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Re: Tobacco Products Scientific Advisory Committee; Notice of Meeting: Written Submission (Docket No. FDA-2017-N-0001)

The Coalition of Independent Tobacco Manufacturers of America (CITMA) respectfully submits these comments in advance of the forthcoming public meeting scheduled for April 6, 2017, to discuss the processes used in review of tobacco product applications, including premarket tobacco, substantial equivalence, and modified risk tobacco product applications.

CITMA is a trade coalition group that represents small tobacco product manufacturers (STPMs), including manufacturers of finished products, their suppliers, and importers. CITMA provides information and advisory support to its member companies to help them understand the impacts of, and comply with, FDA regulations applicable to the manufacture and distribution of tobacco products. CITMA and its members have had extensive experience with the substantial equivalence process since 2011 and would therefore like to share their views on FDA's review of substantial equivalence reports, as well as provide practical suggestions for improvements to the process.

THE SUBSTANTIAL EQUIVALENCE PROCESS

Section 905(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides an "expedited" pathway to bring to market a new tobacco product that is "substantially equivalent" (SE) to a "predicate product," i.e., a product that was on the domestic market "as of" February 15, 2007 (or another product that FDA has determined to be substantially equivalent to a product on the market "as of" February 15, 2007). *See* 21 U.S.C. §§ 387j(a)(2)(A)(i), 387e(j)(1)(A)(i). "Substantially equivalent" means that the tobacco product at issue either: (1) has the same characteristics as the predicate product or (2) has different characteristics, but the information submitted in the applicant's report demonstrates that the differences do not raise different questions of public health. 21 U.S.C. § 387j(a)(3)(A). Congress intended the substantial

equivalence process to be a streamlined "notification" process,[1] one that would be less onerous and more expeditious than a full premarket approval process. Indeed, the FFDCA states that SE reports must be submitted "at least 90 days prior to" introducing a new tobacco product into interstate commerce. 21 U.S.C. § 387(j)(1). This provision was modeled after the 510(k) device review process that requires FDA to conduct its review within 90 days. *See* 21 U.S.C. § 360(n).

Nevertheless, six years since the first industry report was filed, the substantial equivalence review process continues to be increasingly burdensome, arbitrary, and inconsistent with statutory intent. Based on publicly available statistics, only 22% of the 3589 provisional[2] reports filed by March 22, 2011, have been resolved, a significant number of which by the applicant's own withdrawal. Of all 6090 SE reports filed with FDA thus far (provisional and regular), only 16% have resulted in orders issued by the Agency; the remaining 84% of the reports are either still pending or were withdrawn by the applicant. FDA continues to request that SE applicants submit information not expressly required under the FFDCA or FDA's implementing regulations, described in any Agency guidance document or webinar, or even requested in previous reviews of SE reports seeking authorization to make similar or identical modifications to the cited predicate products. Indeed, the Agency still refuses to provide industry with adequate guidance concerning how the Agency will apply the statutory standards and what information companies must provide in SE reports.[3]

Lack of Guidance

FDA's requirements relating to the content of SE reports have been a constantly moving target. The Agency has requested new and different information over time, even from the same company for the same modifications in different reports. FDA continues to add new requirements retroactively to previously filed SE reports, sending applicants requests for additional and more specific information, most of which has never been articulated in any written or oral FDA guidance to industry.

Indeed, FDA has thus far provided very little industry guidance and instead appears to be regulating company by company and report by report in a completely arbitrary fashion. The Agency has publicly posted documents from reviews of successful SE reports, documents from reviews of unsuccessful provisional SE reports, and summary information about its bases for issuing not substantially equivalent (NSE) orders in response to regular (i.e., non-provisional) SE reports for products not yet on the market. However, most of the specific information in the review documents that would provide relevant and useful direction to industry (e.g., product

[1] *See* 21 U.S.C. § 387j(a)(4)(A).

[2] The term "provisional" report refers to an SE report filed for a product introduced or modified between February 15, 2007, and March 22, 2011, for which the manufacturer submitted an SE report on or before March 22, 2011. A product subject to such a report may remain on the market pending FDA review of the report. *See* 21 U.S.C. § 387j(a)(2)(B). In the event FDA issues a negative order in response to a provisional SE report, the interim marketing exception ceases to apply to the subject product, which then must come off the market.

[3] We acknowledge that FDA attempted to issue a proposed SE regulation back in January 2017, but the proposed regulation was withdrawn prior to publication consistent with the Trump Administration's January 20, 2017, "Regulatory Freeze Pending Review" memorandum.

specifications or other comparative data, the modifications that were the subject of the report, testing that was requested or submitted, etc.) has been broadly redacted, offering little, if any, meaningful practical information that would increase industry's understanding of the SE process.

In light of this dearth of public information and CITMA's complaints to FDA regarding a lack of guidance in this area, CTP Office of Science officials repeatedly advised CITMA to file a request with FDA under the Freedom of Information Act (FOIA) to obtain information about the SE review process. CITMA filed an initial request for "Reviewer guide to train staff re SE review process" on October 30, 2013, to which FDA never responded. On November 5, 2015, CITMA filed another FOIA request for "CTP review of SE Reports – Reviewers' Guide 1/1/12 – 11/3/15." After six months, CITMA was informed that the November 2015 request was too complex and should be narrowed. On May 16, 2016, CITMA filed another FOIA request for "CTP substantial equivalence report reviewers' guide, guidance, checklist most recent re internal CTP review of SE reports 5/11/16 – 5/31/16." On February 3, 2017, FDA provided a partial response to the May 2016 FOIA request providing only two out of at least eight sections of the SE reviewer guides. In addition to providing only a fraction of the documents requested, meaningful sections of the response were redacted by FDA (e.g., virtually all of the specific numerical values cited in the guides). On March 1, 2017, CITMA filed an appeal of these redactions with the Deputy Agency Chief FOIA Officer of the U.S. Department of Health and Human Services on the basis that the redactions were improperly withheld under Exemptions 4 and 5 of the FOIA.

FDA's report-by-report review in the absence of meaningful or specific guidance has resulted in a process that is both arbitrary and capricious. Indeed, the process has even proved to be too onerous for the largest tobacco companies, including R.J. Reynolds Tobacco Co. (RJR), which, as discussed below, received four NSE orders for provisional SE reports. This is particularly the case in the context of the irrational timeframes FDA has established for manufacturers to respond to information requests, most of which seek voluminous data that have never been described in any FDA guidance document and that many small manufacturers have never created or possessed.

Irrational Timeframes

Although the Agency now has performance measures[4] for its review of regular SE reports, it has taken the position that it does not have enough experience with provisional reports (after many years) to establish performance measures for this much larger category of reports. It is not clear why FDA's experience with regular reports is not likewise relevant to provisional reports, which are substantively identical. Moreover, despite its failure to act in a timely manner in reviewing provisional reports, FDA has set draconian deadlines for applicants to respond to detailed and demanding information requests and has issued draft guidance[5] formalizing its policy to refuse to grant extensions to any regular SE report applicant and to most if not all provisional SE report

[4] *See* Memorandum from CTP Director to CTP Deputy Director (Apr. 18, 2014), *available at* http://www.fda.gov/downloads/tobaccoproducts/newsevents/ucm393908.pdf.

[5] *See* FDA, (*Draft) Guidance for Industry: Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product* (July 2014), *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM404898.pdf.

applicants. (While the document remains in draft form, FDA appears to have implemented the policies on extension requests proposed therein.) When manufacturers do file extension requests, FDA has in some cases neglected to respond in a timely manner, thereby vitiating the utility of an extension in any event.

FDA typically allows 30 to 60 days for a response to an Advice and Information Request (AIR) letter and 30 days for response to a Preliminary Finding (PFind) letter to fully address often numerous, complex, duplicative, unclear, or inconsistent technical requests for information, much of which even very sophisticated larger manufacturers do not normally compile on a routine basis. Importantly, these timeframes are, in effect, actually even shorter than the stated numbers of days (that are themselves insufficient) in that:

1. The clock begins to run from the date of the mailed FDA correspondence, which may not be received by the company for several days;
2. The timeframe includes non-business days (e.g., weekends and holidays) and, if the deadline falls on a non-business day, FDA expects to receive the response on the previous business day (a practice that does not follow the standard legal convention of accepting the submission or filing on the next business day);
3. The timeframe terminates upon actual receipt by FDA rather than the date the response is postmarked;
4. FDA has not provided timely responses to companies' requests for clarification or explanation of its information requests, thereby preventing companies from effectively processing responses while they wait to hear back from the Agency; and
5. Many Agency requests are received in the mail with no advance notice, often bundled together with 25-50 separate product requests after several years of inactivity.

Thus, for example, if FDA gave a company 30 days to respond to an information request dated February 17, 2017, FDA's current approach would have required receipt of the response by FDA no later than Friday, March 17, providing the company only 14 business days on which to work on the response in light of the following factors:

- February 17 was a Friday, the following Monday was a federal holiday, and so the company may not have received the letter until perhaps February 23 or 24, depending on its location.
- February 24 was a Friday, and so, if the letter was received in the late afternoon on that day, work could not realistically have begun until the next business day or Monday, February 27.
- 30 days from February 17 was actually March 19, but that is a Sunday, and so the response would need to have been received on the previous Friday (March 17).
- FDA accepts responses only in hard copy format sent to its Document Control Center or via electronic filing, refusing to permit companies to use more convenient and expeditious email or fax. Because the electronic filing system has historically been unreliable, small companies generally send responses via overnight mail. Therefore, the response must have been completed and sent by March 16.

For a small company going through the SE process, perhaps for the first time, without the benefit of any up-to-date guidance or access to information disclosed only to other companies in the context of their individual reviews, a 14-day response time is grossly insufficient and unfair. The process of responding to a deficiency letter often involves reviewing and processing the numerous information requests (including determining which requests can and cannot be addressed by internal resources), consulting suppliers and outside experts, developing data and information (including in a majority of cases requiring laboratory work to be performed by an outside lab with limited capacity and many customers), and then preparing and validating the actual response. Where a small company must rely heavily on information from suppliers, consultants, attorneys, and laboratories to respond to FDA requests, which is generally the case, meeting the deadline can be especially challenging, and whether the company can actually do so remains largely out of its control.

The short response timeframes also leave little time for the company to obtain any needed clarification from FDA prior to embarking on this process, and essentially no time if FDA does not respond to the clarification request in a timely manner. If the company attempts to obtain an extension to allow for the extra time needed to obtain a clarification from FDA, or information from consultants or suppliers, it must then allocate some of its limited time and resources during the response period to prepare a detailed extension request, which is required to address each and every request for information contained in the FDA correspondence. This makes meeting the original deadline more challenging still, particularly where FDA's expectations continue to change and expand over time.

Arbitrary Information Requests

In the absence of sufficient written guidance from FDA that both provides notice to industry regarding FDA's expectations and requires consistency in those expectations, FDA's information requests in the context of SE reviews have been inconsistent, arbitrary, and capricious. What was adequate in one case has proved to be inadequate in another. As but one example, FDA has requested certain data regarding harmful and potentially harmful constituents (HPHC) for both new and predicate products. However, the Agency has asked about different smoke constituents in different reports that cite identical modifications. For a change to state-law-required fire safe cigarette (FSC) paper, for instance, we are aware of at least three different requests for HPHC data: one requested only tar, nicotine, and carbon monoxide (TNCO) data, and an SE order was issued in part on the basis that the values were not significantly different; another additionally requested data for acetaldehyde, formaldehyde, and benzene (in addition to TNCO); and the last requested data for benzo[a]pyrene, acetaldehyde, and benzene (in addition to TNCO). Accordingly, even if all industry members had access to all of these requests, which they do not, they would not know which one to consult for guidance or what to expect from FDA in the context of any individual review.

In addition, in the context of reviewing SE reports for cigarettes, FDA is requesting "target specifications and upper/lower range limits (i.e., pass/fail criteria)" for as many as twenty-eight "key design specifications/parameters" for both the predicate and new product, as well as "test data confirming that design parameter specifications … are met (i.e., measured values of design

parameters), including test protocols, quantitative acceptance (pass/fail) criteria, data sets, and a summary of the results for the design parameters" for both predicate and new product. The "specifications" sought by FDA have continued to expand over time; again, what was sufficient to support an SE order in 2014 is no longer sufficient to support an order in 2017.

Importantly, many of the "specifications" sought by FDA are not truly specifications because most (if not all) cigarette manufacturers do not use these parameters in the manufacturing process and, in the absence of good manufacturing practice (GMP) regulations for these products (which have not even been proposed), are not required to do so. Indeed, most small manufacturers had never heard of some of these parameters when FDA asked about them, and FDA has provided no guidance to industry on this issue. Through this process, FDA has essentially imposed backdoor GMPs while avoiding required notice-and-comment rulemaking. This has not only overly burdened small manufacturers; it appears that even the largest tobacco companies have been unable to develop the documentation sought by FDA in the context of SE reviews.

For example, on September 11, 2015, FDA issued NSE orders to RJR for four of its cigarette products. As the second largest tobacco company in the United States, one would expect that RJR would be able to meet any documentation requirement imposed by FDA. This appears not to be the case. In the Technical Project Lead memoranda for these SE reports, FDA observed that RJR failed to provide target specifications and upper and lower range limits for cigarette band porosity and upper and lower range limits for filter total denier and denier per filament. FDA also asserted that RJR failed to provide full test data to confirm that target specifications for various features were met. In addition, RJR apparently did not "fully characterize" the tobacco blends used in the cigarettes. If RJR is unable to adequately respond to FDA's current information requests during SE reviews, it is unclear how any small manufacturer is expected to navigate the process.

Unreasonable and Potentially Impossible Burden of Proof

Although FDA has not articulated it to industry as a whole, FDA appears to have established a standard for the "different questions of public health" criterion that in many cases industry could never meet, even with unlimited resources. For instance, FDA has imposed on applicants the burden to conclusively rule out any impact on consumer perception or consumer use for ingredient differences, even those as minor as components of non-characterizing flavors or substituted sweeteners. Indeed, at the outset, FDA appears to presume that all differences in flavoring components (even in products without any characterizing flavor) could enhance product appeal and palatability and therefore influence initiation behaviors, tobacco dependence, and continued use, thereby raising "different questions of public health." The Agency then shifts the burden to the applicant to prove otherwise without any guidance on the nature of the scientific support required to prove this negative. Thus, in lieu of establishing a product standard for flavored tobacco products, which would require FDA to go through notice and comment rulemaking and meet its statutory burden to demonstrate that the standard is appropriate for the protection of public health, the Agency has manipulated the SE process to impose a backdoor ban on flavors.

Even one of the largest tobacco companies in the United States, with its vast resources and in-house scientists, was unable to meet FDA's expectations in this regard. As an example, from the review documents of SE0000281, although largely redacted, it appears that RJR submitted data and information to support the company's position that differences in sweeteners and other non-characterizing flavoring ingredients in the compared cigarette products did not raise different questions of public health. FDA summarily dismissed these data, and its brief explanation for this action is for the most part redacted.

Without any publicly available information from FDA in guidance or elsewhere on how a company might meet its burden of proof in this context, obtaining an SE order for any new product that does not contain precisely the same flavoring components in the same amounts as those in the predicate product, including when the predicate product has a different characterizing flavor,[6] appears to be impossible. Based on FDA's implementation of the SE process to date, in order to meet FDA's apparent current burden of proof of demonstrating that any change in flavoring ingredients does not enhance product appeal or palatability, a new product would likely have to have exactly the same flavoring ingredients (including sweeteners) in the same or lower amounts as the predicate product. Indeed, in July 2016, FDA issued an NSE order for a menthol cigarette (Maverick Menthol Silver) that cited as a predicate a non-menthol cigarette without even giving the applicant an opportunity to demonstrate that the modification did not enhance product appeal or palatability, apparently presuming that such a showing was in fact impossible.

Again, Congress could not have intended this approach – which operates essentially as a ban on new or different flavors or flavor ingredients – when it established the SE "notification" pathway. This approach can have particularly draconian impacts when, for example, companies had to change flavoring ingredients after February 15, 2007, due to circumstances completely out of their control (e.g., decisions by suppliers to cease doing business with the industry, discontinuation of supplied ingredients, etc.).

Similarly, the evidentiary standard for product quantity change SE reports is unreasonable. FDA has taken the position that a change in product quantity in a product package, even if the per weight composition of additives, ingredients, and other features remains the same, renders it a new tobacco product requiring premarket review, and this position has been upheld by a U.S. District Court. FDA has purportedly offered a more "streamlined" SE report option for these kinds of changes.[7] However, the burden established in these product quantity change SE reports – that the applicant submit "scientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product compared to the

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[6] *See* FDA, *Brief Summary of "Not Substantially Equivalent Determinations*" (Sept. 15, 2015), *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM462409.pdf ("Addition of a new characterizing flavor may cause the new product to raise different questions of public health because initiation may increase and/or cessation may decrease. Addition of menthol as a characterizing flavor to a predicate product that does not contain menthol as a characterizing flavor. This causes the new product to raise different questions of public health as it relates to initiation, dependence, and cessation.").

[7] FDA, *Guidance for Industry, Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)* at 5-6 (Dec. 2016) (SE FAQ).

predicate product"[8] – is insurmountable for most small companies. As with flavor ingredients, FDA appears to presume that all differences in quantity, both increases and decreases, alter consumer behavior (i.e., harm perceptions, use intentions, and use behavior) in a negative way and then shifts the burden to the applicant to prove otherwise using scientific data. Submission of such behavioral research was not contemplated by Congress in the context of SE reports (unlike in the context of premarket tobacco product applications and modified risk tobacco product applications, where the statute references such studies) and should not be required for product quantity changes.

Industry Needs Clear Guidance or Regulation

The substantial equivalence review process has proved to be overly burdensome, arbitrary, and inconsistent with statutory intent. FDA continues to be overwhelmed with the number of SE reports for currently regulated products now six years into the review process and SE reports for newly deemed products are due by February 8, 2018. Importantly, numerous products have been removed from the market thus far as a result of the SE process, a majority after pressure from FDA to withdraw pending reports in the face of overwhelming information requests and unreasonably short response deadlines. It is clear from the SE experience so far that significant and meaningful changes to the process are needed, including the issuance of clear and comprehensive guidance for each category of products.

We understand that FDA attempted to issue a proposed regulation relating to SE reports which was subsequently withdrawn pursuant to the dictates of a memo from the White House. In the interim, FDA must address the following industry concerns:

1. Provide clear, established, consistent expectations for contents of SE reports per product category and Agency transparency in implementing those requirements;
2. Establish validated protocols and acceptable ranges for any required constituent testing;
3. Enforce of GMPs only after full rulemaking procedures following statutory requirements;
4. Establish reasonable timeframes for requests for additional information, particularly those that require laboratory testing and/or scientific analysis;
5. Enforce product standards for flavored non-cigarette products only after full rulemaking procedures following statutory requirements;
6. Establish guidelines and procedures for the submission of streamlined Same Characteristic SE Reports for differences that do not qualify as minor modifications to tobacco additives but that are not "significant" enough to qualify the products' characteristics as "different" and therefore trigger a showing that the new product does not raise "different questions of public health;
7. Establish and clearly communicate reasonable evidentiary standards for product quantity changes; and
8. Establish expedited SE procedures for changes required for compliance with state or local laws.

In particular, CITMA requests specific relief from FDA as follows.

[8] SE FAQ at 9.

1. Same Characteristics Reports

FDA should use the "same characteristics" SE pathway for certain cigar products, for state-mandated changes to LIP cigarette paper, and for other relatively insignificant modifications such as a different ink-stamp or removal of an ink-stamp on a cigarette.

As noted above, the FFDCA authorizes FDA to issue an order finding SE when FDA finds that the new tobacco product, when compared to a predicate tobacco product, either: (1) has the same characteristics as the predicate tobacco product; or (2) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by FDA, that demonstrates that it is not appropriate to regulate the product under the more extensive premarket requirements because the product does not raise different questions of public health.[9] The FFDCA defines "characteristics" broadly as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."[10]

In Philip Morris USA Inc. v. FDA,[11] the U.S. District Court for the District of Columbia interpreted the "same characteristics" prong of the definition of "substantially equivalent" as "seemingly . . . intended for physical changes that were more than 'minor,' [and thus not eligible for an SE exemption,] but yet not so significant so as to require a showing, through clinical data if demanded, that 'the product does not raise different questions of public health.'"[12] The court based this reading, in part, on Congress's intention that FDA implement the SE requirements consistent with FDA's preexisting SE pathway for medical devices, although the FDA has thus far refused to do so.[13] In the context of medical devices, a new premarket clearance is required only where there is a change to or modification of a legally marketed device and that change could significantly affect its safety or effectiveness. The burden is on the 510(k) holder/applicant to decide whether or not a modification could significantly affect safety or effectiveness of the device.

The *Philip Morris* decision leaves open what review standard FDA should apply for SE reports involving a product with the "same characteristics" as the cited predicate product (i.e., differences that do not qualify as minor modifications to tobacco additives but that are not "significant" enough to qualify the products' characteristics as "different" and therefore trigger a showing that the new product does not raise "different questions of public health") and what types of changes qualify for "same characteristics" review. FDA has so far taken the position that any physical difference between the compared products means the products have "different characteristics" requiring a showing that the new product does not raise different questions of

[9] 21 U.S.C. § 387j(a)(3)(A).

[10] 21 U.S.C. § 387j(a)(3)(B).

[11] 2016 U.S. Dist. LEXIS 108276 (D.D.C. Aug. 8, 2016).

[12] Id. at *52.

[13] Id. at *52-53.

public health. The *Philip Morris* decision guts that approach and creates a new category of non-significant changes for SE purposes: those that do not render the products' characteristics "different" and instead permit a finding that they remain the "same." Arguably, in such cases, the statute does not permit substantive review at all (as with the now moot "Same Characteristics" SE report pathway for label changes).

FDA should establish specific categories of same characteristic reports, such as for state-mandated changes to LIP cigarette paper, and for other modifications such as a different ink-stamp on a cigarette or use of a different adhesive in a cigarette or cigar product. Same characteristics reports should also be permitted for certain cigar products. Many cigars are composed of the same basic ingredients and vary only in agricultural differences in the dark, air-cured tobacco leaves used. Thus, for example, cigars of the same length and ring gauge that contain the same general type and variety of tobacco and a similar adhesive should be viewed as having the "same characteristics" because any differences between the products do not qualify as minor modifications to tobacco additives but are not "significant" enough to qualify the products' characteristics as "different" and therefore trigger a showing that the new product does not raise "different questions of public health."

As in the medical device context, FDA should provide specific guidance for manufacturers to conduct their own analysis of whether a new product has the "same characteristics" as the cited predicate.[14] Products that fall in this "same characteristics" category as compared to a cited predicate product should be required to file only basic information about the two products and should not be required to "fully characterize" both products or submit any constituent testing or other data.

2. FDA Must Issue Product-Specific SE Regulations or Guidance and Should Delay Compliance Dates for Deemed Products Until 24 Months After Publication of Product-Specific Final Regulations and/or Guidance

FDA's approach to SE reports since 2011 is arbitrary and capricious. It has not publicly communicated any of its key expectations, and regulated industry is expected to respond to ever-changing requirements within unreasonable timeframes. At a minimum, FDA must provide to industry a comprehensive list of common information and data requests for each product category and guidance on acceptable testing ranges for relevant constituents. This will allow industry to prepare high quality reports, which will reduce the Agency's workload and expedite the review process.

The submission of SE reports for deemed products on the market as of August 8, 2016, should not be required prior to 24 months from FDA's publication of final regulations or guidance relating to SE reports for the specific category of deemed products. In addition, the compliance period should extend until FDA completes its review of these SE reports and should not be set at an arbitrary one year cut-off.

[14] See, e.g., Deciding When to Submit a 510(k) for a Change to an Existing Device (FDA 510(k) Memo K97-1) (January 10, 1997).

3. FDA's Approach to Product Quantity Changes Must Be Revisited

Behavioral data should not be required in the context of product quantity change reports. Alternatively, the burden should be shifted to FDA to demonstrate that a particular quantity change has a demonstrable impact on consumer use behavior.

4. FDA Must Establish an Expedited SE Pathway to Comply with Legally-Mandated Modifications.

FDA must establish procedures to accommodate product changes made to comply with state and other laws, such as state low ignition propensity cigarette paper requirements for cigarettes or package quantity changes to comply with minimum package sizes for certain cigar products.

Thank you for your review and consideration.

Sincerely,

Kevin Altman