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Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA– 2013–N-1588 Agency Information Collection Activities; Proposed Collection; Comment Request; Exemptions From Substantial Equivalence Requirements for Tobacco Products

Dear Sir or Madam:

The Cigar Association of America, Inc. ("CAA") is a leading national trade organization representing the interests of cigar manufacturers, importers, distributors, and major suppliers of the industry. CAA was founded in 1937 as a non-profit trade organization. Today, its 35 member companies come from all sectors of the industry, from major manufacturers of handmade premium cigars to producers of machine-made cigars. CAA members manufacture a significant share of the large, premium, little, and filtered cigars sold in the United States. Its members also include internet retailers of cigars, as well as leaf, and other suppliers to the cigar industry. CAA is a key stakeholder in the implementation of any regulation of cigars, as these regulations significantly affect its members' ability to conduct business.

CAA writes today to comment on the above referenced request for comment ("Request for Comment") on Agency Information Collection Activities relating to Exemptions from Substantial Equivalence Requirements for Tobacco Products ("SE EX Reports"). This is not the first time CAA has submitted comments regarding the Substantial Equivalence process as it relates to cigars.[1] CAA builds on these other substantive submissions with its comments to this Request for Comment. This Request for Comment asks for comments on four topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.[2] CAA will offer comments first on what is and is not known about the content of an SE EX application and, second, on FDA's burden estimates for this pathway.

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[1] CAA has submitted numerous comments to FDA regarding the Substantial Equivalence Process under dockets for Proposed Rules, Advanced Notices of Proposed Rulemaking and Requests for Comments on Information Collection Activities and incorporates the following specific comments by reference. *See* CAA comments to Docket No. FDA-2013-N-1558 (submitted Fed. 24, 2014); CAA comments to Proposed Deeming Rule Docket No. FDA 2014-N-0189 (submitted Aug. 7, 2014); CAA comments to the Advanced Notice of Proposed Rulemaking: Regulation of Premium Cigars Docket No. FDA-2017-N-6107 (submitted July 25, 2018) ("the Substantial Equivalence Process as currently implemented is fundamentally flawed to premium cigars."); CAA comments to Regulatory Reform FDA-2017-N-5095 (submitted Feb. 5, 2018) (" FDA has to date provided no guidance on any product specific requirements for what cigar substantial equivalence applications would need to contain.").

[2] Agency Information Collection Activities; Proposed Collection; Comment Request; Exemptions from Substantial Equivalence Requirements for Tobacco Products. 83 Fed. Reg. 46,501, 46,502 (Sept. 13, 2018).

I. The SE EX Pathway – what it is, and what it is not

Under the Tobacco Control Act, the SE EX pathway (sometimes referred to as the "minor modifications" pathway) is intended for "tobacco products that are modified by adding or decreasing the quantity of an existing tobacco additive, if the Secretary determines that – (1) such modification would be a minor modification of a tobacco product that can be sold under this Act."[3] The SE EX pathway is the one pre-market tobacco product application pathway for which FDA has promulgated a Final Rule regarding the contents of such a request for exemption.[4] Notwithstanding the Final Rule, however, there remains uncertainty as to precisely what is to be included in such an application, and what modifications would qualify for the exemption.

The Final Rule for the SE EX pathway states the following are required for any application:

- A detailed explanation of the purpose of the modification;
- A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing the quantity of an existing tobacco additive;
- A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug and Cosmetic Act;
- A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug and Cosmetic Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health;

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[3] Family Smoking Prevention and Tobacco Control Act §905(j)(3)(a) ("Tobacco Control Act" or "TCA")).

[4] *See* 21 C.F.R. §1107.1.

- A certification summarizing the supporting evidence and providing a rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;
- Other information justifying an exemption; and
- An environmental assessment.[5]

This is the extent of the formal guidance industry has regarding the SE EX pathway. FDA recently stated it estimates that an SE EX application should be "short" -- approximately 25 pages.[6] Proposed length aside, however, FDA has not given industry any indication of the specific modifications it would accept as "minor." Further, as was stated at the Public Meeting, industry has made numerous requests to FDA for specifically identified categories of minor modifications that could be used for the SE EX pathway.[7] As is often the case, and as similarly noted in CAA's comments to the Request for Comment on Information collection regarding Substantial Equivalence Reports, industry is left to guess how to proceed.

In the Tobacco Control Act, Congress recognized that changes to tobacco products can -- but do not always -- raise different questions of public health.[8] Further, Congress recognized there are modifications that can be made to tobacco products where an inquiry into whether those

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[5] *See* 21 C.F.R. §1107.1.

[6] *See* Tobacco Product Application Review- A Public Meeting, October 22-23, 2018 ("Public Meeting"). The transcript and slide presentations from this meeting have not yet been made public, however, CAA representatives were in attendance.

[7] *See* Public Meeting.

[8] Congress actually recognized that most changes or modifications to tobacco products do not raise different questions of public health. If a new tobacco product has the "same characteristics" as a predicate tobacco product it is assumed to not raise different questions of public health, further an SE Order can only be entered for a new tobacco product that has "different characteristics" that "does not raise different questions of public health." TCA sec. 910(a)(3)(A).

modifications raised different questions of public health was simply unnecessary. As FDA recently shared at the Public Meeting, the SE EX pathway can even be used to make a minor modification to a product that is allowed to be marketed pursuant to a PMTA Marketing Order, even though the SE pathway itself is not open to the product (as a product that has received a marketing order through the PMTA pathway cannot serve as a predicate product).[9] What FDA has not done, similar to its failings for the SE process itself, is define "minor modification." The Tobacco Control Act does not define this term, nor does the Final Rule for the contents of an SE EX report. Industry is again left to guess and surmise what FDA will accept as a "minor modification."

Manufactured products undergo many very simple changes for which the SE EX pathway could be used. Tobacco products are no different. What is different is that the SE EX pathway will be used for at least six, if not more, categories of tobacco products, all which could have incredibly different "minor modifications." For instance, a minor modification to a cigarette, changing from standard paper to fire safe compliant paper, is an incredibly different modification than using a different HTL binder for a cigar.

FDA should create categorical exemptions to the SE products for certain classes of minor modifications.[10] CAA believes the changes described below should not be subject to pre-market

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[9] *See* Public Meeting.

[10] FDA needs to do the work for the 905(j) process for tobacco products that it has done for the 510(k) process for medical devices. For the 510(k) process FDA has extensive Guidance for industry on when and what changes require a 510(k) application. *See* Guidance for Industry and Food and Drug Administration Staff: Deciding When to Submit a 510(k) for a Change to an Existing Device. (Oct. 25, 2017). For the 510(k) process it is acknowledged that there are changes made to medical devices that will not require a 510(k) report – the same should be true for the 905(j) process.

review at all or, if forced into pre-market review, should be given categorical exclusions to the SE process – minor modifications where the SE EX pathway is used:

- *Supplier Changes* - if a manufacturer has to change suppliers of an ingredient or additive, FDA has previously indicated that this change could be the subject of a regular SE Report, or that in the context of an SE Report, a company will need to explain how these alternative ingredients do not raise a different question of public health. Substituting one ingredient for another does not raise any question about the product -- and manufacturers should not have to put minor alterations to a product such as this through any pre-market review. If FDA insists on these changes needing to be reviewed, they should be subject only to the SE EX pathway.
- *Product Standards* - If FDA promulgates a product standard and a product is changed only to conform to that standard, the SE EX pathway should be used for those changes. FDA has indicated that its current view is that an SE Report would be required for this type of mandated change to a product. In the only proposed product standard FDA has issued to date, the agency stated:

> A smokeless tobacco product that has been modified to comply with the product standard would be a "new tobacco product" and subject to premarket review. FDA believes that changes made solely to bring a smokeless tobacco product into compliance with the proposed rule would be appropriate for an SE submission.[11]

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[11]Proposed Rule: Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products. 82 Fed. Reg. 8004, 8009 (Jan. 23, 2017).

This means that any product standard FDA imposes would require ALL products within that class of tobacco products to go through the regular SE process. By imposing a tobacco product standard, FDA will have already determined that the standard is "appropriate for the protection of the public health."[12] Assuming a product standard might create "different characteristics" in the predicate and new tobacco products, FDA is taking the position that these products would need to go through the SE Pathway. This makes no sense, as these products by definition do "not raise different questions of public health" -- they are being implemented for the "protection of the public health." Requiring products subject to a product standard to have to file SE Reports (i) is not an efficient use of agency resources to review these Reports; and (ii) will require industry to not only endure the burden of implementing the product standard, but then be held to a public health standard that should not apply to changes required by FDA action. Instead, there should be categorical exclusion for all products that are modified only to conform to a product standard.

- *Packaging* - FDA has implied that changes to the so-called "container closure system" may require the product to file an SE Report. The "container closure system" appears to be any packaging that touches the tobacco product, whether the packaging touches the product or not. FDA has not yet defined this term, using it only in decisions on Substantial Equivalence applications, so once again industry is left to guess what is, and is not, subject to review. CAA does not believe that

[12] Tobacco Control Act sec. 907(3)(A).

packaging changes of any kind create a new tobacco product. The definition of "tobacco product" in the Tobacco Control Act is "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product."[13] This definition does not include "packaging," which is separately defined in the Tobacco Control Act as "a pack, box, carton, or container of any kind, or if no other container, any wrapping (including cellophane) in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers."[14] These are two very distinct definitions. As Judge Mehta noted:

> Finally, it is important that none of the actual terms that Congress used to define the term "new tobacco product" – and thus to initiate substantial equivalence review – can be read to encompass anything other than the physical attributes of the product itself, as distinct from its label or the package in which it is contained."[15]

Packaging changes, whether FDA uses an undefined term of a "container closure system" or not, should not have to undergo pre-market review. At most these products should have to show why they fall into a categorical exemption from substantial equivalence review and file an SE EX.

- *Product Quantity* - Changes such as to product quantity would more appropriately be done through the SE EX pathway than the SE Pathway, to preserve both industry and FDA resources. By requiring product quantity changes to submit SE EX applications

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[13] Tobacco Control Act Sec. 101(a).

[14] Tobacco Control Act Sec. 900(13).

[15] *Philip Morris USA Inc. v. United States Food and Drug Admin.*, 202 F. Supp. 3d 31, 50 (D.D.C. 2016).

rather than SE applications, FDA would still be requiring the application to provide a "detailed explanation of the purpose of the modification," but would allow both FDA and industry to more efficiently utilize resources. For example, it makes little sense for industry to prepare, and for FDA to review, full SE Reports because a package of five cigars is now sold as a package of six. FDA, however, currently requires a full SE Report for these types of minor modifications to products.

- *Changes in non-tobacco additives* - Tobacco product manufacturers at times try to modify certain non-tobacco additives, such a glycerin in roll-your-own tobacco, or adhesive in cigars, which do not change smoke yields, or otherwise change the ultimate experience or deliverable to the consumer. To date, however, FDA has not defined these changes as a categorical exemption to the SE process.
- *Changes in physical design* - Certain physical design changes can be made to a product that, again, will not change the smoke yields or any consumer deliverable. For instance, a cigar can have a shagged or unfinished cigar foot, or a rounded or pigtailed cigar head. These aesthetic changes do not alter the characteristics of the cigars or raise different questions of public health. CAA believes product changes like this should not have to go through any pre-market review; however, if they are, the SE EX pathway would be the most appropriate.

These are but a few examples of minor modifications where categorical exemptions should be made; there are others, depending on the product. Each category should have its own list of categorical exemptions – such as changing to fire safe cigarette paper in a cigarette product.

FDA needs to both define "minor modification" and provide industry with categorical exemptions across all categories, and within each tobacco product category.

II. FDA's Estimates

The lack of definition of "minor modification" and the lack of clarity of the types of changes that can be brought through the SE EX pathway make FDA's estimates in the Request for Comment particularly troubling. FDA estimates that 812 respondents will submit SE EX applications *annually*.[16] This is only an increase of 312 respondents from FDA's previous estimate of 500.[17] Further, as with the previous estimate, FDA estimates that each of these respondents will submit only one response.[18] FDA provides no reasonable explanation of how these estimates were derived.

Moreover, FDA does not state what types of changes these applications will be made for, or what products will be utilizing the pathway. The only attempted explanation for these estimates is the following: "FDA's estimates are based on full analysis of economic impacts and information gathered from other FDA-regulated products. Based on review of current information collection, we have made no adjustments to our burden estimate."[19] FDA fails to explain how it estimates it will receive 812 SE EX applications in a year, when it has only

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[16] 83 Fed. Reg. at 46,503.

[17] Agency Information Collection Activities; Proposed Collection; Comment Request; Exemptions from Substantial Equivalence Requirements for Tobacco Products. 76 Fed. Reg. 76,838, 76,840 (Dec. 19, 2013).

[18] *Id.*

[19] 83 Fed. Reg. at 46,504.

received 153 in 9 years in total. And it is perplexing that, with the addition of the newly deemed products, FDA has not even doubled its expected estimates when the volume of newly deemed products vastly outnumbers that of originally regulated products.[20]

FDA has estimated that each SE EX application will take 24 hours to prepare – 12 hours for the actual substantive application and 12 hours for the Environmental Assessment ("EA").[21] This translates to 1.5 full working days (assuming an eight hour work day) to complete an SE EX application. CAA believes this drastically underestimates, as usual, the time required to prepare any submission to the agency.

In addition, FDA currently requires an EA or an Environmental Impact Statement ("EIS") for SE EX and SE Reports for all tobacco products, which will include cigars and other newly deemed products. FDA, however, has created a categorical exception to this requirement -- for Provisional SE Reports.[22] Categorical exceptions can be made for a "category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS."[23]

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[20] Further, FDA is considering the appropriate regulatory treatment of premium cigars, including possible exemption (which CAA supports). There is no mention in these burden estimates as to whether they include premium cigars in the estimates or not. *See* Advance Notice of Proposed Rulemaking: Regulation of Premium Cigars. 83 Fed. Reg. 83 Fed. Reg. 12,901 (Mar. 26, 2018).

[21] 83 Fed. Reg. at 46,504.

[22] National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exceptions, 80 Fed. Reg. 57,531 (Sept. 24, 2015).

[23] *Id.* at 57,532.

FDA determined that "certain classes of tobacco products normally do not cause significant environmental effects" and "certain actions on tobacco-related applications do not result in significant environmental impacts to the quality of the human environment."[24] FDA justified providing a categorical exclusion for Provisional SE Reports because "[a]ctions on provisional SEs reports, by contrast will relate only to product already on the market." By definition, a product for which FDA grants an SE EX application is "exempt" from premarket review, and is not a "new tobacco product." Much like the categorical exclusion FDA provided for Provisional SE Reports, all SE EX reports should receive a categorical exclusion and not have to submit an EA.

This is the definition of requiring industry to submit something that has no "practical utility." Looking at the modifications made to products granted an SE EX, there was clearly no need for an EA. The modifications include items such as changing quantities of water and sodium chloride in smokeless tobacco, or changing to fire safe compliant cigarette paper, or deletion of monogram ink on a cigarette. None of these changes could have an impact on the "quality of the human environment." If FDA intends to limit the SE EX pathway to the narrow confines it currently occupies, CAA strongly suggests that FDA revisit this policy and provide for a categorical exception from the requirement of an EA for SE EX applications. If, however, FDA were to adopt categorical exclusion such as those CAA has offered as examples above, then EAs might be appropriate for this pathway.

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[24] *Id.*

CAA hopes that FDA will soon tackle the fundamental task of defining "minor modification," and also release both general categorical exclusions and product-specific categorical exclusions to the SE pathway. FDA promotes the SE EX pathway as one that should be utilized by industry in a similar manner to the SE pathway and the PMTA pathway; however, until FDA provides more foundational guidance, this pathway will remain underutilized, causing less efficiency for agency review and for industry. CAA hopes these comments offer perspective on the clear need for product specific categorical exemptions and a definition of "minor modification" so that proper estimates of the burden of information on the cigar industry can be calculated.

Sincerely,

Craig P. Williamson

Craig P. Williamson
President
Cigar Association of America, Inc.