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

Re: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration – Docket FDA-2017-N-5093

Dear Sir or Madam:

As part of the implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," and Executive Order 13777, "Enforcing the Regulatory Reform Agenda," the U.S. Food and Drug Administration ("FDA") has solicited comments identifying regulatory reforms that could achieve meaningful burden reduction, consistent with the law and FDA's public health mission.

FDA's request is timely and coincides with Commissioner Gottlieb's recent statements regarding the Agency's effort to develop a "comprehensive regulatory plan" that more appropriately and efficiently regulates tobacco and nicotine under the authority conferred by the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"). Of particular note to these comments, Commissioner Gottlieb has noted that he has directed the Center for Tobacco Products ("CTP") to

> "explore aspects of the current application review process. In particular, I have asked CTP to consider whether its current plan, which is to review all of the so-called Provisional Substantial Equivalence products, is an effective use of its resources and whether it should continue to pursue the current approach to these reviews. I have asked CTP to consider whether there is an approach that makes more sense, and whether by not reviewing some of those products, those review resources could be freed up for other purposes and greater clarity could be provided to the market".[1]

[1] FDA, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (Jul. 28, 2017), available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last accessed 12/3/17).

We are grateful that Commissioner Gottlieb has acknowledged (at least tacitly) the inefficiencies and unnecessary burdens, on both CTP and the industry, of the current premarket review regime administered by the Agency.

These comments focus upon two areas where the CTP's current guidance/regulatory approach for currently regulated products should be modified as called for in the Executive Orders and suggest that CTP follow a similar approach as it moves forward in the future with guidance/regulations on cigars. First, in Section I below, we describe why CTP's current requirement that changes in quantity be subject to the SE process should be abandoned, as a matter of law (the language of the Tobacco Control Act does not support that such changes should be part of the SE process) and as a matter of efficient regulatory policy since CTP has not pointed to any evidence, and we are not aware of any, that quantity changes (either increases or decreases) will cause consumers to change their behavior or impact the behavior of non-consumers. Second, in Sections II-IV below, we offer comments as to why the present path to market process, most notably the Substantial Equivalence (SE) process, is not operating properly and should be replaced with a more workable, efficient process similar to that in place for medical devices. The current process has forced applicants to prove that minor product modifications do not present different questions of public health, when there simply is no research to support that the modifications at issue present any, much less, different health issues to the consumer, in violation of the Administrative Process Act (APA). This, unfortunately, is not the first time that we have attempted to address many of these issues.

On March 3, 2011, we joined a comment letter that identified the inefficiencies and burdens that would result from the approach to premarket regulation, and specifically, the framework for reviewing Provisional Product Substantial Equivalence Reports ("Provisional SEs"), that CTP was in the process of developing at the time.[2] We would refer you to that comment letter in connection with your review of the current SE process at CTP.

We believe the comments were prescient in anticipating these inefficiencies and burdens of CTP's proposed approach to premarket review. Indeed, and unfortunately, CTP's implementation of the SE review process has only become more unreasonable, arbitrary and burdensome as the subsequent years have passed.

I. FDA Should Revisit CTP's Product Quantity Change SE Application Requirements for Currently Regulated Products and Ensure That CTP Not Adopt a Similar Approach for Newly Deemed Cigar Products.

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[2] Comment of King Maker Marketing, Inc.; Commonwealth Brands, Inc.; JT International U.S.A., Inc.; Sherman's 1400 Broadway NYC, Ltd. re: Substantial Equivalence Guidance Proposed Rule on Substantial Equivalence Exemption – Dockets FDA-2010-D-0635 and FDA-2010-N-0646 (Mar. 3, 2011), available at http://www.regulations.gov/document?D=FDA-2010-N-0646-0006 (last accessed 11/10/17).

CTP has taken the position that changes to the product quantity in a tobacco product's package renders that product a "new tobacco product," even if all other product characteristics remain constant (i.e., identical per weight composition design features, heating source, and other features of the product).[3] Such product quantity changes require submission of a "Product Quantity Change SE Application."[4] We believe this interpretation is unreasonable and has led to unnecessary submissions for currently regulated products.

We have consistently taken the position that the language of the Tobacco Control Act does not support CTP's position that a company must justify an increase or decrease in usual product quantity through the SE pathway.[5] The SE pathway is concerned with and should be concerned with changes to the product itself. In addition, we remain gravely concerned that CTP has stated that both a decrease and an increase in the amount of a tobacco product can impact a consumer or non-consumer's behavior, yet cannot cite any research or other data to support this conclusion.[6] Simply put, there is no rationale or scientific justification supporting a conclusion that an increase or decrease in the amount of a tobacco product within a package has a potential impact on public health that merits application of FDA's draconian and lengthy premarket review process.[7] As such, we believe it is essential that FDA alter its approach to product quantity changes when all other product characteristics remain constant (i.e., identical

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[3] *See* FDA, Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)*, available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf [hereinafter "Third SE FAQ Guidance"].

[4] *See id.* at 6.

[5] We acknowledge that one court has taken a contrary position, *Philip Morris USA, Inc., v. FDA,* 202 F. Supp. 3d 31 (D.D.C. 2016), though it is difficult to reconcile the court's finding on this discrete issue given its conclusion 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 the physical attributes of the product itself…" *Id., at 51.*

[6] Letter to Gerard J. Roerty, Jr., Swedish Match North America, Inc. re: Swedish Match North America's Request for Supervisory Review of FDA's November 10, 2015, Not Substantially Equivalent Order for STN: SE0010528 (Appeal STN: AP0000017) (Jan. 13, 2017), available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM540974.pdf (last accessed 06/22/17).

[7] None of the sources to which FDA cites in support of the notion that tobacco product quantities impact consumer behavior and, as a result, public health, implicate, for example, smokeless tobacco or cigars. *See* FDA, Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)*, at 7 n. 10-11, available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf [hereinafter "Third SE FAQ Guidance"].

per weight composition design features, heating source, and other features of the product), either by clarifying that such changes do not result in "new tobacco products," or that a premarket application will not be required in the event of such change.

The need for a change in this aspect of premarket review is particularly acute in the case of cigars. Historically, the "same" cigar may be sold by a manufacturer in multiple packaging configurations. For instance, the cigar may be included in a "sampler" pack of multiple (different) cigars, may be sold individually, or may be sold in multiple units. In any case, the manufacturer does not modify the cigar itself in any way in creating these separate packaging configurations. It therefore stands to reason that requiring each configuration to become independently subject to premarket review will exponentially increase the number of cigar premarket submissions, with no corresponding health benefit. Rather, CTP resources will be committed to unnecessary reviews, submissions will languish, and FDA will be ineffective in achieving the public health mandates of the Tobacco Control Act. Any belief that a "Product Characteristics Change SE Report" will result in a streamlined and efficient process is pure folly based on the number of overall submissions CTP will be required to review, which will likely run in the several thousands.

In summary, the effect of product quantity on consumer and non-consumer behavior is unknown. What is certain is the vast drain on FDA resources that would result from applying premarket review to cigar quantity changes. The Agency would be better served by exempting from premarket review product quantity changes that have no bearing on the consumed tobacco product itself.

II. FDA Should Revise its Current Unduly Burdensome SE Approach to Conform to the Requirements of the APA.

As noted above, unpredictable requirements have been a staple of the SE review process. In our experience, over the course of FDA's SE evaluation of various products, FDA has requested new and different information over time even for the same modification in different reports. Often, the burden of proof required to meet FDA's "different questions of public health" standard is insurmountable in practice. To illustrate, in Advice Information Requests received with the past 12 months, FDA challenges certain low inclusion GRAS ingredients in our smokeless tobacco products as raising different questions of public health, because they could be permeation enhancers. FDA has not cited any scientific support for its position and we are aware of none.

FDA's approach essentially requires industry to "prove a negative," and is unduly burdensome. Under this approach, industry is forced to predict potential FDA objections that, due to lack of scientific support, are unforeseeable. FDA may continue to adopt new objections, despite a lack of scientific support, with industry responsible for the cost of developing data to meet FDA's "different questions of public health" standard. In the context of changes to a medical device, the regulatory framework upon which the SE process was based,[8] FDA has

[8] *See* Section IV, *infra.*

recognized the undue burden on industry imposed by this approach, stating "[i]t is not necessary to focus on hypothetical risks that are not supported by scientific evidence…"[9]

Further, FDA's current approach violates the APA. Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, [or] an abuse of discretion."[10] To avoid acting arbitrarily and capriciously, FDA, like any other agency, must articulate a satisfactory explanation for any action undertaken—including denying an SE application—by demonstrating a "rational connection between the facts found and the choice made."[11] FDA cannot, for example, rationally conclude that a low inclusion GRAS ingredient present in smokeless tobacco at levels FDA has accepted for other non-combusted products raises new questions of public health on the basis that it hypothetically could be a permeation enhancer, because it would lack any evidentiary basis for that conclusion.[12]

Principles of administrative law do not permit the agency to simply shift the burden to the Company to disprove the agency's hypothetical risk. Courts routinely police the requirement that agencies have adequate supporting evidence—rather than simple conjecture—to support their conclusions.[13] FDA has set forth no standard that industry could realistically aim to satisfy

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[9] FDA, Guidance for Industry: Deciding When to Submit a 510(k) for a Change to an Existing Device, (Oct. 25, 2017) at 41, available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm514771.pdf.

[10] 5 U.S.C. § 706(2)(A).

[11] *Prometheus Radio Project v. FCC*, 373 F.3d 372, 389–90 (3d Cir. 2004), *as amended* (June 3, 2016) (quotation omitted).

[12] *See, e.g., Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983) (concluding that agency action was arbitrary and capricious where analysis supporting its conclusion was "nonexistent"); *Ctr. for Auto Safety v. Fed. Highway Admin.*, 956 F.2d 309, 314 (D.C. Cir. 1992) ("An agency action is arbitrary and capricious if it rests upon a factual premise that is unsupported by substantial evidence."); *City of Holyoke Gas & Elec. Dep't. v. FERC,* 954 F.2d 740, 743 (D.C. Cir. 1992) ("The Commission must support its decision with enough data to enable an adversely affected party, and by extension a reviewing court, to understand its [conclusion] …, as well as the underlying assumptions."); *Owner-Operator Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 206 (D.C. Cir. 2007) (vacating regulatory provisions because the cost-benefit analysis supporting them was based on an unexplained methodology); *Lands Council v. McNair*, 537 F.3d 981, 987 (9th Cir. 2008) (en banc) (similar); *see also Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.,* 448 U.S. 607, 653 (1980) (OSHA's new standard for the permissible exposure limit on airborne concentrations of benzene was not supported by substantial evidence where the agency's rationale for lowering the permissible exposure limit was based not on any scientific or clinical finding, but rather on a "series of assumptions indicating that some leukemias might result from exposure").

[13] In *Prevor v. FDA*, for example, the District Court for the District of Columbia determined that FDA acted arbitrarily and capriciously when the agency failed to adequately articulate why it was classifying a chemical solution as a drug and device "combination product," rather than as a device.

to successfully disprove that an ingredient posing hypothetical risk raises a new question of public health. As the D.C. Circuit has repeatedly held, "it must be possible for [a] regulated class to perceive the principles which are guiding agency action" in specific decisions.[14] FDA cannot simply regulate on the basis of "I know it when I see it," which is effectively FDA's current approach to the SE standard.[15] FDA should revise its approach to premarket review to provide greater clarity, reduce undue burden on industry, and comply with the legal requirements found in the APA.

III. FDA Should Revise its Current Approach to Implementation of the SE Pathway to Remove Excessive Administrative Burden on Both the Agency and Industry.

FDA's current approach to premarket review is complicated by Agency guidance documents which (i) evidence an overly broad interpretation of SE requirements and mandate a host of unnecessary SE filings and (ii) fail to account for the practical realities of manufacturing with an agricultural product such as tobacco. The existing regulatory framework effectively requires that any change to a tobacco product's ingredients or additives be reported to FDA in an SE Report, regardless of the nature, intent, or permanency of the change. All of these considerations should be key factors in determining whether a change implicates questions of public health such that it requires FDA premarket review. Moreover, narrowly applying these factors to tobacco products is impractical, if not impossible, in light of the regional, climatic, and agricultural variability in tobacco crops. Finally, FDA's narrow interpretation of the statutory definition of substantial equivalence means that any change to a tobacco product, irrespective of how minor, is considered to automatically raise "different questions of public health." Thus, FDA's current implementation of the SE process has resulted in a deluge of premarket review

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895 F. Supp. 2d 90 (D.D.C. 2012). The Court found that FDA "did not rely on any studies or other scientific analysis in its classification" and "failed to provide an explanation based on qualitative analysis or scientific information," and held FDA's decision was based on nothing more than unfounded conjecture. *Id.* at 97-99. Similarly, in *Serv. Employees Int'l Union, AFL-CIO v. Gen. Servs. Admin.*, 830 F. Supp. 5, 10 (D.D.C. 1993), the District Court for the District of Columbia evaluated a GSA regulation providing that contractors must retroactively reimburse GSA for any wage or fringe benefit increases paid by GSA later determined by Secretary of Labor to be at substantial variance with prevailing wage and fringe benefits in the area, and found that GSA's promulgation of the regulation was arbitrary and capricious because the administrative record was comprised solely of "unsubstantiated assumptions." *Id.*

[14] *Pearson v. Shalala*, 164 F.3d 650, 660-61 (D.C. Cir. 1999) (determining FDA's requirement that "significant scientific agreement" among experts that a claim was supported by available evidence before allowing such a claim violated the APA because FDA offered no defining framework for satisfying that standard).

[15] *Id.*; *see also City of Vernon v. FERC*, 845 F.2d 1042, 1048 (D.C. Cir. 1988) ("When [an agency] chooses to rely on the mechanism of a prima facie case, it must have a theory of what a prima facie case is before it rejects claims for failure to meet that standard. ... [The agency] must say what elements are necessary and sufficient to make a prima facie case, instead of merely noting the absence of particular elements that may or may not be part of a prima facie case.").

submissions, many of which are for inconsequential and/or minor (from a public health perspective) changes that Congress never intended be subject to the SE process in the first place.

Further, CTP has utilized A/I letters to impose other regulatory burdens, in the form of information requests that address issues not properly part of the SE process. As a practical matter, FDA has required applicants to demonstrate the safety of a modified tobacco product in absolute terms, rather than pursuant to a comparison to an existing product, which essentially reads "substantial equivalence" out of the statute. For instance, FDA has used A/I letters to impose good manufacturing practices ("GMPs") and good laboratory practices ("GLPs"), notwithstanding the fact that FDA's proposed rule applying GLP regulations to nonclinical laboratory studies of tobacco products has not yet been finalized.[16]

As a result of this approach, FDA has been unable to keep pace with the Agency's premarket review workload and failed to meet its own performance measures.[17] Indeed, Commissioner Gottlieb has identified the consequences of this approach, and questioned whether it "is an effective use of [CTP] resources and whether [CTP] should continue to pursue the current approach to" premarket reviews, particularly its approach of reviewing all provisional SE Reports, or whether instead "those review resources could be freed up for other purposes and greater clarity could be provided to the market."[18]

The numbers speak for themselves. FDA has received a total of 6,724 Product Applications – premarket applications, regular and provisional SE Reports, SE Exemption Requests, and modified risk submissions – since program inception, and only 2,274 have received Final Actions, representing a 33.8% completion rate.[19] Once Premarket Tobacco Application ("PMTA") refuse-to-accept and refuse-to-file decisions,[20] regular and streamlined

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[16] Good Laboratory Practice for Nonclinical Laboratory Studies, 81 Fed. Reg. 58342 (Aug. 24, 2016).

[17] *See* Memorandum from CTP Office of Science Director to CTP Deputy Director (Apr. 18, 2014), available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/UCM485185.pdf (last accessed 10/31/17).

[18] FDA, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (Jul. 28, 2017), available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last accessed 12/3/17).

[19] FDA, Cumulative Number of Product Applications Received Since Inception, available at https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=%20CTP-OS-total-product-submissions-since-Program-Inception (last updated Jun. 30, 2017) (last accessed 10/31/17).

[20] FDA, Tobacco Product Marketing Orders, available at https://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm339928.htm (last accessed 10/31/17) (identifying 362 PMTA Final Actions as "Refuse-to-Accept" and 4 as "Refuse-to-File").

SE Report withdrawals,[21] and Same Characteristic SE Report cancellations[22] are removed from the total number of "final actions," the Agency's completion rate falls to 2.6%. Simply put, FDA has issued final orders granting or denying a PMTA or SE Report for fewer than 3% of total submissions received, despite the fact that over six years have elapsed since industry submitted more than 3,500 Provisional SE Reports before the March 22, 2011 statutory grace deadline. Even if one classifies PMTA and SE Report "refuse-to-accept" and "refuse-to-file" decisions as "final actions," there is still only an 8% completion rate. This adjustment is critical as it reflects the large number of SE Reports withdrawn by industry as a result of Judge Amit P. Mehta's opinion in *Philip Morris USA, Inc. v. FDA*,[23] which expressly repudiated FDA's erroneous application of SE review to tobacco product labeling changes.

Moreover, based on publicly available statistics, less than a third of the 3,593 provisional SE Reports filed by March 22, 2011, have received final actions, which includes an applicant's withdrawal of its own SE Report.[24] In addition, FDA reports that nearly all of the 6,125 industry SE submissions have generated one or more A/I letters from CTP, meaning that nearly 6,125 *additional* sets of data and information have also been collected as part of the Agency's current SE review process. Put simply, FDA's current approach to implementing the substantial equivalence pathway is draining scarce Agency and industry resources without advancing the regulatory goals elucidated by Congress.

IV. FDA Should Revisit the Approach Taken by the Agency's Various Substantial Equivalence Guidance Documents and Instead Adopt a Model Based on the Successful 510(k) Program, which Provided the Historical Model for the Tobacco Product Regulatory Framework in the First Instance.

In drafting Section 905(j), Congress imported the concept of "substantial equivalence" from the requirements applicable to "new" medical devices pursuant to Section 510(k) of the FDCA. Indeed, in both its wording and its intent, Section 905(j) is modeled on Section 510(k), under which a medical device manufacturer must submit a premarket notification demonstrating that a new or modified device is substantially equivalent to a legally marketed predicate device (the "510(k) Program").

As we noted in our 2011 comment letter and proposal, in creating the 510(k) Program, FDA concluded that it "should not require a premarket notification for every change…since too

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[21] *Id.* (identifying 1,328 regular and streamlined SE Report withdrawals as of Jan. 17, 2017).

[22] *Id.* (identifying 405 Same Characteristic SE Report Cancellations as of Jan. 17, 2017).

[23] 202 F. Supp. 3d 31 (D.D.C. 2016).

[24] FDA, Cumulative Number of Provisional Substantial Equivalence (SE) Reports Received Since Program Inception, available at https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OS-total-provisional-SE-since-Program-Inception (last updated June 30, 2017) (last accessed 10/31/17).

many…changes are made on a regular basis."[25] To that end, as part of the 510(k) program, FDA has promulgated a highly regarded and successful guidance document that places the onus on manufacturers to make the initial determination regarding whether a medical device modification requires a 510(k) submission. Manufacturers use a decision-tree set forth in FDA guidance to document the basis for a determination that no submission is required. FDA implemented the device modification guidance because of the routine nature of device modifications, the fact that manufacturers are best positioned to assess the impact of such modifications, and the need to lessen the administrative burden on the Agency.

We urge FDA to work with the tobacco product manufacturers to develop and implement a similar guidance document that sets forth a decision-tree, placing the onus on manufacturers to initially determine whether certain changes to a tobacco product need not be reported to FDA under the "minor modification" criteria set forth in Section 905(j)(3), concurrently with FDA's implementation of Section 905(j)(3) regulations. Further, FDA should categorically exempt certain other types of changes, such as changes necessitated by the imposition of a tobacco product standard under Section 907, from reporting under Section 905(j) and Section 910.

A. The 510(k) Program Provides a Clear Model for an Effective and Efficient Premarket Review Program

FDA acknowledged that the use of subjective language in the regulations, such as the terms "significantly" and "major," would necessarily lead to distinct and potentially inconsistent interpretations, and determined that medical device manufacturers were the most qualified to reach the correct interpretation and determinations regarding reportability.[26] FDA therefore placed the onus on industry to make these interpretations in the first instance,[27] and issued a guidance document that includes a flow chart, or decision-tree, for a medical device manufacturer to follow, and document a determination whether a particular modification triggers the need to make a filing for the modified device. FDA retains the authority to inspect a manufacturer's documentation regarding its determinations that a modification to a marketed product is exempt from a filing under Section 510(k), and to initiate enforcement if the Agency disagrees with the manufacturer's determination(s).

As a result of the decision to place the onus to determine the impact of a change to a medical device on the manufacturer, FDA reviews only "those changes that pose the potential to significantly impact safety and effectiveness."[28] This allows FDA to more efficiently and effectively utilize its resources to review those submissions that are necessary to protect the

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[25] FDA, *Establishment Registration and Premarket Notification Procedures, Final Rule*, 42 Fed. Reg. 42,519, 42,522 (Aug. 23, 1977).

[26] FDA, Deciding When to Submit a 510(k) for a Change to an Existing Device (Jan. 10, 1997), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf [hereinafter "510(k) Guidance"].

[27] *See* 42 Fed. Reg. 42520, 42522 (Aug. 23, 1977).

[28] 510(k) Guidance, *supra* note 29, at 12.

public health. Indeed, FDA noted in the preamble to its proposed 510(k) rule that the Agency had received more than 480 SE submissions in a three-month period,[29] evidencing the administrative strain that broad substantial equivalence review can impose on the Agency. In addition to reducing the administrative burden on FDA, the decision-tree framework preserves flexibility for medical device manufacturers to engage in routine modifications to their products without prohibitively complex and time-consuming administrative requirements.[30] Finally, FDA's device modification decision-tree itself, has been enormously successful for both the medical device industry and FDA, by striking a balance between the pronouncement of broad, subjective principles that are difficult to follow and detailed enumeration of specific standards, which the guidance notes would be an impossible task.[31]

Under Section 905(j) of the FDCA, a tobacco product manufacturer seeking to commercialize a "new" tobacco product must submit, at least ninety (90) days in advance of introducing the product to market, notification setting forth the basis for the manufacturer's determination that the proposed tobacco product is "substantially equivalent" to a tobacco product that is legally marketed. Per Section 905(j)(3) of the FDCA, FDA is empowered to exempt "minor modifications" to the additives used in a tobacco product from the 905(j) filing requirement in circumstances where FDA premarket review "is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health."[32]

In particular, we believe that FDA ought to place the onus on manufacturers to make the initial determination, regarding whether a modification is "minor" according to the criteria set forth in Section 905(j)(3). FDA may assist tobacco product manufacturers in reaching these determinations by issuing a decision-tree guidance document that follows the medical device model for decision-making and documentation, based on enumerated logical breakouts of changes that may be made to a tobacco product. In particular, the tobacco product decision-tree would be intended to facilitate the identification of those changes that would not generally require FDA premarket review in order to ensure that the changes would be appropriate for the protection of public health. The categories of changes that would not generally require premarket reviews would include: (i) modifications intended to ensure tobacco product consistency; (ii) modifications that do not raise public health concerns; (iii) changes in "commodity" ingredients; and (iv) changes in ingredients that are not incorporated in the consumer product. Further, we believe adoption of the medical device framework is necessary in order to successfully implement Section 905(j) in a way that does not unduly burden industry or FDA. We believe such a program would include two elements: (1) a guidance document setting forth a "minor modification" decision-tree under Section 905(j)(3) that would place the initial onus on manufacturers to identify those types of changes that may raise different questions of public health and therefore require FDA premarket review, and (2) regulations that categorically

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[29] FDA, Establishment Registration and Premarket Notification Procedures, Proposed Rule, 41 Fed. Reg. 37,457, 37,459 (Sept. 3, 1976).

[30] 510(k) Guidance, *supra* note 29, at 12.

[31] *Id.* at 2.

[32] *See* 21 U.S.C. § 387e(j)(3).

exempt certain categories of changes due to the lack of public health concern associated with such changes. Each of these elements is described further below.

B. A "Minor Modification" Decision-Tree Under Section 905(j)(3)

Under Section 905(j) of the FDCA, a tobacco product manufacturer seeking to commercialize a "new" tobacco product must submit, at least ninety (90) days in advance of introducing the product to market, notification setting forth the basis for the manufacturer's determination that the proposed tobacco product is "substantially equivalent" to a tobacco product that is legally marketed. Under Section 905(j)(3), FDA is empowered to exempt "minor modifications" to the additives used in a tobacco product from the 905(j) filing requirement in circumstances where FDA premarket review "is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health."

In implementing the "minor modification" exemption from the 905(j) filing requirement, we urge FDA to adopt the successful framework governing medical device modifications under the analogous provisions of Section 510(k). In particular, we believe that FDA should place the onus on manufacturers to make the initial determination regarding whether a modification is "minor" according to the criteria set forth in Section 905(j)(3). FDA may assist tobacco product manufacturers in reaching these determinations by issuing a decision-tree guidance document that follows the medical device model for decision-making and documentation, based on enumerated logical breakouts of changes that may be made to a tobacco product. In particular, the tobacco product decision-tree would be intended to facilitate the identification of those changes that would not generally require FDA premarket review in to ensure that the changes would be appropriate for the protection of public health. These categories of changes would include:

1. <u>Modifications Intended to Ensure Tobacco Product Consistency</u>. FDA has stated that the Agency does not intend to enforce the requirements of Section 905(j) and Section 910 for tobacco blending changes "required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product."[33] However, tobacco product manufacturers may make minor changes to additives for other reasons, to achieve the same ultimate objective – consistency.

As FDA correctly notes in its guidance document addressing the listing of tobacco product ingredients under Section 904, "in some circumstances manufacturers add ingredients based upon manufacturing specifications to affect product characteristics (e.g., to adjust for total sugars or to achieve a particular pH) resulting in the manufacturer adding varying amounts from batch to batch."[34] These changes are not intended to permanently alter the tobacco product's

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[33] *See* FDA, Third SE FAQ Guidance, at 15; FDA, Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (Jan. 5, 2011), at 4 [hereinafter "SE Guidance"].

[34] *See* FDA, Guidance for Industry: Listing of Ingredients in Tobacco Products (Revised)* (Jan. 2017), at 12, available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM52

characteristics; rather, they are intended to assure consistency across product characteristics. In addressing this common practice in the context of Section 904 ingredient reporting, FDA recommends that tobacco product manufacturers provide a "range of permitted quantities (e.g., add between 1.01 and 1.05 mg to the product," and the "targeted outcome (e.g., in order to achieve a pH of 7.1)," in each case as those values are derived from the applicable manufacturing specifications for that ingredient.[35] FDA then confirms that only permanent changes to those specifications, rather than varying a quantity of an ingredient from batch-to-batch within the specified range, triggers an obligation to report under Section 904.

However, FDA's SE guidance documents, including the Agency's January 2017 Third SE FAQ Guidance do not provide the same flexibility. Rather, under the Third SE FAQ Guidance, minor variances in ingredient quantities from batch-to-batch – even if made according to predetermined specifications and for the purpose of meeting "target outcomes" – would result in each batch constituting a "new tobacco product," as the manufacturer has "changed" an ingredient.[36] It stands to reason that the flexibility provided by FDA in Section 904 reporting should also be applied to Section 905(j) reporting as part of a 905(j)(3) exemption.

2. **Modifications That Do Not Raise Public Health Concerns.** Under Section 904(c)(3) of the Tobacco Control Act, "if at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing."[37] The reason Congress required a *postmarket* report in this context seems obvious: manufacturers should be incentivized to make such "benign" changes immediately, without a 90-day premarket waiting period under Section 904(c)(1) or substantive premarket review by FDA under Section 905(j).

However, FDA's interpretation of the substantial equivalence provisions, as outlined in the Third SE FAQ Guidance, has torpedoed this incentive structure.[38] As an example, CTP has not agreed to a streamlined process for reductions of HPHCs. A manufacturer

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7044.pdf [hereinafter "Ingredient Listing Guidance"]; FDA, Guidance for Industry: Listing of Ingredients in Tobacco Products (Nov. 2009), at 9 [hereinafter "First Ingredient Listing Guidance"].

[35] *Id.*

[36] Third SE FAQ Guidance, *supra* note 3, at 15 (stating, "blending changes that are intended to alter the chemical or perception properties of the new product (e.g., nicotine level, pH, smoothness, or harshness) compared to the predicate product, should be reported under sections 910 or 905(j)).

[37] 21 U.S.C. § 387d(c)(3).

[38] Third SE FAQ Guidance, *supra* note 3, at 15 (explaining that "[a]ny modification made to the level of an additive in a product after February 15, 2007, renders the product a new tobacco product subject to one of the regulatory pathways to market (i.e., a premarket tobacco application under section 910(b), an SE Application under section 905(j), or a request for an exemption from the substantial equivalence requirements under 21 C.F.R. 1107.1)").

seeking to make such a change would be required to submit a Section 905(j) report and, because the "new" tobacco product is not identical to the predicate, the "same characteristics" pathway for demonstrating substantial equivalence would be unavailable and the manufacturer's premarket submission would need to include data demonstrating that the new tobacco product's "different characteristics" do not raise different questions in public health. FDA's interpretation of the substantial equivalence provisions, as outlined in its various guidance documents, therefore acts as a disincentive to making benign or even beneficial changes to a tobacco product. Indeed, a manufacturer may be disinclined to spend thousands of dollars preparing a Section 905(j) premarket report when it could just as easily continue marketing the prior version of the product. Of course, this disincentive applies only to those tobacco product manufacturers which manufacture products for which an adequate predicate exists.

3. Changes in "Commodity" Ingredients. FDA's January 2017 Ingredient Listing Guidance distinguishes between ingredients that are complex and made to a tobacco product manufacturer's specifications, and those that are not (the latter category known as "commodity" ingredients). The guidance acknowledges that "many of the complex ingredients purchased for use in tobacco products are proprietary blends,"[39] and therefore that manufacturers need not provide listing information for substances "contained in a complex purchased ingredient when the ingredient is not made to your specifications."[40] The guidance further clarifies that such complex ingredients may be provided by multiple suppliers and used "interchangeably" in a single tobacco product.[41] This reflects the reality of the tobacco industry, in which ingredients are often purchased pursuant to purchase orders, as opposed to long term supply ingredients, and manufacturers frequently change vendors for business and other reasons. To the extent such a "commodity" ingredient may be purchased from several vendors, and used "interchangeably" in a tobacco product according to the manufacturer's specifications, there is no legitimate basis on which to conclude that a change in vendor will result in different characteristics that potentially raise different questions of public health. Notwithstanding this common-sense insight, under the Third SE FAQ Guidance, a manufacturer is required to submit an SE Report or SE Exemption Request if the manufacturer switches commodity ingredient suppliers and the ingredient provided by the new supplier is not "identical in every respect" to the ingredient supplied by the first ingredient supplier.[42]

4. Changes in Ingredients That Are Not Incorporated in the Consumed Product. Changes in the packaging and in the ingredients used in a tobacco product's packaging

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[39] *See* Ingredient Listing Guidance, *supra* note 37, at 11; *see also* First Ingredient Listing Guidance, *supra* note 37, at 8.

[40] *Id.*

[41] *Id.*

[42] *See* Third SE FAQ Guidance, *supra* note 3, at 14 (explaining that if a tobacco product commercially marketed as of February 15, 2007, contained food-grade sodium carbonate from one supplier and a subsequent product *was identical in every respect* except that it contained food-grade sodium carbonate in the same amount from a second supplier, FDA would not consider the second product to be a new product; therefore, submission of a marketing application such as an SE application would not be required) (emphasis added).

and other components should not be subject to reporting under Section 905(j) and Section 910, unless the manufacturer knows or intends that the ingredient added to (or otherwise modified in) the packaging or component will be incorporated in the consumed product. The FDCA defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."[43]

Historically, FDA interpreted "components, parts, and accessories" to include "tobacco, paper, and filters."[44] Indeed, the January 2011 SE guidance refers to the "component parts" of tobacco products as included rolling papers, filters, and filter tubes.[45] However, when FDA promulgated the Deeming Rule, it defined "component or part" as "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics, or (2) to be used with or for the human consumption of a tobacco product."[46] Subsequently, in a January 2017 internal appeal decision overturning a Not Substantially Equivalent ("NSE") order, CTP Deputy Director Richard J. Turman clarified CTP's position that "packaging is a component or part [of a tobacco product] where it is intended or reasonably expected to alter or affect the tobacco product's performance, composition, or characteristics… FDA refers to this subset of packaging as the 'container closure system.'"[47] Accordingly, FDA asserts that "where packaging is a component or part of a tobacco product, evaluation of changes to the packaging is within the scope of the SE review process."[48]

With respect to packaging and these component parts, unless the ingredient is incorporated in the consumed product, there is no rationale for requiring FDA premarket review of whether the change in the ingredient is appropriate for the public health; the ingredient will not in fact be ingested by humans. This result is consistent with the position taken by FDA in the ingredient listing guidance documents, which note that "when the manufacturer knows or intends

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[43] *See* Ingredient Listing Guidance, *supra* note 37, at 8.

[44] *Id.* at 3.

[45] *See* SE Guidance, *supra* note 36, at 5.

[46] Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (codifying component or part definition in 21 C.F.R. § 1143.1).

[47] Letter to Gerard J. Roerty, Jr., Swedish Match North America, Inc. re: Swedish Match North America's Request for Supervisory Review of FDA's November 10, 2015, Not Substantially Equivalent Order for STN: SE0010528 (Appeal STN: AP0000017) (Jan. 13, 2017), available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM540974.pdf (last accessed 06/22/17).

[48] *Id.*

that an ingredient added to any type of packaging will become incorporated into the consumed product, that ingredient is considered to be added by the manufacturer to the tobacco product."[49]

Further, Judge Amit P. Mehta's opinion in *Philip Morris USA, Inc. v. FDA*[50] – a federal district court case expressly reviewing FDA's SE review framework – provides additional support for this view as applied to packaging and ingredients used in packaging.[51] In that case, Judge Mehta explained that "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 the physical attributes of the product itself, as distinct from its label *or the package* in which it is contained."[52] The court added, "[t]he term 'modification' is described parenthetically to 'includ[e] a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient.' ...Again, all of those terms refer only to the physical attributes of a tobacco product—not its labeling or *packaging*."[53] Thus, the court's opinion, along with the position historically taken by FDA in its ingredient listing guidance documents, clarifies that changes to the package in which a tobacco product is contained (or changes to anything other than the physical attributes of the product) are not sufficient to initiate substantial equivalence review, provided the ingredient is not incorporated into the consumed product. FDA should permit manufacturers to make this initial determination of reportability under Section 905(j) and Section 910 for the same reason that FDA deferred to manufacturers in the ingredient listing context for an initial determination of whether the manufacturer "knows or intends" that the ingredient will be incorporated in the consumed product.

Given the structure of the Tobacco Control Act, and particularly the ingredient reporting obligations set forth in Section 904, there is no basis on which to conclude that Congress intended that the above categories of tobacco product modifications would presumptively become subject to premarket review under Sections 905 and 910. Rather, changes within these enumerated categories should be deemed "minor modifications" subject to an exemption from reporting under Section 905(j)(3). Further, just as FDA acknowledged that medical device manufacturers are best positioned to assess the impact of product modifications, FDA should place the onus on tobacco product manufacturers to determine whether a particular tobacco product modification requires reporting under Section 905(j) and Section 910. To that end, FDA should work with tobacco product manufacturers to draft a guidance document setting forth a modification decision-tree under Section 905(j)(3), using the above categories as logical breakouts.

Preparation of such a decision-tree would not be unnecessarily burdensome. The lessons learned from implementation of the medical device modification decision-tree would facilitate

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[49] *See* First Ingredient Listing Guidance, *supra* note 37, at 5; *see also* Ingredient Listing Guidance, *supra* note 37, at 8.

[50] *Philip Morris USA, Inc.*, *supra* note 26.

[51] *Id.*

[52] *Id.* at 51 (emphasis added).

[53] *Id.* (emphasis added).

the prompt development of the tobacco product modification decision-tree, and ample data are available to FDA to ensure that the system is effective. For instance, with respect to modifications intended to ensure tobacco product consistency, FDA will possess each tobacco product manufacturer's "range of permitted quantities" and "targeted outcome" for ingredients used in tobacco products. As such, an increase or decrease in amount of a particular additive, provided the quantity remains in an existing range/specification, would not be reportable under Section 905(j) and Section 910; only a permanent change in that permitted range/specification would be reportable. Similarly, with respect to tobacco product changes that do not raise public health concerns, FDA may by regulation designate those additives that are not human or animal carcinogens or otherwise harmful to health under intended conditions of use. This list can be used by manufacturers in determining whether a particular tobacco product modification is reportable under Section 905(j) and Section 910, or is instead subject to an exemption under Section 905(j)(3). In any case, these changes will otherwise be reported to FDA pursuant to Section 904(c) and, with respect to all changes, FDA possesses the authority to review underlying documentation regarding tobacco product modifications pursuant to the current Good Manufacturing Practices regulations to be issued under Section 906.[54]

5. **Changes in Product Quantity in Product Packages.** FDA has taken the position that changes to the product quantity in a tobacco product's package renders that product a "new tobacco product," even if all other product characteristics remain constant (i.e., identical per weight composition design features, heating source, and other features of the product).[55] For the reasons documented above, changes in the product quantity in a tobacco product's package, when all other product characteristics remain constant, should not be subject to reporting under Section 905(j) and Section 910, as such changes have no clear impact on public health.

C. Modifications That Should Be Automatically Exempt

While, as described above, FDA may reduce the administrative burden on the Agency and the tobacco product manufacturing industry by placing the onus on manufacturers to make initial determinations regarding whether certain types of changes trigger the need for a filing pursuant to Section 905(j) and Section 910, certain other categories of changes should be categorically exempt from these filing requirements. Such categorical exemptions would permit FDA and tobacco product manufacturers to focus resources on reviewing modifications that could change the public health profile of a tobacco product. For this reason, FDA should also promulgate a regulation categorically exempting the following two types of changes: (i) changes due to operation of law and (ii) changes to components effectuated by third parties.

1. **Changes Due to Operation of Law.** FDA should clarify that tobacco product changes implemented to comply with changes in law do not convert the products to

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[54] We acknowledge that Section 905(j)(1)(A)(ii) requires a manufacturer to submit a premarket report in connection with a modification that the manufacturer believes is subject to a Section 905(j)(3) exemption. Contrary to the SE Proposed Rule, which estimates that such a report may cost $35,000 to compile and process, we believe it would be more appropriate to permit manufacturers to submit a simple electronic notification to FDA.

[55] *See* Third SE FAQ Guidance, *supra* note 3, at 5.

"new" tobacco products triggering Section 905(j) substantial equivalence requirements. If such changes were to create a "new" tobacco product subject to Section 905(j) or 910, virtually all tobacco products on the market would be "new," and FDA would receive a deluge of submissions for no legitimate regulatory or public health purpose. For example, cigarettes were prohibited from containing characterizing flavors as of September 22, 2009, and as such, many manufacturers "modified" their products within the Statutory Grace Period to bring their products into compliance.[56] Similarly, FDA has announced that it will issue several Advance Notices of Proposed Rulemakings ("ANPRMs") that might result in legally-mandated changes to affected tobacco products.[57] Products will have to be modified to conform to any additional tobacco product standards under Section 907 arising from such rulemaking.

Substantial equivalence submissions for legally required modifications would be unduly burdensome, would serve no regulatory or public health purpose, and would unnecessarily divert valuable Agency and industry resources. Indeed, with FDA's estimate that each such report will require 360-man hours[58] and substantial financial resources to compile, requiring reports for this subset of products could drive small manufacturers out of business with essentially no regulatory benefit. FDA should therefore explain that the requirements of Sections 905(j) and 910 do not apply to modifications implemented to comply with a change in law. Moreover, for these same reasons, FDA should apply this approach retrospectively to SE Reports submitted for tobacco product changes implemented to comply with changes in law, allowing manufacturers to withdraw such SE Reports, as these products are not "new" tobacco products subject to Section 905(j) substantial equivalence requirements.

2. <u>Changes to Components Effectuated by Third-Party Vendors</u>. The SE Guidance states that finished tobacco product manufacturers are responsible for submission of Section 905(j) premarket reports in connection with changes to tobacco product components, even if the changes are effectuated by a third-party vendor. To illustrate, the January 2011 SE Guidance explains that if a filter supplier changed the conformation of its filters or changed its ingredients, the finished cigarette manufacturer would be responsible for including this change as part of it submissions in a new product application.[59] FDA's position on such changes was recently confirmed in the Third SE FAQ Guidance, which states that if a supplier of a component begins using a new processing aid for a subcomponent, such a change is considered a change in the tobacco product's composition requiring submission of an SE Report, SE Exemption request,

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[56] 21 U.S.C. § 387g(a)(1)(A).

[57] *See* FDA, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (Jul. 28, 2017), available at https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (last accessed 12/3/17) (announcing FDA will develop ANPRMs "to identify the issues FDA would need to address… to regulate nicotine in combustible cigarettes" and "to address the issue of flavored tobacco products"); FDA, FDA's Plan for Tobacco and Nicotine Regulation, available at https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm (last updated Nov. 29, 2017) (last accessed 12/3/17) (announcing FDA will issue an ANPRM regarding premium cigars).

[58] *See* SE Guidance, *supra* note 36, at 14.

[59] *Id.*

or PMTA, even if the change is so minor that it is not even capable of being quantified in the finished product.[60]

Finished product manufacturers may not be aware of these types of changes where the stock-keeping unit remains the same and the components continue to meet specifications established by the manufacturer. For the same reasons FDA should exempt changes to a tobacco product that are not intended to permanently alter the product's characteristics, FDA should not require 905(j) premarket submissions in connection with supplier-initiated component changes that do not impact the finished manufacturer's specifications for the tobacco product. Put another away, a finished product manufacturer should be responsible only for changes that materially and permanently impact the characteristics of that manufacturer's products; the component supplier should be responsible for reporting permanent changes to the characteristics of that supplier's components.

V. The SE Review Process is Intended to Provide an Abbreviated Pathway to Market, and Thus Should Not Become a Mechanism to Prevent Introduction of New Products.

FDA has turned the abbreviated 90-day[61] premarket review pathway into a prolonged premarket review process of indeterminate duration (often lasting more than six years), which has frozen the industry and undermined the lawful sale of tobacco products. FDA should use this opportunity to revisit its approach and adopt the recommendations previously provided by our 2011 comment letter.

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[60] *See* Third SE FAQ Guidance, *supra* note 3, at 16.

[61] *See* 21 U.S.C. § 387e(j)(1).

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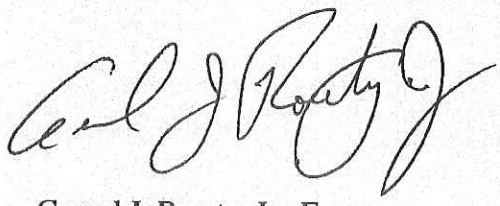
I appreciate your consideration of these comments, and look forward to continuing to work with the Agency on meaningful opportunities to promote regulatory efficiency and reduce administrative burden, consistent with the law and FDA's public health mission.

Respectfully,



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