March 3, 2011

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

Re: Substantial Equivalence Guidance and Proposed Rule on Substantial Equivalence Exemption – Dockets FDA-2010-D-0635 and FDA-2010-N-0646

Dear Sir or Madam:

We are tobacco product manufacturers and importers who have issues of common concern regarding the U.S. Food and Drug Administration's ("FDA's") effort to implement the provisions of Section 905(j) the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act").[1] We therefore provide the following consolidated comments on the recently-issued guidance document regarding the demonstration of "substantial equivalence" under Section 905(j) (the "SE Guidance"),[2] as well as the Agency's proposed rule regarding the implementation of the "minor modification" exemption to the substantial equivalence requirements of Section 905(j) ("SE Proposed Rule").[3]

In drafting Section 905(j), Congress imported the concept of "substantial equivalence" from the requirements applicable to certain medical devices pursuant to Section 510(k) of the FDCA. Under Section 510(k), a company may market a new or modified medical device only if, following submission of a pre-market notification, FDA determines that the device is substantially equivalent to a legally marketed predicate device (the "510(k) Program"). When FDA implemented this section of the FDCA, it took several years to develop a 510(k) Program that was clear and manageable for both industry and FDA. We therefore recognize the challenge of promulgating and implementing Section 905(j), which, unlike the 510(k) Program, governs changes to products containing an inherently-variable agricultural crop. We anticipate that the SE Guidance and SE Proposed Rule represent the first step in what is likely to be a

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1 The signatories to this letter include Commonwealth Brands, Inc., JT International U.S.A., Inc., King Maker Marketing Inc., Sherman's 1400 Broadway NYC, Ltd., and Swedish Match North America, Inc.

2 FDA, *Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products; Availability*, 76 Fed. Reg. 789 (Jan. 6, 2011) (with SE Guidance available at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf) [hereinafter "SE Guidance"].

3 FDA, *Tobacco Products, Exemptions from Substantial Equivalence Requirements*, 76 Fed. Reg. 737 (Jan. 6, 2011).

lengthy implementation process, and we hope that the ideas and concepts introduced in these comments facilitate a program that is transparent in its obligations, and manageable for both FDA and industry. To that end, these comments make the following points:

- FDA must provide supplemental, written guidance addressing past modifications to tobacco products for which Section 905(j) filings are due on March 22, 2011. The SE Guidance is focused on the demonstration of substantial equivalence in connection with *prospective* changes to *currently-marketed* tobacco products. Thus, many of the data submission recommendations set forth in the SE Guidance are not relevant to the discrete category of 905(j) submissions due in March. In many cases, these submissions will cite modifications to tobacco products made in the *past*, and for which a "predicate" tobacco product no longer exists for purposes of qualitative and quantitative testing. We therefore urge FDA to provide further, written clarification regarding the Agency's expectations for this discrete category of submissions.

- In implementing Section 905(j), we urge FDA to revisit the approach taken in the SE Guidance and instead draw on the lessons of the 510(k) Program, which vests manufacturers with the responsibility to determine initially whether a particular modification to a medical device requires a pre-market submission. The SE Guidance, if applied as drafted, will cause both FDA and the tobacco industry to devote a significant amount of resources in preparing and reviewing Section 905(j) submissions which do not further the public health goals of the Tobacco Control Act. A more reasonable implementation scheme would attach FDA pre-market review to the more limited subset of tobacco product changes which truly raise different questions of public health.

- To that end, FDA should utilize the "minor modification" exemption set forth in Section 905(j)(3) to recognize that certain types do not raise different questions of public health, and, as such, should not require submission and review of a pre-market report under Section 905(j). In particular, FDA should issue a guidance specifying logical break-outs for determining whether certain changes may be exempt from reporting under Section 905(j)(3), using as a guide the highly-regarded medical device modification flowchart FDA promulgated as part of the 510(k) Program. These categories of changes would include:

  - *Changes Intended to Ensure Consistency*. As FDA has recognized in implementing Section 904, manufacturers of tobacco products often add (or modify the quantity of) ingredients to ensure that specifications are consistently met. Such changes are, by design, *transitory* in nature and are not intended to permanently alter the characteristics of the tobacco product.

- *Changes That do Not Raise Public Health Concerns*. When a tobacco product manufacturer decreases or eliminates an additive, or adds or increases an additive that has been deemed by FDA as not harmful to health, the manufacturer must submit listing information to FDA under Section 904 on a *post-market* basis. It stands to reason that Congress did not intend to require manufacturers to otherwise report the same changes in a *pre-market* report under Section 905.

- *Changes In "Commodity" Ingredients*. As FDA has recognized, tobacco product manufacturers frequently obtain commodity ingredients from a variety of vendors, and use those commodity ingredients interchangeably in the manufacturing process. Use of an interchangeable ingredient obtained from different manufacturers in accordance with pre-defined specification tolerances for use in the tobacco product should not be presumptively reportable under Section 905.

- *Changes In Packaging and Other Components*. Changes in the packaging text or graphics, or in the ingredients used in packaging and components, where the tobacco product manufacturer does not know or intend that the ingredient become incorporated in the consumed product, should not be reportable, as such changes have no impact on public health (and therefore cannot raise different questions of public health).

- Further, other categories of changes should be categorically exempt from the Section 905 and Section 910 reporting requirements. For example, changes due to operation of law, such as changes necessitated by a tobacco product standard implemented under Section 907, do not raise public health concerns and should therefore be categorically exempt from reporting pursuant to a regulation issued under Section 905(j)(3).

- The SE Guidance states that any tobacco product modified after March 22, 2011 may not be marketed until FDA issues a substantial equivalence order under Section 910(a)(2), even if such an order is not issued within ninety (90) days of a manufacturer's Section 905(j) submission. Until FDA issues regulations implementing the "minor modification" provision of Section 905(j)(3), it would be inequitable, arbitrary and indeed unworkable for FDA to follow-through on this position taken in the SE Guidance. Instead, FDA must extend the period of enforcement discretion currently provided to submissions for grandfathered products to *all* submissions filed before the effective date of Section 905(j)(3) regulations.

We believe FDA's adoption of the recommendations set forth in these comments will result in a pre-market review framework under Section 905 that is efficient and sufficient to allow FDA to meet its statutory mandates under the Tobacco Control Act.

I. FDA Should Promptly Issue Supplemental Guidance Clarifying The Agency's Expectations With Respect to 905(j) Filings Due on March 22, 2011

The substantial equivalence framework FDA proposes to establish in the SE Guidance is understandably designed to apply to substantial equivalence determinations for products first introduced *after* the period from February 15, 2007 through March 22, 2011 (the "Statutory Grace Period"). However, many of the recommendations in the SE Guidance are not appropriate for, or applicable to, new tobacco products first marketed during the Statutory Grace Period. We therefore urge FDA to publicly acknowledge the forward-looking focus of the SE Guidance, its lack of relevance to historical modifications, and the Agency's intent to review reports due on March 22, 2011 accordingly. FDA's supplemental guidance should also clarify FDA's expectations regarding the following issues raised in the initial draft of the SE Guidance.

A. Inapplicable Data Submission Requirements

The SE Guidance contemplates that a predicate tobacco product will be available for qualitative and quantitative testing as part of a substantial equivalence review. This prospective approach is inadequate when applied to substantial equivalence reports for "new" tobacco products first introduced during the Statutory Grace Period.

The SE Guidance requires a manufacturer to provide "sufficient information" to enable FDA to reach a determination that a new or modified tobacco product is substantially equivalent to a marketed predicate. Based on this principle, the SE Guidance provides "recommendations" on the information FDA "believes a typical 905(j) report may need to include in order to demonstrate substantial equivalence."[4] In particular, the SE Guidance states that a "905(j) report should provide side-by-side quantitative and qualitative comparisons of the new tobacco product with the predicate tobacco product with respect to all product characteristics"[5] and recommends that the 905(j) report be organized by the list of characteristics set forth in Section 910(a)(3), which include design features, ingredients, materials, heating source, composition, and "other features."

According to FDA, the "other features" category contemplates that the 905(j) report will include the "levels of [harmful or potentially harmful constituents, or HPHC] in tabular format, with a side-by-side comparison with the predicate tobacco product," as well as "quantitative levels in smoke using both the International Organization for Standardization and Canadian Intense smoking regimens."[6] The SE Guidance similarly recommends that the

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4 SE Guidance, *supra* note 2, at 7.

5 *Id.* at 8.

6 *Id.* at 11.

manufacturer provide quantitative calculations of ingredients and materials in the predicate and new tobacco product. This recommendation presents two problems in practice. First, FDA has not yet established an HPHC list, as the statute does not require such a list until April 1, 2012,[7] and the Tobacco Products Scientific Advisory Committee has not finalized the constituents to include on such list. Second, even if a list of constituents were available, this information cannot be compiled if the predicate product is not available for testing.

The SE Guidance similarly contemplates that data, including comparative health impacts studies, will be included in the 905(j) filing for a new tobacco product that has different characteristics than the predicate (*e.g.*, in the case of a new ingredient). Obviously, this information cannot be compiled if the predicate product is not available for testing, and no such studies were conducted prior to application of the law and release of the SE Guidance. If manufacturers do not submit this data with their 905(j) reports, FDA may determine that the products are not substantially equivalent. This would preclude application of the substantial equivalence pathway for "new" products marketed during the Statutory Grace Period – contrary to Congress's explicit intent to include this subset of products within the framework of 905(j).[8]

We believe that, with respect to products first marketed during the Statutory Grace Period, "sufficient information" for purposes of a substantial equivalence demonstration would include that information generally available to manufacturers at the time the product was first introduced into commerce. This information would include a description of characteristics required in regulatory filings at the time (i.e., prior to enactment and implementation of the Tobacco Control Act). For example, tariff classifications include generic tobacco product characteristics that can be used to support a finding of substantial equivalence. We therefore urge FDA to permit manufacturers to reference to generic characteristics (e.g., "wrapper tobacco," "filler tobacco," "acetate filter") that were commonly and demonstrably used by tobacco product manufacturers prior to February 15, 2007 in demonstrating the substantial equivalence of a new tobacco product first introduced during the Statutory Grace Period.

B. Appropriate Predicate Products

The Tobacco Act permits the use of a predicate tobacco product that is no longer available for quantitative and qualitative testing, or that is available but manufactured by a third party. However, we are concerned that the SE Guidance has not clearly accounted for this fact. Indeed, the SE Guidance, FDA's Frequently Asked Questions website ("FAQs"),[9] and FDA

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[7] 21 U.S.C. § 387d(e); Tobacco Control Act, Pub. L. No. 111-31, § 6, 123 Stat. 1776, 1783 (2009).

[8] 21 U.S.C. § 387e(j)(2) (setting forth a distinct deadline and procedure for substantial equivalence reporting for products marketed after February 15, 2007 and before March 22, 2011, thereby suggesting that Congress contemplated that the 905(j) pathway should be available for these products).

[9] FDA, *Frequently Asked Questions: Substantial Equivalence, available at* http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForIndustry/ucm237528.htm (last visited Jan. 28, 2011) [hereinafter, "FAQs"].

substantial equivalence webinars[10] have provided conflicting guidance regarding the tobacco products that may be used as predicates for purposes of Section 905(j) submissions. We therefore urge FDA to issue supplemental guidance clearly recognizing that manufacturers may refer to predicate tobacco products that are no longer available or that are manufactured by third parties in compiling Section 905(j) reports.

The SE Guidance defines a proper predicate as "a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007" (the "Grandfather Date") or a product for which FDA has previously issued a substantial equivalence order under Section 905(j).[11] However, FDA's FAQs define an appropriate predicate as (i) a tobacco product commercially marketed as of February 15, 2007 "that has not been modified" or (ii) a tobacco product for which FDA has issued a substantial equivalence order and that complies with the other requirements of the Tobacco Control Act.[12] Further, during the January 25, 2011 webinar, FDA appeared to further narrow the scope of this first category of predicates; in response to a question regarding the categories of predicates that may be used, FDA declared that an appropriate predicate for a substantial equivalence determination is either a grandfathered product, "meaning it was commercially marketed on February 15, 2007, *and has not had a modification and sold after that date with a modification*"[13] or a product found substantially equivalent by FDA.

These statements are inconsistent with the statutory language and must be clarified. The statute clearly contemplates that a tobacco product marketed as of February 15, 2007, even if it was later modified (thus triggering a 905(j) filing) and discontinued, may serve as a predicate tobacco product. An alternate interpretation would impose an additional condition on the use of a grandfathered product as a predicate – that it must not have been modified and sold in its modified form – which is not supported by the plain language of the Tobacco Control Act and creates an absurd result when applied to "new" tobacco products (*i.e.*, "modifications") marketed during the Statutory Grace Period.

First, the statute does not require that a grandfathered tobacco product cited as a predicate in a Section 905(j) report be "unmodified," *i.e.*, in the same form as it was on February 15, 2007, and therefore still on the market. Rather, Section 905(j) defines these grandfathered tobacco products as those marketed in the United States "as of" February 15, 2007. Moreover, Section 910(a)(3)(C) provides only that "a tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market *at the initiative*

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10 FDA, *Substantial Equivalence Webinar Series*, *available at* http://www.fda.gov/TobaccoProducts/ResourcesforYou/ForIndustry/ucm239639.htm (last visited Jan. 28, 2011).

11 SE Guidance, *supra* note 2, at 4.

12 FAQs, *supra* note 9.

13 FDA, *Small Business Follow-up*, Jan. 25, 2011, *available at* https://collaboration.fda.gov/p95488776/ (beginning at the 1 hour 30 minute mark) (emphasis added).

of the FDA or that has been determined by a judicial order to be misbranded or adulterated"[14] (emphasis added). This language provides clear evidence of Congress's understanding that a grandfathered product that has been removed from the market for *other* reasons (such as a modification resulting in a "new" product) may still serve as a predicate. This result is also consistent with the framework Congress established for medical devices, under which devices marketed on the Grandfather Date served as predicates for future submissions, regardless of whether or not such devices were marketed at the time of a substantial equivalence filing. Here, we believe the Grandfather Date established in the Act establishes the predicate baseline against which all future 905(j) submissions will be made. The wording of the statute and the clear analogy to the medical device framework for determining substantial equivalence (which allows manufacturers to cite discontinued predicates) support this interpretation.

Second, imposing the restriction that a grandfathered predicate must not have been modified (and thus, must still be on the market) would effectively prohibit the use of the substantial equivalence pathway for *all* products modified during the Statutory Grace Period. Such a result would be a departure from the statutory intent, which requires that manufacturers of "new" (*i.e.*, "modified") tobacco products first marketed during the Statutory Grace Period submit a 905(j) report by March 22, 2011. If the prior version of the product cannot serve as a predicate precisely because it was modified, the modified version is left without a predicate for comparison. This, in turn, precludes the submission of a 905(j) report and subjects the modified product to the requirements of Section 910. Congress never intended this absurd result that would follow directly from FDA's limited definition of the appropriate predicate. We therefore urge FDA to clarify that its statements regarding the scope of permissible predicates are not intended to preclude a tobacco product modified during the Statutory Grace Period from using as its predicate the pre-modified version on the market as of February 15, 2007.

With respect to predicate products manufactured by a third party, we recognize that the SE Guidance does not explicitly prohibit a filing on such a basis. However, much of the information described in the SE Guidance as a required part of a 905(j) submission (*e.g.*, design feature specifications, listing of ingredients, listing of materials, and listing of constituents) is likely in many, if not all, cases to be trade secrets of and proprietary to the manufacturer. As such, they would not be available to a potential competitor seeking to market a substantially equivalent tobacco product. In our view, Congress did not intend that the Tobacco Control Act stifle competition, which would be the effect of requiring information which is unavailable to the party seeking to submit it. We therefore urge that FDA issue revised guidance confirming that unrelated third party products may be used as predicates and that, in such cases, the submitting party need only submit its best estimates of unavailable information. FDA could then verify such best estimates against information filed by the unrelated third party manufacturer under Section 904 or Section 905.

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[14] 21 U.S.C. § 387j(a)(3)(C).

II. FDA Should Revise the SE Guidance, and Implement the SE Proposed Rule, In a Fashion That Reflects the 510(k) Program

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 pre-market notification demonstrating that a new or modified device is substantially equivalent to a legally marketed predicate device. As part of that 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 bases 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 Pre-Market Review Program

Under Section 510(k) of the FDCA, any person who proposes to market a medical device must notify FDA ninety (90) days in advance of its introduction into interstate commerce. If FDA determines that the proposed device is "substantially equivalent" to a legally marketed predicate device, FDA will issue a letter "clearing" the device for marketing.[15] In implementing these provisions, FDA noted that it "should not require a premarket notification for every change…since too many…changes are made on a regular basis."[16] FDA concluded that changes with little to no impact on health should be exempt from the substantial equivalence filing requirement, and issued regulations establishing that only those modifications that could "significantly affect the safety or effectiveness of the device" or that constitute a "major change or modification" in the device's intended use require a submission under Section 510(k).[17]

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

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15 21 U.S.C. § 360(k); 21 C.F.R. Part 807, Subpart E.

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

17 21 C.F.R. § 807.81(a)(3).

qualified to reach the correct interpretation and determinations regarding reportability.[18] FDA therefore placed the onus on industry to make these interpretations in the first instance,[19] 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."[20] This allows FDA to more efficiently and effectively utilize its resources to review those submissions that are necessary to protect the public health. Indeed, FDA noted in the preamble to its proposed 510(k) rule that the Agency had received more than 480 substantial equivalence submissions in a three-month period,[21] 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.[22] Finally, the 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."[23]

The principles and circumstances that led FDA to promulgate and implement the 510(k) program are directly relevant to the issues faced by FDA as it seeks to implement Section 905(j) of the Tobacco Control Act. First, the "substantial equivalence" standard set forth in Section 905(j) is derived directly from Section 510(k) regulations. Second, just as the 510(k) regulations use subjective terminology, Section 905(j) and Section 910 use terms such as "minor," "same" and "different" characteristics, and "different questions of public health," which are subject to differing interpretations. Third, like medical devices manufacturers, tobacco product manufacturers routinely modify products, and indeed do so more frequently than

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18 U.S. Food and Drug Admin., *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"].

19 *See* 42 Fed. Reg. 42520, 42522 (Aug. 23, 1977).

20 510(k) Guidance, *supra* note 18, at 12.

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

22 510(k) Guidance, *supra* note 18, at 12.

23 *Id.* at 2.

medical device manufacturers. In fact, the clear differences in why and how often a tobacco product manufacturer may modify a tobacco product in comparison to a medical device manufacturer compels the conclusion that the need to "preserve flexibility," as FDA did in adopting the 510(k) Program, is more acute with respect to tobacco. Medical devices are subject to comprehensive and detailed manufacturing specifications; tobacco leaf is inherently variable. As such, whereas medical device manufacturers *choose* to *permanently* modify medical devices through an exacting design control process, tobacco product manufacturers are often *forced* to make *transitory* modifications in order to ensure that a tobacco product maintains the same essential characteristics over time. Further, whereas medical device manufacturers subject component and accessory suppliers to exacting specifications under long-term supply agreements, tobacco product manufacturers often buy "off-the-shelf" commodity ingredients via purchase orders. Tobacco product manufacturers therefore have much less control over vendors, and often have the need to quickly switch suppliers.

As other commenters have noted,[24] the SE Guidance does not account for these practical realities of the tobacco product manufacturing industry. It instead requires that any change to a tobacco product's ingredients or additives be reported to FDA in connection with a Section 905(j) report, regardless of the nature, intent, or permanency of the change – the key factors in determining whether the change is truly one that requires FDA pre-market review. Further, the SE Guidance narrowly interprets the "same characteristics" prong of the substantial equivalence definition to mean "identical," which means as a practical matter that manufacturers will need to devote resources to determining whether any change to a tobacco product, no matter how minor, raises different questions of public health. As such, far from allowing FDA to focus its resources on those types of tobacco product modifications that may, in fact, raise different questions of public health, the SE Guidance is more apt to result in a deluge of pre-market submissions for inconsequential changes to tobacco products. Moreover, FDA's current approach to implementing Section 905(j) provides no flexibility for tobacco product manufacturers to engage in routine modifications to their products without the need to adhere to the prohibitively complex and time-consuming administrative requirements set forth in the SE Guidance.

For these reasons, FDA should re-visit the approach taken in the SE Guidance and instead adopt a model based on the 510(k) Program. 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. The lessons drawn from FDA's effort to implement an effective and efficient 510(k) Program compel the conclusion that a broad interpretation of the Section 905(j) reporting mandate – as manifested in the SE Guidance – will impose an incredible and unnecessary administrative burden on the Agency and the tobacco product manufacturing industry, as it is bound to receive submissions for which pre-market review is unnecessary to further the public health goals of the Tobacco Control Act. Further, FDA has concluded that 905(j)(3) reports will likely cost, on average, $35,000, evidencing the burden on industry of an onerous reporting mandate. The 510(k) program, as it exists today, provides a clear model for

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[24] *See, e.g.*, Lorillard Tobacco Company Comments to Docket No. FDA-2010-D-0635-0007 (Feb. 4, 2011); Altria Client Services Comments to Docket No. FDA-2010-D-0635-0006 (Feb. 8, 2011).

how FDA can mitigate these concerns while ensuring that the Agency complies with its mandate of reviewing modifications to tobacco products that do indeed raise different questions of public health. Adoption of such a program would also be more reflective of the practical reality of the tobacco product manufacturing industry, and, in particular, the frequency of, and need for, modifications to tobacco products.

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 pre-market review, and (2) regulations that categorically 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 pre-market 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 pre-market review in order 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>. The SE Guidance states that FDA 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."[25] 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,

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[25] SE Guidance, *supra* note 2, at 4.

"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."[26] These changes are not intended to permanently alter the tobacco product's 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.[27] 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. The SE Guidance does not provide the same flexibility. Rather, under the SE Guidance, minor variances in ingredient quantities from batch-to-batch – even if done according to predetermined specifications and in order to meet "target outcomes" – would result in each batch constituting a "new tobacco product," as the manufacturer has "changed" an ingredient. 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. <u>Modifications That Do Not Raise Public Health Concerns</u>. 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." The reason Congress requires a *post-market* report in this context seems obvious: manufacturers should be incentivized to make such "benign" changes immediately, without a 90-day pre-market waiting period under Section 904(c)(1) or substantive pre-market review by FDA under Section 905(j). However, the SE Guidance torpedoes this incentive structure. A manufacturer seeking to make such a change in additives 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 pre-market submission would need to include data demonstrating that the new tobacco product's "different characteristics" do not raise different questions in public health. The SE Guidance therefore acts as a *disincentive* to making benign changes to a tobacco product – a manufacturer may have no incentive to spend thousands of dollars preparing a Section 905(j) pre-market report when it could just as easily continue marketing the prior version of the product.

3. <u>Changes in "Commodity" Ingredients</u>. FDA's Ingredient Listing Guidance distinguishes between ingredients that are complex and made to a tobacco product

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[26] FDA, *Final Guidance for Industry: Listing of Ingredients in Tobacco Products* (Nov. 2009), at 9, *available at* http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf [hereinafter "Ingredient Listing Guidance"].

[27] *Id.*

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,"[28] and therefore that manufacturers need not provide listing information for substances "contained in a complex purchased ingredient where the ingredient is not made to your specifications."[29] The guidance further clarifies that such complex ingredients may be provided by multiple suppliers and used "interchangeably" in a single tobacco product.[30] This reflects the reality of the tobacco industry, in which ingredients are often purchased pursuant to purchase orders, not 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.

4. <u>Changes in Ingredients That Are Not Incorporated in The Consumed Product</u>. Changes in the packaging and in the ingredients used in a tobacco product's packaging 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)."[31] In its Ingredient Listing Guidance,[32] FDA interpreted "components, parts, and accessories" to include "tobacco, paper, and filters." Similarly, the SE Guidance refers to the "component parts" of tobacco products as included rolling papers, filters, and filter tubes. With respect to packaging and these component parts, unless the ingredient is incorporated in the consumed product, there is no rationale for requiring FDA pre-market review of whether the change in the ingredient is appropriate for the public health; the ingredient will not in fact be ingested by humans. The same rationale is even more applicable if the only changes are in the text, graphics, or other informational aspects of the packaging. This result is consistent with the position taken by FDA in the Ingredient Listing Guidance, which notes that "when the manufacturer knows or intends 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."[33] 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

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28 *Id.* at 8.

29 *Id.*

30 *Id.*

31 21 U.S.C. § 321(rr)(1) (emphasis added).

32 Ingredient Listing Guidance, *supra* note 26, at 3.

33 *Id.* at 5.

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 pre-market 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 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.[34]

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

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[34] We acknowledge that Section 905(j)(1)(A)(ii) requires a manufacturer to submit a pre-market 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.

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.

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 "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, as of September 22, 2009, cigarettes may no longer contain characterizing flavors, and as such, many manufacturers have "modified" their products within the Statutory Grace Period to bring their products into compliance.[35] Similarly, once FDA establishes additional tobacco product standards under Section 907, products will have to be modified to conform to those requirements. Substantial equivalence submissions for these modifications, which are required by law, will be unduly burdensome, serve no regulatory or public health purpose, and unnecessarily divert valuable Agency and industry resources. Indeed, with FDA's estimate that each such report will require 360 man hours[36] 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.

2. Changes to Components Effectuated by Third-Party Vendors. The SE Guidance states that finished tobacco product manufacturers are responsible for submission of Section 905(j) pre-market reports in connection with changes to tobacco product components, even if the changes are effectuated by a third-party vendor. The SE Guidance provides as an example 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.[37] Finished product manufacturers may not be aware of these changes where the SKU 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) pre-market 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.

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35 21 U.S.C. § 387g(a)(1)(A).

36 SE Guidance, *supra* note 2, at 14.

37 *Id.*

D. Period of Enforcement Discretion

Section 910(a)(2)(A) states that new tobacco products may be marketed pursuant to the abbreviated Section 905(j) procedures if a tobacco product manufacturer has received an order from FDA finding the new tobacco product substantially equivalent to the identified predicate, or if the tobacco product is exempt from reporting pursuant to Section 905(j)(3). The SE Guidance provides that tobacco product manufacturers submitting Section 905(j) reports for new tobacco products first introduced during the Statutory Grace Period may continue to market their products unless and until FDA issues an order finding the new tobacco product not substantially equivalent to the identified predicate. However, for tobacco products first introduced following the Statutory Grace Period, the SE Guidance states that the products may not be marketed until FDA issues an order finding the new tobacco product substantially equivalent to the predicate – even if it has been more than 90 days since the Section 905(j) report was submitted.

In the absence of regulations and/or guidance setting forth exemptions under Section 905(j)(3), FDA's position stands to result in profound dislocation in the tobacco product manufacturing industry. Exemptions from reporting are essential to a workable system; FDA is bound to receive a significant volume of submissions for minor and inconsequential changes to tobacco products, such as those described above, before such exemptions are issued. For example, a manufacturer may be prevented from marketing a "new" tobacco product that includes a reduced level of an additive under this policy, while such a change would otherwise require a 60-day *post-market* report under Section 904(c). Such a result would eviscerate the intent of Congress and would prevent tobacco product manufacturers from making considered business decisions. Indeed, there is no telling how long it may take FDA to review a Section 905(j) report, given the Agency's disregard of the 90-day timeline set forth in Section 905 and the likelihood that FDA will be deluged with filings.

We therefore believe it is incumbent upon FDA to extend the enforcement discretion provided to new tobacco products first introduced during the Statutory Grace Period to those new tobacco products first introduced prior to the finalization of regulations and/or guidance implementing Section 905(j)(3). Specifically, tobacco product manufacturers introducing products prior to the effective date of such regulations and/or guidance should be permitted to market their products unless and until FDA issues an order finding the product not substantially equivalent to the identified product. The extension of enforcement discretion to this category of filings would permit FDA to spend the time it needs to review submissions, and would allow manufacturers to make reasoned business decisions.

III. FDA Should Provide Further Clarification Regarding When a Product with "Different Characteristics" Raises "Different Questions of Public Health"

Under Section 910(a)(3)(A), a new tobacco product will be deemed "substantially equivalent" to a predicate if it "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 this section because the product does not raise different questions of public health." The SE Guidance does not address the criteria for

determining when a product that has different characteristics than the predicate raises "different questions of public health."

As noted by other commenters to the SE Guidance docket, FDA has essentially interpreted the "same characteristics" prong of the substantial equivalence definition to mean that the proposed tobacco product must be *identical* across all characteristics to a single predicate tobacco product.[38] As a result of this extremely narrow interpretation of "same characteristics," we believe it is essential for FDA to provide detailed guidance on the circumstances that will give rise to "different questions of public health." We submit that the substantial equivalence pathway is intended to serve as an avenue for manufacturers to demonstrate only that their products are "substantially equivalent," and *not* that new products *serve* or *improve* the public health. As such, any interpretation of the "different questions of public health" prong should not be tied to objective markers of public health impact and instead should be based on a *relative* comparison of the public health impact between the predicate and the new product. In the medical device context, FDA uses a similar "relative" comparison; it does not require that a substantial equivalence filing demonstrate that the product is "safe and effective" but rather merely that the modified device does not raise "different questions" of safety and effectiveness.

[38] *See, e.g.*, Japan Tobacco International, USA Comments to Docket No. FDA-2010-D-0635-0004 (Feb. 8, 2011).

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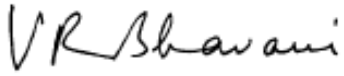
We appreciate your consideration of these comments. We look forward to working with FDA to assist in implementation of the substantial equivalence requirements, including the substantial equivalence exemption under Section 905(j)(3).

Respectfully,



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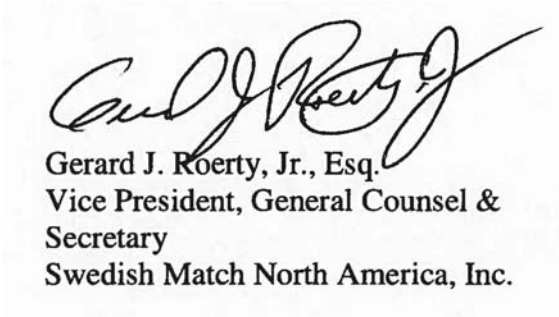

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