to restrict underage access to their products, or to verify the age of a potential product purchaser through manufacturer-controlled channels (e.g., online). It is evident, however, that these products are presented in a manner that appeals to minors and is likely to increase underage use: by promoting their discreet form and using flavors that FDA acknowledges are popular with underage

---

[16] *See* Enforcement Priorities Guidance at 19.

[17] *See id.* at 2 n.2 ("As with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance document does not apply to any deemed product that was not on the market on August 8, 2016."); *id.* at 3 ("This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization.").

[18] *See, e.g.*, "'It's Rampant': Disposable Flavor Pods Are the New Thing in Vaping," N.Y. Times (Jan. 31, 2020), available at https://www.nytimes.com/2020/01/31/health/vaping-flavors-disposable.html?action=click&module=Top; "Disposable E-Cigarettes, Sweet and Fruity, Escape FDA Restrictions," Wall St. J. (Jan. 29, 2020), available at https://www.wsj.com/articles/disposable-e-cigarettes-sweet-and-fruity-escape-fda-restrictions-11580308276.

users.[19] FDA should take prompt enforcement action against these products under its stated enforcement priorities for ENDS products without adequate measures to prevent underage access and for ENDS products which are targeted to minors or whose marketing is likely to promote use by minors, regardless of product type.

JLI supports FDA's decision to focus its enforcement efforts on ENDS products that pose a particular risk to underage use. The recent proliferation of single-use, disposable products, such as Puff Bar, STIG, and Eonsmoke, and the apparent appeal of those products to minors highlight a rapidly changing marketplace, but FDA already has the tools and has outlined its ability to enforce against illegal products or products that are directly encouraging or promoting underage use. The Company urges the Agency to promptly apply the principles in the Enforcement Priorities Guidance to clear these products from the market and reduce the potential for underage uptake.

C. Codification of Age-Verification Measures for Remote Sales

JLI appreciates FDA's effort to clarify in the Enforcement Priorities Guidance the types of measures it expects manufacturers and retailers to employ to prevent underage access to ENDS and other tobacco products. A number of the factors identified in the Guidance as relevant to this assessment appropriately center on the use of adequate age-verification technologies, including, for online sales, the use of "an independent, third-party age- and identity-verification service that compares customer information against third-party data sources, such as public records."[20]

JLI has implemented such age-verification processes on its own e-commerce platform, and has advocated for the adoption of category-wide age-verification requirements.[21] Given the volume of ENDS and tobacco product sales occurring online rather than in brick-and-mortar outlets, particularly those that may involve underage users,[22] the Company agrees that a focus on specific age-verification requirements for remote sales is not only appropriate, but also necessary to combat the problem of underage access.

---

[19] *See supra* notes 9 to 15 and accompanying text; *see also* Enforcement Priorities Guidance at 21–27 (outlining enforcement priorities for ENDS products without adequate measures to prevent minors' access and for ENDS products which are targeted to minors or whose marketing is likely to promote use by minors).

[20] *Id.* at 22.

[21] *See* JUUL Labs, "Youth Prevention — JUUL Labs Continues to Build on National Program to Reduce Underage Use," https://www.juul.com/youth-prevention.

[22] *See generally* FDA, Draft Guidance for Industry, Modifications to Compliance Policy for Certain Deemed Tobacco Products (Mar. 2019), available at http://bit.ly/2MTeaVA, at 11 (discussing data from the Population Assessment of Tobacco and Health (PATH) study, the National Youth Tobacco Survey (NYTS) study, and other studies showing trends in underage access to ENDS products from online retailers).

To that end, we respectfully urge FDA to establish age-verification requirements governing remote sales (including online sales) through rulemaking, consistent with the Family Smoking Prevention and Tobacco Control Act (TCA). The TCA directed FDA to publish a final rule that was "identical" in relevant part to regulations the Agency issued in 1996 prohibiting the sale and distribution of cigarettes and smokeless tobacco to minors.[23] In line with this directive, FDA published the final rule, codified at 21 C.F.R. Part 1140, in March 2010,[24] and later amended the rule to cover deemed tobacco products as part of the Agency's 2016 Deeming Rule.[25]

As was the case for the 1996 regulations, the current regulations focus on sales made through brick-and-mortar retail establishments, and do not expressly address the sale and distribution of tobacco products that occur through remote sales or "non-face-to-face" exchanges (*e.g.*, online sales). For example, the current regulations require retailers to verify a purchaser's age "by means of photographic identification containing the bearer's date of birth" unless the purchaser appears to be over a certain age.[26] This assessment of whether a purchaser appears to be over a certain age can be made in the normal course by a retail clerk in a direct, face-to-face interaction, but is impracticable to effectuate in a non-face-to-face exchange between an online retailer and online purchaser.

Consequently, the TCA includes a separate provision, titled "remote sales," that directed FDA to "promulgate regulations regarding the sale and distribution of tobacco products that occur through means *other than* a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age . . . including requirements for age verification," within 18 months after the date of enactment.[27]

While FDA issued an advance notice of prosed rulemaking (ANRPM) in September 2011[28] to obtain information related to the remote sales provision, including "non-face-to-face sale and distribution of tobacco products," the Agency appears to have withdrawn the

---

[23] *See* Pub. L. 111-31, § 102, 123 Stat. 1776, 1830-33 (June 22, 2009).

[24] 75 Fed. Reg. 13225 (March 19, 2010).

[25] *See* 81 Fed. Reg. 28974, 29103 (May 10, 2016); *see also* 21 C.F.R. § 1140.14(b).

[26] 21 C.F.R. § 1140.14(a)(2), (b)(2). Under the T21 legislation, Congress amended section 906(d) of the Federal Food, Drug, and Cosmetic Act (FDCA) to change the minimum age from "18 years" to "21 years," and to add a provision stating that "It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age." *See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, Div. N, tit. I, § 603(a) (Dec. 20, 2019). The T21 legislation also requires that FDA publish a final rule within 180 days of enactment updating its age verification requirements under 21 C.F.R. Part 1140 to require age verifications for "individuals under the age of 30." *Id.*, Div. N., tit. I, § 603(b)(1).

[27] 21 U.S.C. § 387f(d)(4)(A)(i) (emphasis added).

[28] 76 Fed. Reg. 55835 (Sept. 9, 2011).

ANRPM in 2017[29] and has not taken further action to promulgate regulations implementing the provision.

Accordingly, although the Enforcement Priorities Guidance makes clear that FDA intends to consider whether retailers use adequate age-verification technology to prevent underage online sales, FDA's current regulations do not specifically address remote sales and the measures needed to prevent underage access. Given the ongoing problem of underage access and FDA's related enforcement priorities, we think it is important and timely for the Agency to augment its current efforts with binding regulations, based on the well-thought-out recommendations in the Enforcement Priorities Guidance.

We encourage FDA to promulgate regulations that address remote sales to further address the growing concern of underage access. As discussed further below, we encourage the Agency to take such steps in conjunction with its efforts to update its Part 1140 regulations pursuant to the T21 legislation to further assure effective implementation and enforcement of the federal minimum-purchasing age for tobacco products, including ENDS.

D. Continued Enforcement against ENDS Products First Marketed after the Effective Date of the Deeming Rule and Illicit, "Black Market" Products

As noted above, JLI welcomes FDA's clarification of its enforcement priorities for deemed tobacco products which were already on the market as of the effective date of the Agency's Deeming Rule (*i.e.*, August 8, 2016). In addition, the Company appreciates the discussion in the Guidance relating to the regulatory tools and enforcement authorities FDA could use to combat a potential rise in illicit, "black market" products given the removal of non-tobacco and non-menthol flavored, cartridge-based ENDS products under the Agency's enforcement policy. As discussed further below, we are hopeful that FDA will supplement the Guidance to elaborate on deemed products that do not have premarket authorization and were *not* on the market on August 8, 2016, as well as details on how FDA will monitor and address black market products.

The Guidance states clearly, for example, that it "does not apply to any deemed product that was not on the market on August 8, 2016,"[30] but it does not expressly remind stakeholders that such products are prohibited from being marketed, regardless of whether they contain non-tobacco or non-menthol flavors, are cartridge-based, or are sold before the 30-day grace period for products subject to the Guidance. Nor does the Guidance state or describe how FDA intends to prioritize enforcement against deemed tobacco products that were solely marketed on or after August 8, 2016.

---

[29] *See, e.g.*, OMB/OIRA Unified Agenda, RIN 0910-AG42, Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products (Spring 2017), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0910-AG43 (listing ANRPM as withdrawn on Aug. 1, 2017).

[30] Enforcement Priorities Guidance at 2 n.2.

To avoid potential confusion and better assure effective implementation, we urge FDA to announce to retailers as soon as practicable that such products cannot be offered for sale at any time or in any form—regardless of flavor type, cartridge status, or the date of sale—unless they receive premarket authorization by the Agency, and that FDA will take action against such products immediately. In addition, we encourage the Agency to consider such products to be a high priority for enforcement, because they came on the market after the effective date of the Deeming Rule, have never complied with FDA enforcement policies related to the sale of deemed products, presumably have not complied with various reporting requirements, including ingredient listing, and have not yet been subject to Agency review.

JLI agrees that "black market" products can pose significant health risks to users due to differences in composition, quality, and manufacturing controls,[31] and that these products are likely to be sold in channels without adequate age-verification requirements, thus increasing the likelihood of underage access.[32] As discussed in the Guidance, "black market" products include "products intended to look like another ENDS product[] that is currently being marketed, products intended to take the place of an ENDS product that a manufacturer has stopped distributing because the product lacks premarket authorization, and ENDS products intended for another country's market but diverted to the U.S. market."[33]

It is helpful and significant that the Guidance warns that black market products "may pose additional health and safety risks to consumers beyond those of the authentic products" and may facilitate underage ENDS use.[34] To avoid potential confusion and facilitate effective implementation, however, we urge FDA communicate to retailers as soon as practicable that such products cannot be offered for sale—regardless of flavor type, cartridge status, or the date of sale—and that FDA will take action against all such products immediately. Furthermore, we hope FDA will clarify how it plans to prioritize enforcement for black market products vis-à-vis other deemed tobacco products marketed without premarket authorization.

---

[31] *Id.* at 28 ("Additional risks posed by these products include the potential that they contain harmful chemicals or constituents that are not present in other products, that they are manufactured using comparatively poor quality controls, and that they are designed in ways that facilitate modifications by distributors or users—all of which increase the risk of adverse events."

[32] *Id.* at 28-29 ("Moreover, to the extent that such products are sold through nontraditional retail channels, such as social sources or online commercial marketplaces that do not include age-verification requirements, they pose an increased risk of being accessed by minors.").

[33] *Id.* at 28.

[34] *Id.*

II. IMPLEMENTING T21 LEGISLATION SWIFTLY AND EFFECTIVELY

On December 20, 2019, Congress passed legislation raising the federal minimum-purchasing age for all tobacco products, including ENDS, from 18 to 21 and directing FDA to update its regulations to reflect the new minimum-age requirement.[35] JLI has long supported raising the federal minimum-purchasing age to 21 and believes this is an important feature in the overall strategy to combat underage uptake, particularly through social sourcing.

Shortly after the T21 legislation was enacted, FDA posted a statement on its website noting that: (i) "[i]t is now illegal for a retailer to sell any tobacco product – including cigarettes, cigars and e-cigarettes – to anyone under 21," and (ii) the Agency will "provide additional details on this issue as they become available."[36] We commend FDA for swiftly issuing this communication; however, further action is needed to notify retailers of the new national age limit and the immediate effect of the legislation to maximize the legislation's impact in combination with FDA's implementation of the Enforcement Priorities Guidance.

While FDA mentions, in a footnote, that the term "minor" as used in the Enforcement Priorities Guidance "refers to individuals under the age of 21" and "FDA is working to update [its] regulations within 180 days, consistent with the timeline set forth in the [T21 legislation],"[37] the Guidance does not otherwise make clear that the federal minimum age requirement is self-executing and, therefore, currently applies to retailers across the United States.[38] JLI believes this important legislative development warrants further clarification by FDA. To help effectuate the reach of the T21 legislation, we encourage FDA to communicate the self-executing and preemptive effect of the new national age limit to state and local authorities as well as retailers.

Whether through FDA's Division of Federal-State relations or some other means, such as letters issued to state or local officials, we think it is critical for FDA to convey clearly that the new age requirement applies immediately and in all jurisdictions throughout the United States, regardless of whether a sale occurs online or at an

---

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

[36] 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.").

[37] Enforcement Priorities Guidance at 3 n. 3.

[38] *See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, Div. N, tit. I, § 603(b), codified at 21 U.S.C. § 387f(d)(5) ("It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.").

independently-owned convenience store 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.[39] To assure effective implementation of the T21 legislation, particularly given the number of states and territories with lower age restrictions on tobacco sales still in effect, we urge FDA to take similar action by notifying state and local officials of the immediate and preemptive effect of the T21 legislation.

In addition, we urge FDA to issue a clear statement to retailers—many of which are small, independently-owned local businesses—informing them of the immediate and nationwide effect of the T21 legislation. Given the importance of this issue, the significance of any enforcement action by FDA, and the Agency's own limited enforcement resources, it is essential that retailers across the country understand and comply with the new age restrictions today. We believe a clear statement from FDA will better assure such compliance.

As noted above, we also respectfully urge FDA to augment its current efforts in implementing the Enforcement Priorities Guidance by taking decisive steps toward promulgating binding regulations that address remote sales. We encourage the Agency to take these steps in conjunction with its efforts to update its Part 1140 regulations on the prohibition of sale and distribution to underage users. While each of these efforts has the potential to curb underage access to tobacco products, they will have a much greater and more widespread impact if conducted in concert with one another, rather than alone.[40]

***

JLI appreciates FDA's establishment of priorities to enforce the premarket authorization requirements for deemed tobacco products, particularly as the May 12, 2020 PMTA submission deadline for currently marketed, deemed products approaches. Effective enforcement, coupled with the regulatory framework that the Agency continues to establish for tobacco products, will preserve the public-health opportunity of less harmful alternatives for adult smokers, while keeping these products out of the hands of those underage.

---

[39] *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.

[40] Indeed, the remote sales provision and the self-executing provision of the T21 legislation are codified in the very same statutory subsection of the FDCA, demonstrating the close relation of these requirements. *See* 21 U.S.C. §§ 387f(d)(4) and (d)(5).

To help strengthen these efforts, the Company encourages FDA to address the ambiguities in the Enforcement Priorities Guidance, discussed above, concerning the scope of the Agency's enforcement priorities and its priorities towards certain classes of illegal tobacco products. In addition, JLI believes that, while FDA has taken an important step forward in identifying the types of age-verification controls needed to better prevent online sales to those underage, there is still a need for rulemaking to formalize and codify regulation of remote transactions. And to assure effective implementation of the T21 legislation, we believe FDA should take action to further clarify that the new federal minimum-purchasing age applies immediately and to all tobacco product retailers across the United States. Given the short timeline for implementation and the considerable public-health issues at stake, JLI respectfully urges FDA to take prompt action to address these considerations.

We thank the Agency for the opportunity to provide comment as it moves forward in implementing this important enforcement policy.

Sincerely,