December 8, 2023

Office of Information and Regulatory Affairs
Office of Management and Budget
1800 F Street, NW
Washington, DC 20405

RE: December 7, 2023 E.O. 12866 Meeting to Discuss the Proposed Rules "Tobacco Product Standard for Characterizing Flavors in Cigars" (RIN 0910-AI28) and "Tobacco Product Standard for Menthol in Cigarettes" (RIN 0910-AI60).

Dear Sir or Madam:

ITG Brands, LLC ("ITGB"), a leading manufacturer and distributor of tobacco products, submits this supplemental comment in conjunction with its December 7, 2023 E.O. 12866 meeting with the Office of Management and Budget ("OMB"). ITGB appreciates the opportunity to meet with OMB to discuss FDA's proposed rules entitled "Tobacco Product Standard for Characterizing Flavors in Cigars" (RIN 0910-AI28) and "Tobacco Product Standard for Menthol in Cigarettes" (RIN 0910-AI60). These rules, if finalized, will have unknown and potentially drastic consequences for the economy, government at all levels, and, most importantly, the public health. Accordingly, ITGB submits this comment to document certain points raised in the meeting.

ITGB is a subsidiary of Imperial Brands PLC, headquartered in Bristol, UK, which is the parent company of numerous international businesses involved in the distribution and sale of tobacco and non-tobacco products. ITGB is currently the third-largest tobacco company in the United States, offering a broad portfolio of some of America's most well-known cigarettes, including Winston, Kool, Salem, Maverick, and USA Gold. ITGB also produces some of the most well-known and popular brands of mass-market cigars, some dating back to 1879.

ITGB agrees with FDA's position that principles of sound regulatory science should govern the Agency's policy actions and decision-making. ITGB supports the proportionate, evidence-based regulation of the tobacco industry in a reasonable, workable, and efficient manner while achieving the goals of the Family Smoking Prevention and Tobacco Control Act ("TCA"). To this end, ITGB has long been deeply engaged with FDA on regulatory and scientific issues associated with the Agency's ongoing efforts to implement provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the TCA, including its efforts to promulgate sound regulations required by these Acts. ITGB thus has a significant interest in, and unique insights regarding, the rulemakings under consideration by OMB.

With respect to the proposed rules, ITGB wishes to document certain points that we raised during the meeting that should inform OMB's ongoing evaluation:

- FDA is required to consider the countervailing effects of the proposed rules, such as the "creation of a significant demand for contraband or other tobacco products" and the "significance of such demand."[1] But as the record indicates, the Agency has failed to meet this statutory obligation.

    - This discrete statutory requirement is codified at Section 907(b)(2) of the FDCA.[2] Comparable statutory provisions in other contexts rarely require the Agency to account for potential contraband and other unintended consequences. As briefly described above, the FDCA obligates FDA to consider all information submitted in connection with a proposed tobacco product standard, "including information concerning the countervailing effect of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products . . . and the significance of such demand."[3]

      ITGB believes that the proposed rule, if finalized, would fail to satisfy this statutory requirement. Indeed, it is evident from the record that FDA did not adequately address in the proposed rule the risk that the proposed product standards will significantly increase illicit market sales of contraband menthol cigarettes and flavored cigars, supercharging the already large illicit market that exists for these products. FDA's discussion of these issues in the proposed rule is, at best, cursory:

        - "There are possible countervailing effects that could occur from the proposed product standard, if finalized. Potential risks to the population, however, would generally only occur among individuals currently using tobacco or smoking cigarettes as FDA concludes there are little to no risks to nonusers of tobacco."[4]

        - "The countervailing effects on current tobacco users could include continued combusted tobacco product smoking, smokers seeking to add menthol to their combusted tobacco product, and the possibility of illicit trade."[5]

        - "[T]he removal of menthol cigarettes from the marketplace could

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1 *See* 21 U.S.C. § 387g(b)(2).

2 *See id*.

3 *Id.*

4 87 Fed. Reg. 26454, 26483 (May 4, 2022).

5 *Id.*

result in some people seeking menthol cigarettes through the illicit trade market. FDA is considering whether illicit trade could occur as a result of a menthol product standard and potential implications."[6]

- "FDA finds that, while there may be countervailing effects that could diminish the expected population health benefits of the proposed standard, such effects would be minimal. Therefore, these effects would not outweigh the potential benefits of the proposed product standard."[7]

➢ FDA has historically lacked—and continues to lack—the resources to address the current illicit market for tobacco products, let alone the looming much larger one for contraband menthol cigarettes and flavored cigars that a ban on such product categories would create. Indeed, the current market is rife with illegal, contraband tobacco products—including certain flavored e-cigarettes, which are putatively a priority for FDA enforcement.[8] FDA's failure to meaningfully clear the market of these illegal products undermines the public health objectives of the statute as a whole, as reputable manufacturers like ITGB are disincentivized to commit the time and resources necessary to obtain premarket authorization from FDA when they will be forced to compete with illegal products that continue to appear at retail with no FDA action.

- FDA announced in January 2020 that it would prioritize enforcement against cartridge-based e-cigarettes marketed in flavors other than tobacco and menthol, citing the higher prevalence of use of these products among youth at the time.[9] And yet, since then, FDA has struggled to clear the market of unauthorized and illegally imported vaping devices.[10] Consider the findings of a recent Centers for Disease Control and Prevention ("CDC") study that analyzed retail scanner data from January 2020 to December 2022. CDC determined that while shares of tobacco-flavored products decreased from 28.4% to 20.1% during this period, unit shares for flavored products (other than mint) increased from 29.2% to 41.3%.[11] Similarly, the market share for

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6 *Id.*

7 87 Fed. Reg. 26396, 26423 (May 4, 2022).

8 *See e.g.*, Christina Jewett, *Illicit E-Cigarettes Flood Stores as F.D.A. Struggles to Combat Imports*, NEW YORK TIMES (Oct. 10, 2023), https://www.nytimes.com/2023/10/10/health/illegal-vapes-ecigarettes-fda.html; Matthew Perrone, *Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors*, ASSOCIATED PRESS (June 26, 2023), https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f.

9 *See* FDA, Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, Apr. 2022, https://www.fda.gov/media/133880/download.

10 Fatma Romeh et. al, *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020-2022*, 72 CENTERS FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND MORTALITY WEEKLY REPORT 672, 674 (2023).

11 *Id.* at 672.

pre-filled, pod-based products decreased from 75.2% to 48%, while the market share for disposable e-cigarettes increased from 24.7% to 51.8%.[12] CDC also collected sales data from the 4-week period ending December 25, 2022, finding that two of the top-five e-cigarette brands in sales during this period were Elf Bar and Breeze Smoke.[13] While FDA issued warning letters to manufacturers and distributors of both of these brands for manufacturing, marketing, distributing, and selling e-cigarettes without premarket authorization,[14] they remain widely available.

- FDA lacks the resources and capabilities to enforce the proposed product standards. Finalizing the rules will thus only serve to further flood the market with unlawful, unregulated tobacco products. In fact, the scope of the black market is already so significant that such manufacturers no longer rely on FDA and DOJ to address the problem. Both R.J. Reynolds and Altria recently filed complaints against manufacturers of illegal vaping devices to tackle the illicit market.[15]

    - Consider, the state of the illicit tobacco market in California. In December 2022, California implemented a regulation restricting the retail sale of flavored tobacco products, including menthol cigarettes, flavored cigars, and e-vapor products with a characterizing flavor of anything other than tobacco.[16] To evaluate the effectiveness of this restriction, the WSPM Group conducted a study of discarded tobacco product packaging in 10 cities in California.[17] The WSPM Group evaluated 15,000 discarded cigarette packs and 4,545 other tobacco product packs.[18] Despite the ban, flavored vapor products remain more than 97 percent of the California market.[19] Worse yet, none of the manufacturers of the brands most frequently identified in the study have obtained or sought FDA premarket authorization for their products.[20] In fact,

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12 *Id.*

13 *Id.* at 674.

14 *See* FDA, Warning Letter to Selon Company Limited d/b/a Elf Bar Flavors (June 16, 2023), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/selon-company-limited-dba-elf-bar-flavors-661240-06162023; FDA, Warning Letter to Breeze Smoke, LLC (May 25, 2023), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/breeze-smoke-llc-655821-05252023.

15 *See* Complaint, *NJOY LLC v. iMiracle HK Limited et al*, 2:23-cv-08798, (C.D. Cal. Oct. 19, 2023) ("Altria Complaint"); Complaint, R.J. Reynolds Tobacco Company, *Re: Certain Disposable Vaporizer Devices Vaporizer Devices and Components and Packaging Thereof* (International Trade Commission Oct. 13, 2023) ("Reynolds Complaint").

16 S. B. No. 793, § 1(b)(1) (2020) (Cal. 2020).

17 *See* WSPM Group, *Empty Packs Survey USA-CA Q2 2023* (Aug. 2023), available at https://www.altria.com/-/media/Project/Altria/Altria/about-altria/government-affairs/public-policy-positions/CA-EDP-Report.pdf.

18 *Id.*

19 *Id.*

20 *See id.* (stating that the main flavor product brands found were Flum, Elf Bar, Lost Mary, Funk Republic, and EBDesign).

FDA has issued dozens of warning letters to retailers throughout the nation for offering some of these brands for sale, such as EB Design, Lost Mary, and Funky Republic.[21]

- Responsible tobacco product manufacturers that have both sought and obtained premarket authorization for their tobacco products no longer rely on FDA to clear unlawful, competing products from the market. Indeed, litigation complaints have been filed against various manufacturers of illegal disposable vaping devices, including against the manufacturers of the brands identified in the WSPM group's study.[22] The complaints describe how FDA's repeated attempts to enforce the statute and regulations against the manufacturers of popular brands such as Breeze and Elf Bar have failed to stop them from importing, marketing, and distributing their illegal products.[23] They describe how these manufacturers target youth in their marketing of these products, using flavors like "Gummy Bear," "Rainbow Candy," and "Watermelon Bubble Gum."[24] And as mentioned above, the complaints note that the market share and sales volume for tobacco-flavored vaping products and pre-filled, pod-based products that have obtained premarket authorization have declined, while the market share of illegal disposable vaping devices has increased.[25] In short, the complaints describe how such manufacturers have thumbed their noses at existing FDA requirements. Both complaints describe, for example, how the manufacturers of Esco Bar and Elf Bar continued marketing and distributing illegal disposable vaping devices despite FDA enforcement actions intended to address these illegal sales.[26]

- In sum, despite FDA's enforcement efforts and policies, the proliferation of illegal tobacco products continues. The problem has been evident for years and remains unabated. In a 2018 fact sheet, for example, the Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF") described the illicit market for counterfeit tobacco products as a "rapidly growing global problem."[27] Indeed, "though the F.D.A. has fired off hundreds of warning letters, the effect is barely felt: [f]lavored vape sales have surged 60 percent

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21 *See e.g*, FDA, Warning Letter to Vapor Authority, Inc. (Nov. 10, 2023), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vapor-authority-inc-671219-11082023; FDA, Warning Letter to D&A Distribution, LLC d/b/a Strictly E-cig (Oct. 06, 2023), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/da-distribution-llc-dba-strictly-e-cig-666519-10062023; FDA, Warning Letter to VR Products I LLC d/b/a eJuiceDB (Aug. 23, 2023), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vr-products-i-llc-dba-ejuicedb-665291-08232023.

22 *See supra* note 15.

23 *See* Altria Complaint at 4; Reynolds Complaint at 4.

24 Reynolds Complaint at 4.

25 Altria Complaint at 30; Reynolds Complaint at 4.

26 Altria Complaint at 35; Reynolds Complaint at 14;

27 Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Fact Sheet – Tobacco Enforcement (May 2018), https://www.atf.gov/resource-center/fact-sheet/fact-sheet-tobacco-enforcement.

over the past three years, to 18 million vaping products a month in June from 11 million a month in early 2020 . . . ."[28] For these reasons, FDA's cursory statements in the preamble—that, for example, "there may be potential countervailing effects [of the proposed rules] that could diminish the expected population health benefits"—fly in the face of the current reality of the tobacco marketplace and the ubiquity of black-market products.

- Similarly, previous bans in the European Union and even the United States have been largely unsuccessful, reinforcing the likely challenges to follow any final rule.

  - Effective May 2020, the European Union banned the sale of menthol cigarettes. Yet in 2021, illicit cigarette consumption increased in the European Union by nearly 1.3 billion (or 3.9%).[29] Indeed, that year, the European Anti-Fraud Office ("OLAF") participated in national and international operations resulting in the seizure of over 430 million illegal cigarette intended to be smuggled into the European Union.[30]

  - Despite implementing a sales restriction in 2010 on all flavored tobacco products other than menthol, mint, and wintergreen-flavored cigarettes, New York state experienced the highest rate of cigarette smuggling in the nation, with nearly 52% of all cigarettes consumed illegally imported.[31]

  - An analysis of the intended and unintended effects of Canada's ban on menthol cigarettes found no evidence that menthol cigarette bans impacted the overall smoking rates for youth in Canada.[32] Likewise, following San Francisco's flavored tobacco product ban, cigarette smoking among high school students increased when compared to seven other districts in Florida, California, New York, and Pennsylvania.[33] These bans thus drove youth and adolescents to search for illicit, contraband flavored products, which are not subject to FDA oversight and therefore threaten to expose them to more harmful constituents than products that conform with government oversight and regulation.

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[28] Christina Jewett, *Illicit E-Cigarettes Flood Stores as F.D.A. Struggles to Combat Imports*.

[29] KPMG, LLC, *Illicit cigarette consumption in the EU, UK, Norway and Switzerland – 2021 Results* (June 23, 2022), https://www.pmi.com/resources/docs/default-source/itp/kpmg-eu-illicit-cigarette-consumption-report-2021-results.pdf?sfvrsn=5fe773b6_2.

[30] Organized Crime and Corruption Reporting Project (OCCRP), *EU Authorities Seized 430 Million Illegal Cigarettes in 2021* (Mar. 1, 2022), https://www.occrp.org/en/daily/16029-eu-authorities-seized-430-million-illegal-cigarettes-in-2021.

[31] Ulrik Boesen et. al, *America's Illicit Smokes Market Set to Get Larger – Banning or raising taxes on cigarettes will increase smuggling activity*, MACKINAC CENTER FOR PUBLIC POLICY (June 29, 2021), https://www.mackinac.org/americas-illicit-smokes-market-set-to-get-larger.

[32] Christopher S. Carpenter and Hai V. Nguyen, *Intended and Unintended Effects of Banning Menthol Cigarettes*, 64 JOURNAL OF LAW AND ECONOMICS 629-650 (2021).

[33] Abigail S. Friedman, *A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California*, 175 JAMA PEDIATRICS 863, 864-865 (Aug. 2021).

- Updated survey data—including data released since we submitted our previous comments—continue to show low youth usage rates of menthol cigarettes.

    - Data from the 2023 National Youth Tobacco Survey ("NYTS") show a decline in overall tobacco product use during 2022-2023.[34] Current use of any combustible tobacco product declined from 5.2% to 3.9%, and current use of cigars declined from 2.8% to 1.8%.[35]

    - 2022 data from the Monitoring the Future National Survey demonstrate that daily smoking prevalence is at an unprecedented low point for all grade levels surveyed.[36]

    - Fundamental analyses of data from the Population Assessment of Tobacco and Health (|PATH") study demonstrate that rates of cigarette use overall, and rates of menthol cigarette use in particular, continue to decline among populations FDA has deemed "vulnerable."[37] One publication that FDA itself has cited concludes that the majority of youth reported using a non-menthol cigarette for their first smoking experience, and that there is no significant relationship between first menthol cigarette use and past 12-month use among the youngest age group (12-17 years).[38]

    - The data show that youth usage of cigars remains at an all-time low.[39] 2022 NYTS data showed past 30-day youth cigar use at 1.85% and past 30-day youth flavored cigar use at 0.83%.[40] 2023 data show past

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[34] *See* Jan Birdsey et. al, *Tobacco Product Use Among U.S. Middle and High School Students – National Youth Tobacco Survey, 2023*, 72 CENTERS FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND WEEKLY REPORT 1174, 1175 (stating that from 2022 to 2023, "among high school students, statistically significant declines ($p<0.05$) occurred in current use of any tobacco product . . . .").

[35] *Id.* at 1175.

[36] *See* Richard A. Miech et. al, *Monitoring the Future National Survey Results on Drug Use, 1975-2022: Secondary School Students*, Monitoring the Future Monograph Series, Ann Arbor, MI: Institute for Social Research, available at https://monitoringthefuture.org/wp-content/uploads/2022/12/mtf2022.pdf.

[37] Population Assessment of Tobacco and Health (PATH) data are publicly available at https://www.icpsr.umich.edu/web/NAHDAP/studies/36231/versions/V37#.

[38] Andrea C. Villanti et. al, *Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1-4 of the PATH Study, 2013-2017*, 23 Nicotine & Tobacco Research 1318-1326 (Aug. 2021).

[39] *See* FDA, News Release, National Survey Shows Drop in E-Cigarette Use Among High School Students, https://www.fda.gov/news-events/press-announcements/national-survey-shows-drop-e-cigarette-use-among-high-school-students#:~:text=Among%20high%20school%20students%2C%20declines,%2C%20representing%20all%2Dtime%20lows. (Nov. 2, 2023).

[40] *Budget Office Urged to Ditch Flavored Cigar Ban*, TOBACCOREPORTER (Nov. 8, 2023), https://tobaccoreporter.com/2023/11/08/budget-office-urged-to-reject-flavored-cigar-ban/.

30-day youth cigar use at 1.6%, and rates of flavored cigar use is expected to remain under 1%.[41] Further, the most recent PATH data showed past 30-day youth use of cigars to be 0.70% and past 30-day youth use of flavored cigars to be 0.14%.[42]

- FDA has authority to address the public health issues cited in the proposed rules using its existing authorities, and without imposing additional burdens on the Agency or other stakeholders, including responsible manufacturers. For instance, FDA can engage in an educational campaign targeting the vulnerable subpopulations it refers to in the preambles to the proposed rules, as it has done so before. In 2022, FDA launched "Next Legends," a campaign that "uses unique branding and tailored messaging . . . specifically designed to educate AI/AN youth on the harmful effects of vaping."[43] FDA notes that the campaign is designed to inspire a new generation of AI/AN teens to live Native strong and vape-free. FDA could efficiently use this campaign as a precedent to launch other initiatives targeting the vulnerable subpopulations it identifies in the preambles, such as African American youth. FDA also has the authority to impose sales and marketing restrictions via regulation on a category of products, if appropriate for the protection of the public health ("APPH"). FDA has essentially done this already, attaching conditions to marketing granted orders requiring companies to take various steps before launching marketing campaigns.

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We thank you for your consideration of this comment. We are grateful for the opportunity to share our perspective with OIRA, and we urge you to take this comment into consideration as you review the proposed rules at issue.

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41 *See* Jan Birdsey et. al, *Tobacco Product Use Among U.S. Middle and High School Students – National Youth Tobacco Survey, 2023*, 72 CENTERS FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND WEEKLY REPORT 1174, 1175 (Nov. 2023).

42 *See* Population Assessment of Tobacco and Health (PATH) data, available at https://www.icpsr.umich.edu/web/NAHDAP/studies/36231/versions/V37#.

43 *See* FDA, Next Legends Campaign, https://www.fda.gov/tobacco-products/public-health-education-campaigns/next-legends-campaign#:~:text=In%202022%2C%20FDA%20launched%20%E2%80%9CNext,about%20the%20harms%20of%20vaping. (Nov. 14, 2023).

Respectfully submitted,

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