U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
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September 15, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Martin A. Makary, M.D., M.P.H.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (Docket No. FDA-2024-N-5471; 90 Fed. Reg. 5032).

Dear Commissioner Makary:

On January 15, 2025, the Food and Drug Administration (FDA) published a proposed rule titled, *Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products*.[1] The proposed rule would establish a maximum nicotine level of 0.70 milligrams per gram of total tobacco in cigarettes and certain other combusted tobacco products. This letter constitutes Office of Advocacy's (Advocacy) public comments on the proposed rule.

The FDA completed a preliminary initial regulatory analysis (IRFA) as required by the Regulatory Flexibility Act (RFA). However, Advocacy is concerned that the proposed rule's imposed costs will be so significant that small tobacco manufacturers, farmers, and retailers will be forced to close business operations.[2] Moreover, small entities including, municipalities with populations of less than 50,000, will incur a burdensome cost of enforcing state laws against illegal trade and sale of tobacco. Furthermore, Advocacy is concerned that the proposed rule lacks sufficient evidence that the maximum nicotine level will minimize risks associated with tobacco products. Industry analysts report that lowering the amount of nicotine in tobacco products may not necessarily improve health and safety concerns. Attempts to reduce or

[1] Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products, 90 Fed. Reg. 5032 (Jan. 15, 2025).
[2] U.S. FOOD & DRUG ADMIN., TOBACCO PRODUCT STANDARD FOR NICOTINE YIELD OF CIGARETTES AND CERTAIN OTHER COMBUSTED TOBACCO PRODUCTS: DOCKET NO. FDA-2024-N-5471, PRELIMINARY REGULATORY IMPACT ANALYSIS, INITIAL REGULATORY FLEXIBILITY ANALYSIS, UNFUNDED MANDATES REFORM ACT ANALYSIS 187 (Jan. 16, 2025), https://www.fda.gov/media/185035/download?attachment (FDA expects "many small firms selling only or primarily combusted tobacco products would decide to shut down … rather than experience the costs of this regulation.") [hereinafter IRFA].

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eliminate current tobacco products will potentially create additional concerns with emerging illicit markets.[3]

Advocacy also believes that the IRFA lacks essential information required under the RFA.[4] Specifically, the IRFA does not adequately discuss the costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs, the proposed rule does not adequately consider significant alternatives which could accomplish FDA's stated objectives while minimizing the economic impact on small entities. Furthermore, the proposed rule was drafted without consideration of the most recent Executive Orders on deregulation.[5]

For these reasons, Advocacy recommends that FDA rescind the proposed rule or alternatively, prepare a supplemental IRFA that accounts for the comments received from affected small entity stakeholders on the economic impact and alternative approaches to achieve its objective.

I. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed herein do not necessarily reflect the views of the SBA or the Administration.

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[6] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[7] If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis to Advocacy for such a determination that adequately supports its certification.[8]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[9] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[10]

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[3] Adam Hoffer, *FDA's Proposed Cigarette Prohibition Would Cost $33Billion in Annual Tax Revenue*, TAX FOUND. (Dec. 18, 2024), https://taxfoundation.org/blog/fda-cigarette-prohibition-tax-revenue.
[4] 5 U.S.C. § 601 et seq.
[5] *See* Exec. Order No. 14,192, 90 Fed. Reg. 9065 (Feb. 6, 2025); *see also* Exec. Order No. 14,219, 90 Fed. Reg. 10583 (Feb. 25, 2025).
[6] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601-612).
[7] 5 U.S.C. § 603.
[8] *Id.* § 605(b).
[9] Small Business Jobs Act of 2010, Pub. L. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).
[10] *Id*.

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[11]

II. The Proposed Rule

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes the FDA to adopt tobacco product standards, including product standards that include provisions for nicotine yields.[12] The FD&C Act also establishes the FDA's authority to require tobacco product manufacturers to establish and maintain records.[13]

On January 16, 2025, the FDA published a proposed rule in the *Federal Register* that would establish a maximum nicotine level in cigarettes and certain other combusted tobacco products.[14] In proposing this rule, the FDA's stated intent is to reduce the addictiveness of the aforementioned products. The agency anticipates that the proposed product standard will benefit the population as a whole and prevent people who experiment with cigarettes and cigars from developing addiction and using combusted tobacco products regularly.[15] Major components of the proposed framework include:

- Limiting the nicotine yield of cigarettes and certain other combusted tobacco products by setting a max nicotine content level of 0.70 milligrams per gram of total tobacco.
- Requiring manufacturers to analyze the nicotine levels of cigarettes and certain other combusted tobacco products covered by the rule using an analytical test method that has been validated in an analytical test laboratory.
- Requiring tobacco product manufacturers to design and implement a sampling plan that covers each batch of finished tobacco product that they manufacture.
- Requiring tobacco product manufacturers to establish procedures for the control and disposition of tobacco products that do not conform to the requirements of this rule.
- Requiring the use of a manufacturing code to serve as a common identifier for production and distribution records.
- Requiring that manufacturers establish and maintain records regarding the results of testing conducted on each batch to determine conformance with the proposed standard.

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[11] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[12] 21 U.S.C. §§ 301-392 (Authorizes the FDA to include product standards that reduce or eliminates smoke constituents or harmful components and or standardize the construction, components, ingredients, additives, smoke constituents and other properties of tobacco products and for restricting the sale of tobacco products to the extent consistent with section 906 (21 U.S.C. § 387f), section 907(a)(3), (a)(4)(A)(i) to (iii), and (a)(4)(B)(i) to (ii) and (iv) to (v)).
[13] 21 U.S.C. 387i (Authority related to adulterated and misbranded tobacco products in sections 902 and 903 (21 U.S.C. § 387b & 387c); authority regarding premarket review of new tobacco products in section 910 (21 U.S.C. 387j); authority related to prohibited acts in section 301 (21 U.S.C. 331); and FDA's rulemaking).
[14] Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products, 90 Fed. Reg. 5032 (Jan. 16, 2025) (to be codified at 21 C.F.R. pt. 1120).
[15] *Id*. at 5,032.

The FDA expects the new product standard to impose costs to the tobacco industry and the broader economy to repurpose land, labor, and capital.[16] The present value of the total estimated costs over a 40-year time horizon of the proposed rule has a primary estimate of $58 billion (ranging from $19.3 billion to $76.2 billion) at a 2 percent discount rate. Additionally, the FDA estimates the tobacco market will face a one-time primary cost with a present value range from $112 million to $700 million rate to read and understand the rule.[17] Producers of combusted tobacco products will incur a primary annualized producer surplus loss ranging from $0.2 billion to $2 billion. The FDA further estimates that manufacturers choosing to reformulate products to comply with the product standard would incur a one-time reformulation cost with a present value range of $.04 billion to $8.8 billion, as well as a one-time FDA review cost with a present value ranging from $0.1 million to $15 million.[18]

III. The FDA's Compliance with Section 603 of the RFA

The FDA determined that this proposed rule, mandating compliance with new product standard requirements, would have a significant economic impact on a substantial number of small ties. Pursuant to section 603 of the RFA, if an agency determines that a rule will have a significant impact on a substantial number of small entities, it must prepare an initial regulatory flexibility analysis (IRFA).[19] The FDA prepared an IRFA[20] that analyzed small entities likely to be impacted by this regulation in three classifications: Tobacco Manufacturers, Retailers and Wholesalers, and Small Governmental Jurisdictions.[21]

Other than referencing "…employment impacts across the tobacco supply chain including tobacco farming…"[22] and further concluding that firms will experience transition costs to reallocate land, labor, and resources, the FDA's IRFA did not include tobacco farming (NAICS Code 11190).[23] Tobacco farms are 30 percent more profitable per acre than other types of farming, which represents an important consideration in the economic impacts of the proposed rule.[24]

The IRFA is designed to refine a rule's cost assumptions by specifically analyzing its impact on small businesses. Pursuant to the RFA, an IRFA must contain:

1) A description of the reasons why regulatory action is being taken.

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[16] *Id.* at 5,113. FDA estimates the economy will incur a one-time transition cost to reallocate productive resources (such as labor and capital) ranging from $4.3 billion to $9.1 billion.
[17] FDA estimates are discounted over 40 years at a 2 percent discount rate.
[18] 90 Fed. Reg. at 5,113.
[19] 5 U.S.C. § 603.
[20] IRFA *sura* note 2.
[21] *Id.* at 183-202.
[22] *Id.* at 82.
[23] 2022 US Census data reports 1,348 of the 1,399 (96.4%) tobacco farms are considered smalls with an average annual receipt amount of $2.5 million according to the SBA size standard.
[24] U.S. Dep't of Agric., Nat'l Agric. Stat. Serv., *Census of Agriculture: 2022 Census Volume 1, Chapter 1: U.S. National Level Data*, https://www.nass.usda.gov/Publications/AgCensus/2022/Full_Report/Volume_1,_Chapter_1_US/ (last accessed Sept. 15, 2025).

2) The objectives and legal basis for the proposed regulation.
3) A description and estimated number of regulated small entities.
4) A description and estimate of compliance requirements, including any differential for different categories of small entities.
5) Identification of duplication, overlap, and conflict with other rules and regulations.
6) A description of significant alternatives to the rule.[25]

Advocacy believes that the IRFA included in the proposed rule is deficient for three reasons. First, the IRFA does not adequately identify nor describe all the regulated small entities. Second, the IRFA underestimates potential impacts to small entities. Third, the IRFA does not adequately discuss specific alternatives that may reduce that economic impact to small entities.

A. FDA Fails to Adequately Identify and Describe the Impacted Small Entities

1. Tobacco Farming

Other than small tobacco manufacturers, wholesalers, retailers, and small governmental jurisdictions, the FDA does not attempt to identify or estimate economic impacts to small tobacco farmers, or other indirectly impacted entities. As previously mentioned, the IRFA does not adequately identify or assess the economic impact on small tobacco farming (NAICS Code 11190).

According to SBA size standards, 96.4 percent of tobacco farms are small businesses. The FDA asserts that the proposed rule will force these small farms to shut down if they cannot repurpose their land, labor, and resources. Per acre, tobacco farms are 15 percent more profitable than other types of crop farming, so transitioning to other crops will reduce land values and profit margins. Advocacy encourages the FDA to properly consider the economic impact and costs to small tobacco farms faced with operating under the proposed rule. The rule may also force small tobacco farmers to completely uproot their growing practices with no guarantee of success. Farmers who choose to continue growing tobacco would face higher costs, unique difficulties in growing low-nicotine tobacco, challenges with exports, and extensive retraining needs. The FDA should consider alternative regulatory solutions that may be less burdensome than requiring small tobacco farms to shut down or repurpose land, labor, and other resources.

The FDA does not address the costs associated with small tobacco exporters. In 2023, the FDA reported that the U.S. exported $1.3 billion worth of tobacco products, both unmanufactured and manufactured tobacco.[26] U.S. small businesses identified as tobacco exporters make up approximately 97.2 percent of all tobacco exporters. On average, those small businesses currently sale 70-75% of tobacco products in the U.S.[27]

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[25] 5 U.S.C. § 603.
[26] U.S. FOOD & DRUG ADMIN, U.S. TOBACCO PRODUCT EXPORTS THAT DO NOT CONFORM TO TOBACCO PRODUCT STANDARDS, 2023. https://www.fda.gov/tobacco-products/rules-regulations-and-guidance-related-tobacco-products/reports-congress#section801p1 (last accessed Sept. 15, 2025).
[27] U.S. Export Value of Tobacco (2025) https://www.statista.com/statistics/1097931/us-exports-of-tobacco-products/

2. Tobacco Manufacturing

The FDA's IRFA indicates that not all impacted small manufacturers were counted in its analysis for various reasons, including the fact that some tobacco manufacturing businesses do not primarily identify as tobacco manufacturers.[28] The IRFA identifies 102 of 143 registered businesses that manufacture affected tobacco products are small according to the size standard of 1,500 or less employees.[29] The IRFA also reports that 69 of 102 impacted small tobacco manufacturers have less than 10 employees, and another 25 have between 10 and 50 employees.[30] These numbers demonstrate that many very small businesses are engaged in tobacco manufacturing.

The IRFA further reports that 92 of the 102 impacted small tobacco manufacturers produce only combusted tobacco products, 6 produce both combusted and non-combusted tobacco products, and the remaining 4 produce only non-combusted tobacco products. These numbers are significant because the FDA predicts many small businesses that only or primarily sell combusted tobacco products would decide to shut down or completely shift from the tobacco industry as a result of the burdensome costs of this regulation.[31]

Given the scope and magnitude of the proposed rule and the fact that the entire tobacco industry would be directly and/or indirectly impacted, the FDA should consider more data and analysis and explore viable alternatives.

3. Tobacco Wholesalers and Retailers

In addition to small tobacco manufacturers, the FDA's IRFA estimates the impact on small wholesale and retail entities using SBA size standard thresholds by associated NAICS code.[32] The IRFA reports that 96.5percent of tobacco product wholesalers are small, and tobacco retailers using various industry codes, including but not limited to grocery stores, gas stations, and drug stores, range from 66.5percent to 86.2percent of small business tobacco retailers.[33] The FDA offers a range between $1,232 and $7,698 per retailer/wholesaler in costs associated to reading and understanding the proposed rule. The FDA also predicts that retailers and wholesalers will face lost revenue from their combusted tobacco product sales but fails to offer any specific cost estimates.[34]

Advocacy spoke with representatives of small convenience products distributors. They believe that the proposed rule would prohibit the legal sale of 99.9 percent of the $82.6 billion of

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[28] IRFA, *supra* note 2, at 183-84.
[29] *Id.* at 183. FDA uses data from CTP's Tobacco Registration and Listing Module Next Generation (TRLM NG) data merged with Dun & Bradstreet firm data (D&B) data to identify business sizes.
[30] *Id.* at 184 (Chart with data pulled from D&B in October 2023).
[31] *Id.* at 187.
[32] *Id.* at 184-85. FDA notes that the estimated percentage of small retailers and wholesalers is likely underestimated because the closest Census size threshold is below the SBA size threshold for identifying small businesses.
[33] *Id.* at 185. Warehouse clubs and supercenters were the only identified tobacco retailers with no small businesses out of the nine businesses reported.
[34] *Id.* at 200.

cigarette sales in the U.S.[35] Moreover, economic theory on consumer demand indicates that ancillary retail sales gross receipts may decrease by over $70 billion due to the proposed rule effective elimination of current tobacco products.[36]

Advocacy also spoke with a representative of 604,000 Hispanic-owned businesses. They shared that tobacco products account for a significant share of foot traffic and revenue for many locally owned convenience stores, gas stations, and independent retailers across their state. They are concerned that the proposed rule would devastate small businesses across America, particularly convenience stores where tobacco-product sales typically account for a significant percentage of revenue. Studies show that tobacco sales also drive additional foot traffic and ancillary purchases that are crucial for the viability of small retailers, especially for convenience stores. The economic impact would ripple through the entire supply chain, affecting retail employees, distributors, wholesalers, and manufacturing workers. The FDA should further engage with the impacted small business stakeholders to develop alternative, less burdensome solutions to the proposed regulation.

4. Small Governmental Jurisdictions

The IRFA reportedly did not have the data to estimate the number of impacted small governmental jurisdictions.[37] Both the IRFA and the published proposed rule request comments on the regulation's unknown data impacts. The third category of small entities that the FDA believes will be impacted by the proposed regulation include small governmental jurisdictions with populations of 50,000 or less.[38] However, the IRFA does not provide any data on the number of impacted small governmental jurisdictions, nor does the IRFA provide any data on the estimated economic impact other than its discussion on the decrease in tobacco product tax revenue.[39]

Despite the fact that the FDA does not expect small governmental jurisdictions to incur any costs associated with enforcing the proposed rule,[40] local law enforcement agencies and their representatives assert that every state has laws on the books requiring enforcement of illegal tobacco sales.[41] For example, the Peace Officers Research Association of California (PORAC) in commenting on the proposed rule on behalf of 83,000 public safety members and 956 public

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[35] Statista, *Cigarettes - United States* (2025), https://www.statista.com/outlook/cmo/tobacco-products/cigarettes/united-states.
[36] Nat'l. Ass'n. of Tobacco Outlets, *Cigarette Nicotine Limits Economic Impact Study* (Dec. 12, 2024), https://www.natocentral.org/cigarette-nicotine-limits-economic-impact-study [hereinafter NATO Report].
[37] IRFA, *supra* note 2, at 186.
[38] *Id.* at 186.
[39] *Id.* at 42-43, 200. FDA estimates the baseline excise tax revenues for cigarette sales over a 40-year time horizon is $526.8 billion dollars that includes $356.8 billion in state revenues.
[40] *Id.* at 200.
[41] Nat'l. Narcotics Officers' Ass'n. Coal., Comment Letter on Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (Mar. 30, 2025), https://www.regulations.gov/comment/FDA-2024-N-5471-1110 (citing NAT'L CTR. FOR HEALTH STAT., DRUG OVERDOSE DEATHS IN THE UNITED STATES, 2003–2023 (Dec. 2024), https://www.cdc.gov/nchs/products/databriefs/db522.htm. in support of its argument that the proposed rule will only increase the sale of illicit black markets to include tobacco sales, currently estimated as an $80 billion dollar a year industry in the U.S.).

safety associations in California documented the dire consequences of the previous FDA regulation of candy-flavored vapor products.[42] FDA received comment from several local governmental small entity stakeholders highlighting the rule's negative impact on public safety, illicit sales, and government revenues. State and local governments would experience significant decreases in tax revenue, while simultaneously facing increased costs for law enforcement to combat the inevitable illicit market.[43]

B. FDA Underestimates the Economic Impact of the Proposed Rule to Small Entities

The National Association of Tobacco Outlets (NATO) report estimates cigarette and other tobacco product sales amounted to over $90 billion overall in 2024.[44] The report further estimates gross sales to decline by $71.4 billion nationwide, with retailers' revenue reducing to $13.9 billion in the first year with additional economic losses in future years.[45]

The FDA's IRFA does not adequately estimate the economic impact to small entities. As noted by the agency, "We expect that small firms would experience long-term changes to their revenue due to the proposed product standard."[46] The FDA further predicts that many small manufacturers would be forced to close businesses if they cannot transition manufacturing and production. However, the IRFA fails to detail or estimate the economic impacts to the entire tobacco industry due to the elimination of a great number of manufactured goods.

Additionally, small tobacco businesses that choose to transition product offerings instead of closing are likely to face significant costs associated with research, development, product design, manufacturing, testing, and other compliance costs related to the regulation. Reducing these burdens should receive greater emphasis in the IRFA and they should be assessed for significance and alternative approaches. The FDA's IRFA emphasizes assessment of annualized cost estimates over a 40-year period and underappreciates product compliance costs.[47] The IRFA should include more data and analysis to provide the public with sufficient consideration on the economic impact of the proposed rule.

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[42] Peace Officers Rsch. Ass'n. of Cal., Comment Letter on Tobacco Product Standard for Nicotine Yield of Cigarettes and Certain Other Combusted Tobacco Products (Jan. 16, 2025), https://www.regulations.gov/comment/FDA-2024-N-5471-0949 (suggesting that the proposed rule would effectively ban the legal sale of cigarettes in the US and ultimately present "severe unintended consequences, including the growth of an unregulated black market that will ultimately undermine both public health and safety objectives.").
[43] Advocacy reviewed several comment letters from local law enforcement stakeholders, including Law Enforcement Action Partnership (LEAP), National Narcotics Officers' Associations' Coalition (NNOAC), Minnesota Sheriffs' Association, and many others.
[44] NATO Report, *supra* note 34, at 2.
[45] *Id.* at 3.
[46] IRFA, *supra* note 2, at 190.
[47] *Id*. at 190-200.

IV. The FDA Failed to Adequately Consider Significant Regulatory Alternatives

The final rule would have an effective date two years after its publication in the *Federal Register*.[48] The FDA considered the idea of delaying the effective date to six years after publication.[49] Despite the fact that a delayed compliance date would reduce reformulation costs for tobacco manufactures by 42.9 percent, the FDA ultimately rejected the alternative due to decreased benefits.

The RFA requires that an IRFA consider significant, alternatives for small entities that minimize their costs, are feasible, and accomplish an agency's objectives. In view of the potentially high costs associated with the rule, the IRFA does not adequately consider significant alternatives which minimize the economic impact of the proposal on small entities. The FDA seeks to reduce the consumption rates of combustible tobacco products by implementing the proposed rule. However, several small tobacco business stakeholders comment that, the FDA can continue experiencing the record lows of cigarette consumption simply through additional educational and awareness campaigns.[50]

Small tobacco industry stakeholders further assert that the FDA should increase awareness and educational campaigns to achieve greater health and safety successes without unnecessarily burdening the tobacco industry. Specifically, stakeholders suggest several solutions, including increasing tobacco use cessation support and concentrating more resources on underage tobacco use prevention. The FDA should seek input from affected small entities for regulatory alternatives that may reduce the regulation's economic burden.

V. Advocacy's Recommendations

Because of deficiencies in the IRFA, Advocacy is concerned that the public has not been adequately informed about the possible impact of the proposed rule on small entities. Small entities have also not been given sufficient information regarding less burdensome significant alternatives to the proposed rule that would meet the FDA's objectives. For these reasons, the FDA should withdraw the proposed rule or prepare and make available for public comment a supplemental IRFA.

The supplemental IRFA should adequately describe the regulated small entities and estimate potential impacts to those entities. The FDA should provide detailed information that will allow the agency to analyze the relative impact of costs based on entity size. The FDA should also

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[48] 90 Fed. Reg. 5032, 5036.
[49] IRFA, *supra* note 2, at 182.
[50] Ctr. for Disease Control, *Burden of Cigarette Use in the U.S., 2022*, https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html (last reviewed Oct. 8, 2024) (reports 11.6% of U.S. adults currently smoke cigarettes down from 14.0% in 2019); Ctr. for Disease Control, *Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States*, *2024* (Oct. 17, 2024), https://www.cdc.gov/mmwr/volumes/73/wr/mm7341a2.htm?s_cid=mm7341a2_w (reports 1.7% of high school students smoke cigarettes, 1.5% of high school students smoke cigars, and 0.5% of high school students smoke pipe tobacco). Both surveys found that cigarette smoking at present is at an all-time low.

analyze costs borne by industry segments where the regulation would require novel or complex compliance measures. Further, the supplemental IRFA must include a broader range of alternatives which accomplish the agency's objectives for the rulemaking, as required by the RFA. Advocacy encourages the FDA to provide a detailed analysis of each potential alternative and to discuss how that alternative may reduce the economic burden on small entities. This analysis should be published in a supplemental IRFA to provide small entities with an opportunity to comment.

The FDA's proposed rule considered extending implementation for small businesses to six years but ultimately rejected the alternative. The proposed rule seeks comments from affected small entities in the tobacco industry on economic impact data and solution alternatives. The FDA should reconsider an extended compliance timeline with meaningful support to small entities, including but not limited to:

- Subsidized or shared lab testing facilities to allow small manufacturers to test new compliant products.
- Cost-effective guidance for testing, sampling and recordkeeping to smalls who cannot afford those staffing/technology demands.
- Exemptions or alternate compliance paths for small operators, accompanied by sunset provisions to ensure companies have a real opportunity to comply before going out of business.
- Coordinated enforcement efforts to focus on illicit trade and protect compliant retailers from unfair competition and local peace officers from enforcing state and local laws.

VI. Additional Issues

A. E.O. 14192 and the Deregulatory Mandate

The proposed rule and IRFA were produced prior to the regulatory mandates established by Executive Order 14192.[51] Executive Order 14192 requires federal agencies to "identify at least 10 existing regulations to be repealed" whenever said agency "publicly proposes …new regulation." Moreover, E.O. 14192 requires the total incremental cost of all new regulations to be significantly less than zero, as determined by the Director of the Office of Management and Budget. That is, E.O. 14192 is a type of regulatory budgeting. If the FDA moves forward with the proposed rule, the agency should comply with the regulatory budgeting by eliminating ten rules while delivering commensurate regulatory relief.

B. E.O. 14219 and the Deregulatory Mandate

The proposed rule also predates the regulatory mandate established by Executive Order 14219.[52] As a result, the proposed regulation's economic burdens trigger E.O. 14219's concern for regulations that pose undue burdens on small tobacco manufacturers, farmers, and wholesale and

[51] Exec. Order No. 14,192, 90 Fed. Reg. 9065 (Feb. 6, 2025).
[52] Exec. Order No. 14,219, 90 Fed. Reg. 10583 (Feb. 25, 2025).

retail businesses. Moreover, the FDA's proposed nicotine-yield reflects a delegation of its authority under the Tobacco Control Act, without clear congressional authorization.

Similar to the RFA, E.O. 14219 instructs agencies to measure new regulations' costs to small businesses. As previously stated, small entities impacted by the rule face substantial compliance costs, including testing, sampling, equipment upgrades, and staffing. Given the fact that the FDA anticipates shifts in tobacco use, the costs may not justify the anticipated public health benefits.

The FDA should consider whether the rule exceeds statutory authority and should incorporate a transparent assessment that demonstrates how the regulation advances constitutional governance, serves the public interest, and maintains proportional representation between costs and benefits.

VII. Conclusion

Advocacy is concerned that the proposed rulemaking and IRFA lack essential information required by the RFA. Advocacy further believes that the proposed regulation will impose greater costs on small entities than FDA assessed. Given the significant impact on small entities, Advocacy recommends the FDA withdraw this proposed rule.

Alternatively, the FDA should provide an adequate description of the affected small entities and a detailed analysis of the impact of the proposed rule to those small entities before proceeding to a final rule. The agency should also provide detailed analysis of specific regulatory alternatives that might reduce the significant economic impact to small entities. This analysis should be published in a supplemental IRFA to provide small entities with an opportunity to comment.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Will Purcell at (202) 374-0420 or will.purcell@sba.gov.

Sincerely,

/s/
Dr. Casey Mulligan
Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/
Will Purcell
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Jeffrey B. Clark, Acting Administrator
Office of Information and Regulatory Affairs