FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0002159 - SE0002164, SE0002166, and SE0014828 – SE0014831

SE0002159: Kent 100s	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	32%
Characterizing Flavor	None
SE0002160: Kent Golden 100s	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None
Additional Property	(b) Cigarette Paper
SE0002161: Kent Golden Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
Additional Property	(b) Cigarette Paper
SE0002162: Kent III 100s	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	60%
Characterizing Flavor	None
Additional Property	(b) (4) Cigarette Paper
SE0002163: Kent III Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	61%
Characterizing Flavor	None
Additional Property	(b) Cigarette Paper

SE0002164: Kent Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	33%
Characterizing Flavor	None
SE0002166: True Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	66%
Characterizing Flavor	None
SE0014828: Kent Golden 100s	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None
Additional Property	(b) (4) Cigarette Paper
SE0014829: Kent Golden Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
Additional Property	(b) (4) Cigarette Paper
SE0014830: Kent III 100s	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	60%
Characterizing Flavor	None
Additional Property	(b) (4) Cigarette Paper
SE0014831: Kent III Kings	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	61%
Characterizing Flavor	None
Additional Property	(b) (4) Cigarette Paper

Common Attributes of SE Reports	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Provisional
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.04.04 10:44:56 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2019.04.04 13:28:39 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002159: Kent 100s	
Product Name	Kent 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
SE0002160: Kent Golden 100s	
Product Name	Kent Golden Lights 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	36%
Characterizing Flavor	None
SE0002161: Kent Golden Kings	
Product Name	Kent Golden Lights Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
SE0002162: Kent III 100s	
Product Name	Kent III Ultra Lights 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	55%
Characterizing Flavor	None
SE0002163: Kent III Kings	
Product Name	Kent III Ultra Lights Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	52%
Characterizing Flavor	None

SE0002164: Kent Kings	
Product Name	Kent Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	17%
Characterizing Flavor	None
SE0002166: True Kings	
Product Name	True Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	61%
Characterizing Flavor	None
SE0014828: Kent Golden 100s	
Product Name	Kent Golden Lights 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	36%
Characterizing Flavor	None
SE0014829: Kent Golden Kings	
Product Name	Kent Golden Lights Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
SE0014830: Kent III 100s	
Product Name	Kent III Ultra Lights 100s
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9mm
Ventilation	55%
Characterizing Flavor	None

SE0014831: Kent III Kings	
Product Name	Kent III Ultra Lights Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9%
Ventilation	52%
Characterizing Flavor	None

The predicate tobacco products are combusted filtered cigarettes manufactured by Lorillard. The applicant acquired Lorillard in 2015.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 22, 2011, FDA received seven provisional SE Reports from Lorillard Tobacco Company. FDA issued Acknowledgement letters to the applicant on August 23, 2011. On October 28, 2011, FDA received an amendment (SE0003745) from the applicant, containing an environmental assessment for the SE Reports. On January 4, 2013, FDA issued an Advice/Information Request (A/I) letter, requesting information needed for the SE Reports to be administratively complete. In response, FDA received amendments on February 1, 2013 (SE0006967), and on February 10, 2014 (SE0010173). On May 11, 2015, FDA issued a Notification letter informing the applicant that substantive scientific review would begin on June 25, 2015. On June 12, 2015, FDA received a general correspondence from Lorillard Tobacco Company informing FDA of the merger of Lorillard Tobacco Company with Reynolds American Inc. and Imperial Tobacco Group (TC0001319). The products in these SE Reports were acquired by R.J. Reynolds Tobacco Company (RJRT) and the Transfer of Ownership for the SE Reports was finalized by FDA on October 1, 2015. On June 24, 2015, FDA received additional information (SE0011997-SE0012003) from the applicant prior to initiating substantive scientific review of these SE Reports, including a notification that Lorillard Tobacco Company was now RJRT. On March 18, 2016, FDA issued an A/I letter to the applicant. On May 17, 2016, FDA received a response to the A/I letter (SE0013358). On August 4, 2016, FDA issued a Preliminary Finding (PFind) letter to the applicant. On August 17, 2016, the applicant requested an extension of time (SE0013581) to respond to FDA's August 4, 2016, PFind letter for SE0002159 and SE0002164. On August 30, 2016, FDA issued an Extension Request Granted letter to the August 17, 2016, request for SE0002159 and SE0002164. On September 2, 2016 (SE0013677) and October 3, 2016 (SE0013718), FDA received responses to the August 4, 2016 PFind letter. On February 21, 2018, FDA conducted a teleconference with the applicant to request clarification of information provided in the applicant's response to the PFind Letter related to use of alternate materials and target specifications and upper and lower range limits of certain product design parameters. During this teleconference, FDA stated that each individual combination of materials would be considered distinct new tobacco products from each other; therefore, for all discreet products identified within the submission, unique STNs would be assigned and FDA would issue acknowledgment letters. On March 7, 2018, FDA received the applicant's response to FDA's request for clarification of information (SE0014569). On July 26, 2018, FDA established four new STNs, SE0014828-SE0014831 which employ an alternative cigarette paper supplier (b) (4) brand cigarette paper) from SE0002160-SE0002163, which utilize (b) (4) brand

cigarette paper. FDA issued Acknowledgment letters to the applicant for SE0014828-SE0014831 on July 27, 2018.

Product Name	SE Report	Amendments
Kent 100s	SE0002159	SE0003745 SE0006967 SE0010173 SE0011998 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent Golden 100s	SE0002160	SE0003746 SE0006968 SE0010173 SE0011997 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent Golden Kings	SE0002161	SE0003747 SE0006969 SE0010173 SE0011999 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent III 100s	SE0002162	SE0003748 SE0006970 SE0010173 SE0012000 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569

Product Name	SE Report	Amendments
Kent III Kings	SE0002163	SE0003749 SE0006971 SE0010173 SE0012001 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent Kings	SE0002164	SE0003750 SE0006972 SE0010173 SE0012002 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
True Kings	SE0002166	SE0003840 SE0006974 SE0010173 SE0012003 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent Golden 100s	SE0014828	SE0003746 SE0006968 SE0010173 SE0011997 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent Golden Kings	SE0014829	SE0003747 SE0006969 SE0010173 SE0011999 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569

Product Name	SE Report	Amendments
Kent III 100s	SE0014830	SE0003748 SE0006970 SE0010173 SE0012000 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569
Kent III Kings	SE0014831	SE0003749 SE0006971 SE0010173 SE0012001 SE0013358 SE0013581 SE0013677 SE0013718 SE0014569

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Rosanna Beltre on January 4, 2013, by Angela Brown on March 11, 2014, and by Jennifer Schmitz on July 27, 2018.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews, dated June 15, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.[1]

[1] Addendum reviews were completed on July 15, 2018 and July 16, 2018, for the inclusion of characterizing flavor and SE0014828-SE0014831. The addendum reviews do not change the conclusion of the initial determination.

4. SCIENTIFIC REVIEW

Scientific reviews[2] were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Selvin Edwards on September 9, 2015, July 5, 2016, and October 21, 2016, for SE0002160-SE0002163, and SE0002166, and on November 4, 2016, for SE0002159 and SE0002164.

The final chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Inclusion of Fire Standards Compliant (FSC) cigarette paper for all SE Reports
  - SE0002160-SE0002163 are identical to SE0014828-SE0014831 except for use of alternate cigarette papers[3]
    - SE0002160-SE0002163 employ (b) (4) cigarette paper (LIP cigarette base paper (b) (4) supplier (b) (4)
    - SE0014828-SE0014831 employ (b) (4) cigarette paper (LIP cigarette base paper 51.0 mg/cig; supplier: (b) (4)
- The FSC cigarette paper contains (b) (4) (b) (4) additives not present in the predicate products

The primary difference between the new and corresponding predicate tobacco products is the inclusion of FSC cigarette paper and that the paper contained (b) (4) (b) (4) additives. The applicant provided measured TNCO yields using two different smoking regimens which showed that the new and corresponding predicate tobacco products produced similar HPHC smoke yields. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Beth Tirio on September 8, 2015, and Madison Rohrbaugh on July 5, 2016, for all SE Reports, Komal Ahuja on November 3, 2016, for SE0002159

[2] The scientific reviews include an evaluation of SE0002159 - SE0002164, and SE0002166. During these scientific reviews both (b) (4) and (b) (4) cigarette papers were evaluated and additional STNs were generated for products with (b) (4) cigarette papers, resulting in SE0014828-SE0014831. Accordingly, even though these scientific reviews only list SE0002159-SE0002164 and SE0002166, the scientific reviews are also applicable to SE0014828-SE0014831.

[3] The applicant originally identified several interchangeable structural components including cigarette paper, tipping paper, plug wrap, filter tow, cigarette seam adhesive, tipping paper adhesive and (b) (4). The final chemistry review stated that the possible combinations of unique new and predicate products due to interchangeable materials was over 1,800 unique products. The applicant withdrew from review all alternate materials except for two cigarette papers (SE0013677) for the new products SE0002160-SE0002163 and SE0014828-SE0014831.

and SE0002164, and Komal Ahuja on January 25, 2017, for SE0002160 – SE0002163, and SE0002166. An addendum to the engineering reviews was completed by Komal Ahuja on June 27, 2017 for all SE Reports.

The final engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the corresponding predicate tobacco products and that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health. The review identifies the following deficiencies that have *not* been adequately resolved:

1. SE0002159-2164 provide measured values for some of the design parameters in the new products. You state that during the August 17, 2016 meeting with FDA (TC0001536) to discuss other RJR products, FDA stated that measured values are sufficient if target specifications and range limits are not available for the new or predicate products. However, this analysis is not the information that was relayed during the August 17, 2016 meeting; FDA conveyed that measured values are acceptable for only the predicate products if specifications were not in place at the time of predicate manufacturing. Measured values do not indicate design specifications since specifications provide the exact manufacturing standard to which each parameter must conform. In order for FDA to make a determination, target specifications and range limits are necessary to characterize the products. You provide measured values for cigarette paper band porosity for all of the new products with (b) (4) paper. Since these are new products in which the target specifications and range limits can be established, the measured values are not acceptable. Furthermore, the supplier COAs list target specifications and range limits for band porosity, but you did not provide your own target specifications and range limits to compare with the COA. Therefore, provide target specifications and range limits for the (b) (4) band porosity in all of the new products.

   If a difference exists in the target specifications or range limits between the new and corresponding predicate products, provide scientific evidence and a rationale for why the difference(s) does not cause the new product to raise different questions of public health.

2. All of your SE Reports provide filter density specifications but do not include data confirming that specifications are met. You state that since filter density target specifications and range limits were calculated and this parameter is a function of defined inputs (filter mass and volume), test data would not be applicable. However, even though the filter mass and volume are defined, there can still be slight variances in measured values of these inputs and therefore differences in the measured filter density. FDA understands that you may not measure filter density directly; however, test data still needs to be provided. The data can be used to confirm whether filter density target specifications are met if all of the inputs for the density calculation are measured. For example, if you use filter mass, length, and radius test data to calculate the filter density, then this approach can be used to validate the filter density target specifications. Otherwise, submit measured test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a

summary of the results for filter density for each predicate and corresponding new product.

Certificates of analysis (COAs) from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

Additionally, for the design parameters listed above that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

3. SE0002160-SE0002163 state, in your August 2016 amendment, that you only intend to employ two cigarette paper materials in the new products. In all of the other products, including the predicate products, only one cigarette paper is used. Furthermore, you state that multiple tipping and plug wrap papers are no longer being used. Therefore, each of the predicate products contains only a single combination of materials with no alternate options, and the only new products with alternate materials are SE0002160-SE0002163. However, in Appendices 232-245 of the August 2016 amendment, you provide a list of all possible product combinations, in which multiple tipping papers, plug wrap papers, filter tows, and adhesives are listed. In these tables, the number of combinations reaches close to 300 unique products for some of the new and predicate products. It is unclear if other multiple materials are being employed since the appendices conflict with your narrative response. Even if the interchangeable materials result in the same 'tar' yields or do not require any other design changes, FDA still considers the use of multiple materials in the same product as a new tobacco product. Clarify this discrepancy and provide an updated response.

   If you are employing multiple tipping papers, plug wrap papers, filter tows, and adhesives along with the multiple cigarette papers, in accordance with section 910(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), each product modification, including use of an alternate material, constitutes a new tobacco product. A material is an alternate material if it has any difference in composition, supplier, or design parameters (target specifications or range limits). Each identified new and predicate product must consist of a single combination of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials. Identify the following:

   a. Every unique material combination in the predicate product that you are comparing to the new product in accordance with Section 910(a)(2)(B) of the FD&C Act.
   b. Every unique material combination in the new tobacco product under Section 905(j)(2) of the FD&C Act. Each specific combination of materials will be considered a single new tobacco product and evaluated individually in accordance with Section 910(a)(2)(B) of the FD&C Act.

Provide the list of ingredients and ingredient quantities for each identified material in each new and predicate product.

Provide the **target specifications and upper and lower range limits** for *all* of the following design parameters for each material in each new and predicate product:

c. Cigarette draw resistance (mm H_2O)
d. Denier per filament (dpf)
e. Total denier (g/9000m)
f. Filter density (g/cm^3)
g. Filter length (mm)
h. Filter ventilation (%)
i. Filter pressure drop (mm H_2O)
j. Tipping paper length (mm)

Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for *all* of the following design parameters for each material in each new and predicate product:

k. Cigarette draw resistance (mm H_2O)
l. Puff count
m. Denier per filament (dpf)
n. Total denier (g/9000m)
o. Filter density (g/cm^3)
p. Filter ventilation (%)
q. Filter pressure drop (mm H_2O)

Certificates of analysis (COAs) from the material supplier may satisfy this portion of the deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

Additionally, if a difference exists between the new and predicate product identified for each SE Report, provide justification for the difference and a scientific rationale for why the difference does not cause the new product to raise different questions of public health. Some options for demonstrating that the differences do not cause the new products to raise different questions of public health include the following:

Option 1: Identify a single unique predicate product (with corresponding ingredients), composed of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material. Additionally, select and identify a single new product (with corresponding ingredients), composed of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material. The identified new product will be the only version of the new product considered for evaluation of substantial equivalence with the identified predicate product. The identified new product will also be the only

material combination permitted. Therefore, alternate materials will not be permitted. Provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for the unique new and predicate products, based on the single combination of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials identified. If a difference exists between the single identified new product and the single identified predicate product, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

Option 2: If you need to list alternate materials for the new and predicate products, you may choose to demonstrate that the use of alternate cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials do not cause the new products to raise different questions of public health. To do this, identify every unique new and predicate product that may result from the integration of each combination of alternate materials. Each identified new and predicate product must consist of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material combination. Provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for each identified new and predicate product, based on all possible combinations of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials. If a difference exists between the new and predicate products identified for each SE Report, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

Option 3: If you need to list alternate materials for the new and predicate products, you may choose to provide a "bracketing" approach to demonstrate that the alternate materials in the new and predicate products do not cause the new products to raise different questions of public health. To do this, specify two unique versions of the new product, and if the predicate contains alternate materials, two unique versions of the predicate product:

- For one of the unique versions of the **new** product, identify a single set of alternate materials that result in the **highest** HPHC yields generated through integration of the alternate materials.
- For the other unique version of the **new** product, identify a single set of alternate materials that result in the **lowest** HPHC yields generated through integration of the alternate materials.
- For one of the unique versions of the **predicate** product, identify a single set of alternate materials that result in the **highest** HPHC yields generated through integration of the alternate materials.
- For the other unique version of the **predicate** product, identify a single set of alternate materials that result in the **lowest** HPHC yields generated through integration of the alternate materials.

Provide a justification for why each version of the new and predicate product is representative of the highest and lowest HPHC yields in the new and predicate products. Additionally, for each version specified, provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for all of the identified new and predicate products. If a difference exists between the identified new and predicate products, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

All predicate product materials selected or used for comparison or bracketing must have been used in the predicate tobacco product as of February 15, 2007, and have been commercially marketed (other than for test marketing).

You stated that you no longer manufacture the predicate product and, therefore, are unable to provide the necessary design parameter data. Even if you no longer manufacture the predicate product, you still need to fully characterize the new and predicate products, and if the characteristics are different, demonstrate that the new products do not raise different questions of public health. Some potential options for obtaining data on the predicate products include, but are not limited to:

- Manufacture the predicate products at present day, consistent with the product composition and design specifications in place at the time the grandfathered predicate product was originally manufactured. In this case, design parameter data should be accompanied by documentation demonstrating that the manufacture of the predicate product at present day is reflective of the grandfathered predicate product at the time of original manufacture.

- Submit design parameter data for products other than the predicate products (referred to as surrogate tobacco products) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco products could be submitted in place of data for the predicate products. However, information and data need to be provided to demonstrate that data for the surrogate tobacco products can be extrapolated to the predicate products. For example, the design parameters specifications for the predicate and surrogate products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products.

4. SE0002159 and SE0002164, in your August 2016 amendment, state that you only intend to employ a single cigarette paper material in the new products. Furthermore, you state that multiple tipping and plug wrap papers are no longer being used. Therefore, each of the new and predicate products contains only a single combination of materials with no alternate options. However, in Appendices 232-245 of the August 2016 amendment, you provide a list of all possible product combinations, in which multiple tipping papers, plug wrap papers, filter tows, and adhesives are listed. In these tables, the number of combinations reaches close to 150 unique products for some of the new and predicate products. It is unclear if other multiple materials are being employed since the

appendices conflict with your narrative response. Even if the interchangeable materials result in the same 'tar' yields or do not require any other design changes, FDA still considers the use of multiple materials in the same product as a new tobacco product. Clarify this discrepancy and provide an updated response.

If you are employing multiple tipping papers, plug wrap papers, filter tows, and adhesives along with the multiple cigarette papers, in accordance with section 910(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), each product modification, including use of an alternate material, constitutes a new tobacco product. A material is an alternate material if it has any difference in composition, supplier, or design parameters (target specifications or range limits). Each identified new and predicate product must consist of a single combination of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials. Identify the following:

a. Every unique material combination in the predicate product that you are comparing to the new product in accordance with Section 910(a)(2)(B) of the FD&C Act.
b. Every unique material combination in the new tobacco product under Section 905(j)(2) of the FD&C Act. Each specific combination of materials will be considered a single new tobacco product and evaluated individually in accordance with Section 910(a)(2)(B) of the FD&C Act.

Provide the list of ingredients and ingredient quantities for each identified material in each new and predicate product.

Provide the **target specifications and upper and lower range limits** for *all* of the following design parameters for each material in each new and predicate product:

c. Cigarette draw resistance (mm H_2O)
d. Denier per filament (dpf)
e. Total denier (g/9000m)
f. Filter density (g/cm^3)
g. Filter length (mm)
h. Filter ventilation (%)
i. Filter pressure drop (mm H_2O)
j. Tipping paper length (mm)

Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for *all* of the following design parameters for each material in each new and predicate product:

k. Cigarette draw resistance (mm H_2O)
l. Puff count
m. Denier per filament (dpf)
n. Total denier (g/9000m)
o. Filter density (g/cm^3)

p. Filter ventilation (%)
q. Filter pressure drop (mm H_2O)

Certificates of analysis (COAs) from the material supplier may satisfy this portion of the deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

Additionally, if a difference exists between the new and predicate product identified for each SE Report, provide justification for the difference and a scientific rationale for why the difference does not cause the new product to raise different questions of public health. Some options for demonstrating that the differences do not cause the new products to raise different questions of public health include the following:

Option 1: Identify a single unique predicate product (with corresponding ingredients), composed of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material. Additionally, select and identify a single new product (with corresponding ingredients), composed of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material. The identified new product will be the only version of the new product considered for evaluation of substantial equivalence with the identified predicate product. The identified new product will also be the only material combination permitted. Therefore, alternate materials will not be permitted. Provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for the unique new and predicate products, based on the single combination of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials identified. If a difference exists between the single identified new product and the single identified predicate product, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

Option 2: If you need to list alternate materials for the new and predicate products, you may choose to demonstrate that the use of alternate cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials do not cause the new products to raise different questions of public health. To do this, identify every unique new and predicate product that may result from the integration of each combination of alternate materials. Each identified new and predicate product must consist of a single cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive material combination. Provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for each identified new and predicate product, based on all possible combinations of cigarette paper, tipping paper, plug wrap paper, filter tow, and adhesive materials. If a difference exists between the new and predicate products

identified for each SE Report, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

Option 3: If you need to list alternate materials for the new and predicate products, you may choose to provide a "bracketing" approach to demonstrate that the alternate materials in the new and predicate products do not cause the new products to raise different questions of public health. To do this, specify two unique versions of the new product, and if the predicate contains alternate materials, two unique versions of the predicate product:

- For one of the unique versions of the **new** product, identify a single set of alternate materials that result in the **highest** HPHC yields generated through integration of the alternate materials.
- For the other unique version of the **new** product, identify a single set of alternate materials that result in the **lowest** HPHC yields generated through integration of the alternate materials.
- For one of the unique versions of the **predicate** product, identify a single set of alternate materials that result in the **highest** HPHC yields generated through integration of the alternate materials.
- For the other unique version of the **predicate** product, identify a single set of alternate materials that result in the **lowest** HPHC yields generated through integration of the alternate materials.

Provide a justification for why each version of the new and predicate product is representative of the highest and lowest HPHC yields in the new and predicate products. Additionally, for each version specified, provide target specifications, upper and lower range limits, and test data generated from testing of cigarette draw resistance, puff count, denier per filament, total denier, filter density, filter length, filter ventilation (%), filter pressure drop, and tipping paper length and HPHCs for all of the identified new and predicate products. If a difference exists between the identified new and predicate products, provide scientific evidence and a rationale for why the difference does not cause the new product to raise different questions of public health.

All predicate product materials selected or used for comparison or bracketing must have been used in the predicate tobacco product as of February 15, 2007, and have been commercially marketed (other than for test marketing).

You stated that you no longer manufacture the predicate product and, therefore, are unable to provide the necessary design parameter data. Even if you no longer manufacture the predicate product, you still need to fully characterize the new and predicate products, and if the characteristics are different, demonstrate that the new products do not raise different questions of public health. Some potential options for obtaining data on the predicate products include, but are not limited to:

- Manufacture the predicate products at present day, consistent with the product composition and design specifications in place at the time the grandfathered predicate product was originally manufactured. In this case, design parameter data should be accompanied by documentation demonstrating that the

manufacture of the predicate product at present day is reflective of the grandfathered predicate product at the time of original manufacture.

- Submit design parameter data for products other than the predicate products (referred to as surrogate tobacco products) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco products could be submitted in place of data for the predicate products. However, information and data need to be provided to demonstrate that data for the surrogate tobacco products can be extrapolated to the predicate products. For example, the design parameters specifications for the predicate and surrogate products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products.

Therefore, the review concludes that the applicant did not demonstrate that the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from an engineering perspective.

I do not believe these deficiencies should be communicated to the applicant as identified in the engineering review because they do not prevent concluding that the new tobacco products are substantially equivalent to the predicate products.

Deficiencies 1 and 2 do not reflect the current approach to substantial equivalence review conducted by engineering.[4] Specifically, the engineering review identifies concerns with a lack of information from the applicant on target specifications and range limits for band porosity (deficiency 1) and lack of test data confirming the specifications have been met for filter density (deficiency 2) and concludes that the applicant has not addressed these concerns. Under the current approach to engineering substantial equivalence review, the applicant has provided sufficient information to determine that these differences in characteristics do not raise different questions of public health. The applicant provided measured or expected values for cigarette paper band porosity for SE0002159-SE0002164 because the applicant states that the cigarette paper employed (b) (4) is manufactured using specifications for band diffusivity instead. Band diffusivity specifications are acceptable in this case in place of specifications for band porosity because, like cigarette paper band porosity, band diffusivity provides a measure of the air permeation. The engineering review indicated that the supplier COAs was provided, but not a manufacturer-specific COA; however, a second COA is not needed for the reasons cited above (band diffusivity is an acceptable alternative specification) and moreover, the supplier's COA provides target specifications and range limits for band porosity in addition to band diffusivity, therefore no additional information is needed.

Additionally, as TPL I considered that non-FSC paper products do not have cigarette paper bands. As such, cigarette paper band porosity would only be applicable to products utilizing FSC paper (i.e., the new tobacco products). Therefore, here, where the predicate does not have cigarette paper bands, no comparison can be made between the predicate and new paper band

[4] See the March 1, 2019 Memorandum, Engineering Review of Substantial Equivalence (SE) Reports for Originally Regulated Products

porosity design parameters. That being said, the existence of the paper bands in the new product where the predicate had none is an important design difference to consider when evaluating whether the change causes the new products to raise different questions of public health. This change was considered by chemistry in section 4.1, and the conclusion is that it does not cause the new tobacco products to raise different questions of public health.

Based on the current approach of engineering review, test data is not always necessary but may be needed when, for example, there is more than minimal difference between the target specification and range limits of the new and predicate tobacco products. With regard to deficiency 2, the engineering review cites a lack of test data confirming the specifications have been met for filter density. However, the target and range of the filter density between the new and predicate tobacco products show minimal differences (less than 1%) for these SE Reports, therefore additional information (i.e. test data) is not needed to confirm these specifications provided by the COAs as it is unlikely there will be any significant changes in HPHCs because of this small difference in the filter density target. Thus, after reviewing the data, I have determined that the applicant provided adequate information to determine that these changes in characteristics (cigarette paper band porosity and filter density) between the new and predicate products do not raise different questions of public health from a product design perspective.

Deficiency 3 and 4 relate to multiple interchangeable materials used in the products, but the applicant clarified that they do not intend to use multiple interchangeable materials other than with the two cigarette papers (manufactured by (b) or (b) (4) . The applicant stated in the response to FDA's August 4, 2016, Preliminary Finding letter (SE0013677) that they only intend to pursue interchangeable materials as it relates to two cigarette papers. Therefore, these deficiencies should not be conveyed to the applicant.

4.3. TOXICOLOGY

Toxicology reviews were completed by Berran Yucesoy on September 29, 2015, and by Wanyoike Kang'ethe on July 11, 2016, for all SE Reports and by Wanyoike Kang'ethe on January 9, 2017, for only SE0002159 and SE0002164.

The final toxicology review concludes that the new tobacco products have different characteristics related to product toxicology compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Inclusion of Fire Standards Compliant (FSC) cigarette paper
- The FSC cigarette paper contains (b) (4) (b) (4) (b) (4) additives not present in the predicate products
- Increases between 20-25% for the ingredients (b) (4) (SE0002159 and SE0002164 only)

Due to the presence of (b) (4) in the FSC banding in all new tobacco products, greater pyrolysis of (b) (4) could occur in the new tobacco products than in the corresponding predicate tobacco products which could increase TNCO yields. Also, the new tobacco products in

SE0002159 and SE0002164 contain greater amounts of (b) (4) and specially (b) (4) than the corresponding predicate tobacco products, which could have significant effects on smoke chemistry or toxicity attributable to the addition of flavoring ingredients such as these. However, the toxicology evaluation has determined that the applicant provided sufficient information to show that the increases in (b) (4) and (b) (4) for SE0002159 and SE0002164 only do not cause the new products to raise different questions of public health from a toxicology perspective. The TNCO yields, measured using two different smoking regimens, showed that the new and corresponding predicate tobacco products produced similar smoke yields for all new and predicate comparisons subject of these SE Reports. The data showed that the mainstream smoke yields from the new products did not differ significantly from those of the corresponding predicate products. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Because the proposed action is issuance of SE orders for these provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and corresponding predicate tobacco products:

- Addition of FSC cigarette paper
- Differences in plug wrap porosity due to the ability to perforate the tipping paper online
- Increase in filter ventilation
- Increases between 20-25% for the ingredients (b) (4) and (b) (4) (SE0002159 and SE0002164 only)

The applicant demonstrated that the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health. The chemistry and toxicology reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews. However, the engineering review concludes that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health. As explained in section 4.2 of this TPL review, I conclude that the deficiencies identified in the engineering review do not prevent concluding that the new tobacco products are substantially equivalent. Therefore, the engineering deficiencies should not be conveyed to the applicant, and I recommend that SE order letters be issued.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

Because the proposed action is issuance of SE orders for these provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0002159 - SE0002164, SE0002166, and SE0014828 – SE0014831, as identified on the cover page of this review.