June 27, 2016

Director Mitch Zeller
U.S. Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: Regulation of Retailers as Manufacturers

Dear Director Zeller:

The National Association of Tobacco Outlets, Inc. (NATO), the Pipe Tobacco Council (PTC), and the International Premium Cigar and Pipe Retailers Association (IPCPR) collectively submit this formal request that the U.S. Food and Drug Administration's Center for Tobacco Products conduct a regulatory impact analysis as required by the Federal Regulatory Flexibility Act on the impact of those provisions in the tobacco deeming regulations that regulate tobacco retailers as manufacturers if retailers purchase bulk pipe tobacco and subsequently sell small quantities to adult consumers and/or blend manufactured legal pipe tobaccos in-store.

In order to allow sufficient time for conducting the statutorily mandated regulatory flexibility analysis, we also request that the effective dates and compliance dates of each of the applicable deeming regulations that relate to the selling and/or blending of pipe tobaccos by retailers be delayed by a minimum of 120 days or as long as needed for the Center for Tobacco Products to complete the analysis.

Regulatory Flexibility Act: Pursuant to the Federal Regulatory Flexibility Act as codified in 5 U.S. Code Section 604(a), a federal agency is required to prepare a final regulatory flexibility analysis when that agency promulgates a final rule. Specifically, this federal regulatory flexibility analysis is required to contain the following statements and descriptions:

(1) a statement of the need for, and objectives of, the rule;

(2) *a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such*

issues, and a statement of any changes made in the proposed rule as a result of such comments (emphasis added);

(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4*) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available* (emphasis added);

(5) *a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record* (emphasis added);

(6) *a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected;* and for a covered agency, as defined in section 609(d)(2), a description of the steps the agency has taken to minimize any additional cost of credit for small entities (emphasis added).

The Final Regulatory Impact Analysis: In the Final Regulatory Impact Analysis issued by the Center for Tobacco Products for the tobacco deeming regulations, the agency did not include the statements, descriptions and estimates as required in 5 U.S. Code Section 604(a), Subdivisions (2), (4), (5) and (6) as shown above relating to retailers that sell and/or blend pipe tobaccos. Rather, on Pages 25 and 26 of the Final Regulatory Impact Analysis, the Center for Tobacco Products summarized public comments and responded as follows:

[Comment]: Comments expressed concern that the term "manufacturer" could be interpreted very broadly, and, as a result, the RIA would not accurately reflect the number of manufacturers. For example, one comment questioned whether individual hand rollers of premium cigars who sell directly to retailers or consumers would be considered manufacturers. Others questioned whether retailers who blend pipe tobacco would be considered manufacturers, or retailers who mix e-liquids, as discussed above. Some comments offered policy recommendations, which are discussed in the preamble to this final rule.

[Response]: FDA has confirmed that retailers who blend pipe tobacco qualify as manufacturers under the FD&C Act….We are unable to estimate the number of retailers who blend pipe tobacco or the number of individual hand rollers of premium cigars who sell directly to retailers or consumers. Without knowing baseline numbers of such entities, it is not possible to estimate exit or compliance costs associated with the rule's expectations for manufacturing activities.

This response by the Center for Tobacco Products does not fulfill the requirements of Subdivisions 2, 4, 5 and 6 of Section 604(a) of the Regulatory Flexibility Act. That is, the response of the Center for Tobacco Products does not include a statement of the agency's assessment of the comments regarding retailers that sell and/or blend pipe tobacco, other than a conclusion that retailers that blend pipe tobaccos are manufacturers for purposes of the Food, Drug and Cosmetic Act. Moreover, the lack of an estimate of the number of retailers that blend pipe tobacco does not comply with the literal requirement that an estimate be made of the number of small retailers to which the deeming regulations on pipe tobacco would apply nor does the agency otherwise state why it was unable to estimate the number of impacted retailers.

In addition, the agency did not include: (1) a description of the reporting, recordkeeping and other compliance requirements of the deeming regulations that relate to the retail sale of pipe tobacco, (2) an estimate of the classes of small retailers that would be subject to the regulations, or (3) the kind of professional skills needed to prepare the required reports or records. Also, the final regulatory analysis did not summarize the steps that the Center for Tobacco Products undertook to minimize the economic impact on small retailers nor explain why an alternative suggested by NATO, PTC and IPCPR was rejected.

The alternative offered by all three trade groups in their respective comments on the deeming regulations recommended that retailers which blend less than 5,000 pounds of pipe tobacco annually be exempt from complying with manufacturer requirements under the deeming regulations. The main reason for this exemption is that retailers which sell and/or blend pipe tobaccos will be selling or blending pipe tobacco products manufactured by companies now subject to the deeming regulations. This means that the pipe tobaccos being sold and/or blended will have already complied with the deeming regulations and it would be unnecessary to have retailers also comply with regulations applicable to manufacturers.

However, the agency's response to these comments and the reasons for the proposed exemption concluded without an explanation that "[a]ll entities that meet the definition of 'tobacco product manufacturer' in section 900(20) of the FD&C Act, including retail establishments that blend pipe tobacco, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers."

To summarize, the final regulatory impact analysis issued by the Center for Tobacco Products for the tobacco deeming regulations lacks the statements, descriptions and estimates that are required under the Federal Regulatory Flexibility Act to inform those parties being regulated of the factual, policy and legal rationales for the position taken by the agency to regulate retailers that sell and/or blend pipe tobacco as manufacturers. For purposes of further review by the Center for Tobacco Products, copies of the comments submitted by NATO, PTC and IPCPR to the FDA regarding the tobacco deeming regulations and the regulation of retailers as manufacturers accompany this correspondence.

Actions Needed to Comply with the Federal Regulatory Flexibility Act

In order for the Center for Tobacco Products to adequately comply with the Regulatory Flexibility Act, we respectfully request that the agency take the following steps:

1. Delay the effective dates and compliance dates of those deeming regulation provisions that relate to the retail sale and/or blending of pipe tobacco at least 120 days or longer.

2. Draft a statement of the assessment by the agency of the issues raised in public comments filed regarding the retail sale and/or blending of pipe tobacco.

3. Compile a description of and an estimate of the number of small entities to which the rule will apply.

   Note: To determine an estimate of the number of tobacco stores nationwide, a significant majority of which sell and/or blend pipe tobacco, Center for Tobacco Products staff should consider researching the U.S. Census economic data for the NAICS Code 453991, Tobacco Stores, which are defined as "establishments primarily engaged in retailing cigarettes, cigars, tobacco, pipes, and other smokers' supplies." The number of tobacco stores that roll cigars is very limited and significantly less than the number of tobacco stores that sell and/or blend pipe tobacco.

4. Draft a description of the projected reporting, recordkeeping and other compliance requirements of the deeming regulation that relate to the retail sale and/or blending of pipe tobacco, including an estimate of the number of small retail businesses which will be subject to the regulations and the type of professional skills necessary for preparation of the regulatory reports.

5. Explain the steps the agency has taken to minimize the significant economic impact on small retailers consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why the other significant alternative(s) proposed by NATO, PTC and IPCPR were rejected.

With the deeming regulations scheduled to take effect on August 8, 2016, we would ask that the Center for Tobacco Products immediately delay the effective dates and compliance dates of those provisions in the deeming regulations that regulate retailers that sell pipe tobacco as manufacturers and complete the regulatory impact analysis as soon as possible. With time being of the essence, please reply to this request to inform us if the effective dates and compliance dates will be delayed. We appreciate your consideration of these requests and we will await your response.

Sincerely,

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