FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0003201, SE0003204, SE0003206, and SE0003208

SE0003201: Union Full Flavor King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	12.4%
Characterizing Flavor	None
SE0003204: Union Gold King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	27.2%
Characterizing Flavor	None
SE0003206: Union Platinum King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	39.2%
Characterizing Flavor	None
SE0003208: Union Menthol King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	14.9%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Heritage Tobacco, LLC
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Not Substantially Equivalent (NSE) Orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.06.19 14:19:29 -04'00'

Matthew J. Walters, Ph.D., M.P.H.
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: 2018.06.19 17:00:03 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0003201: Union Full Flavor King Box	
Product Name	Union Full Flavor King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	12.4%
Characterizing Flavor	None
SE0003204: Union Gold King Box	
Product Name[1]	Union Gold King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	27.2%
Characterizing Flavor	None
SE0003206: Union Platinum King Box	
Product Name[2]	Union Platinum King Box
Package Type	Box
Package Quantity	20 cigarettes

[1] The Office of Compliance and Enforcement (OCE) requested additional information to complete the predicate evaluation. Because the Office of Science (OS) requested that OCE perform an addendum to capture the characterizing flavor associated with the predicate tobacco product as well as to perform a final predicate evaluation review, OCE performed Independent Evidence Research (IER). The IER did yield additional evidence to demonstrate commercial marketing and upon reevaluation of the evidence submitted, OCE determined that there is sufficient information to link the evidence submitted to the predicate product. OCE notes that despite the representation made by the applicant the results of the IER appear to suggest that the name of the predicate product as it was commercially marketed in the United States as of February 15, 2007 included "Lights" instead of "Gold." Therefore, based on the totality of the evidence, including independent evidence research conducted by OCE, OCE can reasonably conclude that the predicate product was commercially marketed (other than exclusively in test markets) as of February 15, 2007. While the predicate product name in the scientific reviews was identified as Union Gold Kings Box, the predicate product has recently been identified as Union King Size Box Pack Lights. This information does not alter the evaluation of the scientific reviews due to the incorrect predicate product name.

[2] The Office of Compliance and Enforcement (OCE) requested additional information to complete the predicate evaluation. Because the Office of Science (OS) requested that OCE perform an addendum to capture the characterizing flavor associated with the predicate tobacco product as well as to perform a final predicate evaluation review, OCE performed Independent Evidence Research (IER). The IER did yield additional evidence to demonstrate commercial marketing and upon reevaluation of the evidence submitted, OCE determined that there is sufficient information to link the evidence submitted to the predicate product. OCE notes that despite the representation made by the applicant the results of the IER appear to suggest that the name of the predicate product as it was commercially marketed in the United States as of February 15, 2007 included "Lights" instead of "Platinum." Therefore, based on the totality of the evidence, including independent evidence research conducted by OCE, OCE can reasonably conclude that the predicate product was commercially marketed (other than exclusively in test markets) as of February 15, 2007. While the predicate product name in the scientific reviews was identified as Union Platinum Kings Box, the predicate product has recently been identified as Union King Size Box Pack Lights. This information does not alter the evaluation of the scientific reviews due to the incorrect predicate product name.

Length	84 mm
Diameter	7.8 mm
Ventilation	39.2%
Characterizing Flavor	None
SE0003208: Union Menthol King Box	
Product Name	Union Menthol King Box
Package Type	Box
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	14.9%
Characterizing Flavor	Menthol

The predicate tobacco products are combusted filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received these four SE Reports from American Cigarette Company (ACC) on March 22, 2011. FDA issued acknowledgement letters on September 15, 2011. FDA issued Advice/Information Request (A/I) letters on December 13, 2012, and May 10, 2013, addressed to ACC. On February 18, 2014, a telecon was held regarding transfer of ownership. On February 19, 2014, FDA received a request for a change in ownership for all ACC products (SE0010217) from Heritage Tobacco LLC. On April 11, 2014, FDA issued an A/I letter to Heritage Tobacco LLC requesting additional information on the change of ownership. On July 11, 2014, FDA issued a Transfer of Ownership acknowledgment letter to Heritage Tobacco LLC for all STNs transferred from American Cigarette Company Inc. FDA issued a Notification letter on July 11, 2014, indicating scientific review was expected to begin on August 25, 2014. On August 19, 2014, FDA received a request from Troutman Sanders on behalf of ACC to withdraw these STNs (SE0010640). A Regulatory Review, finalized on January 30, 2015, concluded that the request to withdraw cannot be processed as the submissions are now under the responsibility of Heritage Tobacco LLC. FDA issued a Preliminary Finding (PFind) letter on June 26, 2015. On July 10, 2015, and August 3, 2015, FDA received the applicant's responses to the PFind letter (SE0012175 and SE0012246). On September 28, 2015, FDA received an amendment in response to Office of Compliance and Enforcement's (OCE) request for information (SE0012416). FDA issued an A/I letter on May 16, 2016. On June 6, 2016, FDA received the applicant's 30-day extension request (SE0013412) to collect information from the records of the former owner. FDA issued an Extension Denied letter on July 13, 2016. On July 13, 2016, FDA received the response to the May 16, 2016, A/I letter (SE0013484) for SE0003204, SE0003206, and SE0003208. On August 9, 2016, FDA received an unsolicited amendment (SE0013558), containing an update to include SE0003201 in their previous response. FDA issued a PFind letter on January 10, 2017, with a response due date of February 9, 2017. On February 7, 2017, FDA received an amendment (SE0013896) including a partial response to the January 10, 2017, PFind letter, and a request for an extension of time to respond completely to the PFind letter. On March 13, 2017, FDA received an amendment (SE0013977) updating the predicate tobacco product information for SE0003204. On March 24, 2017, FDA issued an Extension Denied letter. On April 5, 2017, FDA's OCE contacted the applicant and requested information for the

predicate tobacco products identified in amendment SE0013977. On April 11, 2017, FDA received an amendment (SE0014027) clarifying that the predicate tobacco product information for SE0003204 was not included in the March 13, 2017, amendment (SE0013977). On July 27, 2017, FDA received the applicant's additional responses to the January 10, 2017, PFind letter (SE0014218). The amendment was considered late as it was received by FDA after the due date of response, February 9, 2017. FDA had completed all scientific reviews prior to receipt of the late amendment (SE0014218). Although FDA does not review amendments received after scientific review has concluded, the technical project lead (TPL) for these SE Reports conducted a cursory review of the unsolicited amendments (SE0014218) and found the conclusions of the previously finalized chemistry, and engineering reviews or this TPL review.[3]

Product Name	SE Report	Amendments
Union Full Flavor King Box	SE0003201	SE0010217 SE0010640 SE0012175 SE0012246 SE0012416 SE0013412 SE0013484 SE0013558 SE0013896 SE0014218
Union Gold King Box	SE0003204	SE0010217 SE0010640 SE0012175 SE0012246 SE0012416 SE0013412 SE0013484 SE0013558 SE0013896 SE0013977 SE0014027 SE0014218
Union Platinum King Box	SE0003206	SE0010217 SE0010640 SE0012175 SE0012246 SE0012416

[3] The amendment SE0014218 was received after the final scientific reviews were completed. The Technical Project Lead (TPL) reviewed this information and the provided additional information does not alter the recommendations of this review. The applicant provided HPHC yields and limited physical design measurements for only three out of the four new products (SE0003201, SE0003204, SE0003208), but did not provide HPHC yield information and physical design measurements for the corresponding predicate products to allow a meaningful comparison and determine whether any differences between the new and corresponding predicate products cause the new products to raise different questions of public health. However, the letter-ready comments will be edited to reflect new information from this amendment.

Product Name	SE Report	Amendments
		SE0013412 SE0013484 SE0013558 SE0013896 SE0014218
Union Menthol King Box	SE0003208	SE0010217 SE0010640 SE0012175 SE0012246 SE0012416 SE0013412 SE0013484 SE0013558 SE0013896 SE0014218

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 Marcella White on September 15, 2011, and December 13, 2012, and Ester Hatton on June 26, 2015, May 13, 2016, and May 22, 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 October 7, 2015 (for all STNs) and May 24, 2018 (for SE0003204 and SE0003206), 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[4].

[4] An addendum review was completed on May 24, 2018 (for SE0003201 and SE0003208), to clarify the characterizing flavor of the predicate tobacco products. The addendum review does not change the conclusion of the initial grandfather determination dated October 7, 2015.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Megan Mekoli on December 10, 2015, September 9, 2016, and April 10, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition 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. All of your SE Reports contain limited information and do not include sufficient detail to identify differences between the new and predicate products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 response, you provide evidence that several components changed in all or some of your products.

    a. The adhesives changed from (b) (4) on 10/25/2007
    b. The tobacco blend changed from (b) (4) on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    However, you are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette could affect the ingredients and may potentially affect the smoke chemistry. Provide a detailed list clearly stating all of the component and ingredient differences between the new and corresponding predicate products. If there are differences between the components of the new and predicate products, provide scientific evidence and a rationale as to why the differences do not cause the new products to raise different questions of public health.

2. All of your SE Reports contain limited blend information and do not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate products. For example, on page 90 of the July 2016 amendment in the submission, you provide a breakdown of a tobacco blend but do not identify to which products this blend pertains. Furthermore, the values for this blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However you do not provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

    We need any other information you may have that uniquely identifies the tobacco used in the new and predicate products. This is the information that you rely on to ensure that the

tobacco used in the new and predicate products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate products. Additionally, your SE Reports list (b) (4) as a type of tobacco in your blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise any new public health concerns. Provide information on ingredient composition of the (b) (4) and all of the following for the new and predicate products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate products may potentially affect the smoke chemistry, which have been shown to affect HPHC quantities. If there are any differences in tobacco blends between the new and predicate products, provide a rationale for each difference with evidence and a scientific discussion for why the difference does not cause the new products to raise different questions of public health.

3. All of your SE Reports provide information about ingredients added to the new and predicate products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate products. For example, your SE Reports do not clearly list ingredients in all components of the new and predicate products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper in the new products. However, the cigarette paper ingredient differences between the new and predicate products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator define the denominator, or the cigarette mass. Therefore, all ingredient quantities cannot be compared.

   There seem to be many errors in the submitted ingredient listings, most notably quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear instruction as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate products are substantially equivalent. Provide a new, detailed side-by-side comparison of only the new and corresponding predicate products in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, include individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)
   c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

If there are any differences in composition between the new and corresponding predicate products, provide scientific evidence and a rationale for why each difference does not cause the new product to raise different questions of public health.

4. All of your SE Reports lack HPHC mainstream smoke data for the new and predicate products. HPHC data can provide useful evidence to demonstrate that the difference in product composition between the new and corresponding predicate products do not cause the new products to raise different questions of public health. Because it is unclear what differences exist between the new and corresponding predicate products, it is unclear what HPHC data would be useful. At a minimum, provide tar, carbon monoxide, and nicotine (total) yields in mainstream smoke of the new and predicate products under both non-intense and intense smoking regimens. However, if there are differences in product characteristics likely to affect HPHC quantities, then provide applicable HPHC data. For example, you state that the cigarette paper changed from non-FSC to FSC in the new tobacco products, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper).

   These HPHC measurements would help determine whether significant changes cause the new products to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. Provide the following information about HPHC testing so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

   a. Reference product datasets (e.g., 1R6F)
   b. Quantitative test protocols and method used
   c. Testing laboratory and their accreditation(s)
   d. Length of time between date(s) of manufacture and date(s) of testing.
   e. Number of replicates
   f. Standard deviation(s)
   g. Complete data sets
   h. A summary of the results for all testing performed
   i. Storage conditions prior to initiating testing

   If your test methods are national or international test standards, identify any deviations from those standards.

   It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate product is not available for testing, there are options which you may choose to pursue to try to demonstrate substantial equivalence. Below are some options, though other alternative options may be acceptable. For example, the predicate product can be manufactured 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, the mainstream smoke HPHC 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. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate products (referred to as surrogate tobacco products) that can be extrapolated to the new and predicate products. In this case, data for the surrogate tobacco products could be submitted in place of data for the predicate and new tobacco products; the data should demonstrate that the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in characteristics to the new and predicate products and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate products should also be submitted.

Therefore, the review concludes that there was inadequate information from a chemistry perspective to determine 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.

4.2. ENGINEERING

Engineering reviews were completed by Erdit Gremi on December 9, 2015, Ouided Rouabhi on September 13, 2016, and Aarthi Arab on April 7, 2017.

The final engineering review concludes that the new tobacco products have different characteristics related to product design 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 with respect to product engineering. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All of your SE Reports provide some information on the design parameters for the new and predicate products. However, your SE Reports do not include all of the design parameters necessary to fully characterize the new and predicate products. In order to adequately characterize the products, it is necessary to compare key design parameters. Provide the target specification and upper and lower range limits for all of the following cigarette design parameters for each new and predicate product:

    a. Cigarette draw resistance (mm H_2O)
    b. Tobacco filler mass (mg)
    c. Tobacco rod density (g/cm^3)
    d. Tobacco oven volatiles (OV) (%)
    e. Tipping paper length (mm)
    f. Cigarette paper base paper basis weight (g/m^2)
    g. Cigarette paper base paper porosity (CU)

h. Cigarette paper band porosity (CU)
i. Cigarette paper band width (mm)
j. Cigarette paper band space (mm)
k. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
l. Filter length (mm)
m. Filter pressure drop (mm H_2O)

Additionally, for all your SE Reports provide the upper and lower range limits for all of the following cigarette design parameters for each new and predicate product:

n. Cigarette length (mm)
o. Cigarette circumference (mm)
p. Filter ventilation (%)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.

If a difference exists between the new and corresponding predicate products, provide a rationale for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.

Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may provide target specification and upper and lower range limits for filter efficiency.

2. All of your SE Reports include design parameter specifications but do not include data confirming that specifications are met. 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 cigarette design parameters for each new and predicate product:

a. Puff count
b. Cigarette draw resistance (mm H_2O)
c. Tobacco filler mass (mg)
d. Tobacco oven volatiles (OV) (%)
e. Filter ventilation (%)
f. Cigarette paper base paper basis weight (g/m^2)
g. Cigarette paper base paper porosity (CU)
h. Cigarette paper band porosity (CU)
i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]

j. Filter pressure drop (mm H_2O)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), state as such and provide a scientific rationale.
Certificates of analysis from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing certificates of analysis for any of the parameters listed above, the certificates of analysis 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 certificate of analysis must be a complete, unaltered certificate of analysis 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.

If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, provide test data as described above for filter efficiency.

3. All of your SE Reports indicate that the new and predicate products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) " and sometimes as (b) (4) ," indicating there may be two different cigarette base papers with different porosities used in one product.

   In accordance with section 910(a)(1)(B) of the FD&C Act, each product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate product must consist of a single combination of cigarette paper, tipping paper, filter tow, and plug wrap materials. Either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

   a. Every unique material combination in the predicate product that was on the market as of February 15, 2007.
   b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. 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.

   For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, provide data generated from testing of design parameters and HPHCs.

You state 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. Additionally, if a difference exists between the new and predicate product 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.

Therefore, the review concludes that there was inadequate information from an engineering perspective to determine 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.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(b), issuance of an order finding a tobacco product not substantially equivalent (NSE) under section 910(a) of the FD&C Act is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND REOMMENDATION

The key differences in characteristics between the new and corresponding predicate tobacco products are unknown because the SE Reports contain insufficient information about the characteristics of the new and predicate tobacco products to make an appropriate comparison. Therefore, the applicant failed to provide sufficient information to support a finding of substantial equivalence. Without sufficient information to compare the new and corresponding predicate

tobacco products, we cannot make determinations of substantial equivalence. Therefore, we cannot be certain that the new products do not raise different questions of public health.

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 issuing NSE orders, it is a class of action that is categorically excluded under 21 CFR 25.35(b). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determine that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

NSE order letters should be issued for the new tobacco products in SE0003201, SE0003204, SE0003206, and SE0003208, as identified on the cover page of this review.

6.1. DEFICIENCIES FOR SE0003201

The NSE order letter for SE0003201 should cite the following deficiencies:

1. Your SE Report contains limited information and does not include sufficient detail to identify differences between the new and predicate tobacco products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 amendment, you provide evidence that several components changed:

    a. The adhesives changed from (b) (4) on 10/25/2007
    b. The tobacco blend changed from (b) (4) on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    You are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette can include changes in the ingredients and may potentially affect the smoke chemistry. A detailed list is needed clearly stating all of the component and ingredient differences between the new and predicate tobacco products. If there are differences between the components of the new and predicate tobacco product, scientific evidence and a rationale are needed as to why the differences do not cause the new tobacco product to raise different questions of public health.

2. Your SE Report contains limited tobacco blend information and does not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate tobacco product. For example, on page 90 of the July 2016 amendment, you provide a breakdown of a tobacco blend but do not identify to which product this blend pertains. Furthermore, the values for this tobacco blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However, you provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

We need any other information you may have that uniquely identifies the tobacco used in the new and predicate tobacco products. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate tobacco products. Additionally, your SE Report lists (b) (4) as a type of tobacco in your tobacco blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise different questions of public health. Information is needed on ingredient composition of the (b) (4) and *all* of the following for the new and predicate tobacco products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry by affecting the HPHC yields. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion is needed for why the difference does not cause the new product to raise different questions of public health.

3. Your SE Report provides information about ingredients added to the new and predicate tobacco products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate tobacco products. For example, your SE Report does not clearly list ingredients in all components of the new and predicate tobacco products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper. However, the cigarette paper ingredient differences between the new and predicate tobacco products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator, define the denominator, or the cigarette mass. Therefore, ingredient quantities cannot be compared.

   There appears to be many errors in the submitted ingredient listings. Most notably, quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear indication as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate product are substantially equivalent. A detailed side-by-side comparison of the new and predicate tobacco products is needed in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, including individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)

c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

If there are any differences in composition between the new and predicate tobacco products, scientific evidence and a rationale are needed for why each difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report lacks HPHC mainstream smoke data for the predicate tobacco product. You did provide ammonia, three aromatic amines, benzo[a]pyrene, carbon monoxide, four carbonyls, nicotine, NNN, NNK, and five volatiles yields under both the ISO and CI smoking conditions for the new product, but you did not provide these HPHC yields for the predicate tobacco product. As such, FDA is unable to determine the differences in characteristics between the new and predicate tobacco products. For example, you state that the cigarette paper changed from non-FSC to FSC, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper). You provided these HPHCs for the new tobacco product, however these HPHCs are also needed for the predicate tobacco product in order for FDA to compare any HPHC differences between the new and predicate tobacco products.

   These HPHC measurements would help determine whether significant changes cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. The following information about HPHC testing is also needed so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

   a. Reference product datasets (e.g., 1R6F)
   b. Quantitative test protocols and method used
   c. Testing laboratory and their accreditation(s)
   d. Length of time between date(s) of manufacture and date(s) of testing.
   e. Number of replicates
   f. Standard deviation(s)
   g. Complete data sets
   h. A summary of the results for all testing performed
   i. Storage conditions prior to initiating testing

   If your test methods are national or international test standards, you need to identify the standard(s) and any deviation(s) from those standards.

   It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate tobacco product is not available for testing, there are options which you may choose to try to demonstrate substantial equivalence.

Below are some options, though alternative options may be acceptable. For example, the predicate tobacco product could be manufactured 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, the mainstream smoke HPHC data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate tobacco product (referred to as surrogate tobacco products) that could be extrapolated to the new and predicate tobacco product. In this case, data for the surrogate tobacco products could be submitted in place of data for the new and predicate tobacco product; the data should demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in characteristics to the new and predicate tobacco product, and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate tobacco product should also be submitted.

5. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report does not include all of the design parameters necessary to fully characterize the new and predicate tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. Target specifications and upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products unless otherwise specified:

    a. Cigarette draw resistance (mm H_2O) (predicate product only)
    b. Tobacco filler mass (mg) (predicate product only)
    c. Tobacco rod density (g/cm^3) (predicate product only)
    d. Tobacco oven volatiles (OV) (%) (predicate product only)
    e. Tipping paper length (mm) (predicate product only)
    f. Cigarette paper base paper basis weight (g/m^2) (predicate product only)
    g. Cigarette paper base paper porosity (CU) (predicate product only)
    h. Cigarette paper band porosity (CU) (predicate product only)
    i. Cigarette paper band width (mm) (predicate product only)
    j. Cigarette paper band space (mm) (predicate product only)
    k. Filter efficiency (%) (predicate product only)
       [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    l. Filter length (mm) (predicate product only)
    m. Filter pressure drop (mm H_2O)

    Additionally, the upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    n. Cigarette length (mm) (predicate product only)

o. Cigarette circumference (mm) (predicate product only)
p. Filter ventilation (%) (predicate product only)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you need to state as such and provide a scientific rationale.

If a difference exists between the new and predicate tobacco product, a rationale is needed for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may have provided target specification and upper and lower range limits for filter efficiency.

6. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including **test protocols, quantitative acceptance criteria, data sets, and a summary of the results** are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

   a. Puff count
   b. Cigarette draw resistance (mm H_2O)
   c. Tobacco filler mass (mg)
   d. Tobacco oven volatiles (OV) (%)
   e. Filter ventilation (%)
   f. Cigarette paper base paper basis weight (g/m^2)
   g. Cigarette paper base paper porosity (CU)
   h. Cigarette paper band porosity (CU)
   i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
   j. Filter pressure drop (mm H_2O)

   For each of the above parameters, the necessary data should be provided on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

   Certificates of analysis from the material supplier may have satisfied this concern. If you choose to address this concern by providing certificates of analysis for any of the parameters listed above, the certificates of analysis 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

certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

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

If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, you should have provided test data as described above for filter efficiency.

7. Your SE Report indicates that the new and predicate tobacco products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) " and sometimes as "(b) (4) ," indicating there may be two different cigarette base papers with different porosities used in one product.

   In accordance with section 910(a)(1)(B) of the FD&C Act, each tobacco product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette paper, tipping paper, filter tow, and plug wrap materials. You should either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

   a. Every unique material combination in the predicate tobacco product that was on the market as of February 15, 2007.
   b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. 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.

   For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, you needed to provide data generated from testing of design parameters and HPHCs. You state that you no longer manufacture the predicate tobacco 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 tobacco product and, if the characteristics are different, you needed to demonstrate that the new tobacco product does not raise different questions of public health. Some potential options for obtaining data on the predicate tobacco product include, but are not limited to:

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

- Submit design parameter data for a tobacco product other than the predicate tobacco product (referred to as a surrogate tobacco product) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco product could be submitted in place of data for the predicate tobacco product. Information and data would need to be provided to demonstrate that data for the surrogate tobacco product can be extrapolated to the predicate tobacco product. For example, the design parameters specifications for the predicate and surrogate tobacco products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products. Additionally, if a difference exists between the new and predicate product identified for each SE Report, scientific evidence and a rationale are needed for why the difference does not cause the new tobacco product to raise different questions of public health.

6.2. DEFICIENCIES FOR SE0003204

The NSE order letter for SE0003204 should cite the following deficiencies:

1. Your SE Report contains limited information and does not include sufficient detail to identify differences between the new and predicate tobacco products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 amendment, you provide evidence that several components changed:

    a. The adhesives changed from (b) (4) on 10/25/2007
    b. The tobacco blend changed from (b) (4) on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    You are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette can include changes in the ingredients and may potentially affect the smoke chemistry. A detailed list is needed clearly stating all of the component and ingredient differences between the new and predicate tobacco products. If there are differences between the components of the new and predicate tobacco product, scientific evidence and a rationale are needed as to why the differences do not cause the new tobacco product to raise different questions of public health.

2. Your SE Report contains limited tobacco blend information and does not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate tobacco product. For example, on page 90 of the July 2016 amendment, you provide a breakdown of a tobacco blend but do not identify to which product this blend pertains. Furthermore, the values for this tobacco blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However, you provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

We need any other information you may have that uniquely identifies the tobacco used in the new and predicate tobacco products. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate tobacco products. Additionally, your SE Report lists (b) (4) as a type of tobacco in your tobacco blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise different questions of public health. Information is needed on ingredient composition of the (b) (4) and *all* of the following for the new and predicate tobacco products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry by affecting the HPHC yields. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion is needed for why the difference does not cause the new product to raise different questions of public health.

3. Your SE Report provides information about ingredients added to the new and predicate tobacco products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate tobacco products. For example, your SE Report does not clearly list ingredients in all components of the new and predicate tobacco products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper. However, the cigarette paper ingredient differences between the new and predicate tobacco products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator, define the denominator, or the cigarette mass. Therefore, ingredient quantities cannot be compared.

   There appears to be many errors in the submitted ingredient listings. Most notably, quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear indication as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate product are substantially equivalent. A detailed side-by-side comparison of the new and predicate tobacco products is needed in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, including individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)

c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

If there are any differences in composition between the new and predicate tobacco products, scientific evidence and a rationale are needed for why each difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report lacks HPHC mainstream smoke data for the predicate tobacco product. You did provide ammonia, three aromatic amines, benzo[a]pyrene, carbon monoxide, four carbonyls, nicotine, NNN, NNK, and five volatiles yields under both the ISO and CI smoking conditions for the new product, but you did not provide these HPHC yields for the predicate tobacco product. As such, FDA is unable to determine the differences in characteristics between the new and predicate tobacco products. For example, you state that the cigarette paper changed from non-FSC to FSC, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper). You provided these HPHCs for the new tobacco product, however these HPHCs are also needed for the predicate tobacco product in order for FDA to compare any HPHC differences between the new and predicate tobacco products.

   These HPHC measurements would help determine whether significant changes cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. The following information about HPHC testing is also needed so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

   a. Reference product datasets (e.g., 1R6F)
   b. Quantitative test protocols and method used
   c. Testing laboratory and their accreditation(s)
   d. Length of time between date(s) of manufacture and date(s) of testing.
   e. Number of replicates
   f. Standard deviation(s)
   g. Complete data sets
   h. A summary of the results for all testing performed
   i. Storage conditions prior to initiating testing

   If your test methods are national or international test standards, you need to identify the standard(s) and any deviation(s) from those standards.

   It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate tobacco product is not available for testing, there are options which you may choose to try to demonstrate substantial equivalence.

Below are some options, though alternative options may be acceptable. For example, the predicate tobacco product could be manufactured 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, the mainstream smoke HPHC data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate tobacco product (referred to as surrogate tobacco products) that could be extrapolated to the new and predicate tobacco product. In this case, data for the surrogate tobacco products could be submitted in place of data for the new and predicate tobacco product; the data should demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in characteristics to the new and predicate tobacco product, and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate tobacco product should also be submitted.

5. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report does not include all of the design parameters necessary to fully characterize the new and predicate tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. Target specifications and upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products unless otherwise specified:

    a. Cigarette draw resistance (mm H_2O) (predicate product only)
    b. Tobacco filler mass (mg) (predicate product only)
    c. Tobacco rod density (g/cm^3) (predicate product only)
    d. Tobacco oven volatiles (OV) (%) (predicate product only)
    e. Tipping paper length (mm) (predicate product only)
    f. Cigarette paper base paper basis weight (g/m^2) (predicate product only)
    g. Cigarette paper base paper porosity (CU) (predicate product only)
    h. Cigarette paper band porosity (CU) (predicate product only)
    i. Cigarette paper band width (mm) (predicate product only)
    j. Cigarette paper band space (mm) (predicate product only)
    k. Filter efficiency (%) (predicate product only)
       [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    l. Filter length (mm) (predicate product only)
    m. Filter pressure drop (mm H_2O)

    Additionally, the upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    n. Cigarette length (mm) (predicate product only)

o. Cigarette circumference (mm) (predicate product only)
p. Filter ventilation (%) (predicate product only)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you need to state as such and provide a scientific rationale.

If a difference exists between the new and predicate tobacco product, a rationale is needed for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may have provided target specification and upper and lower range limits for filter efficiency.

6. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including **test protocols, quantitative acceptance criteria, data sets, and a summary of the results** are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

   a. Puff count
   b. Cigarette draw resistance (mm H_2O)
   c. Tobacco filler mass (mg)
   d. Tobacco oven volatiles (OV) (%)
   e. Filter ventilation (%)
   f. Cigarette paper base paper basis weight (g/m^2)
   g. Cigarette paper base paper porosity (CU)
   h. Cigarette paper band porosity (CU)
   i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
   j. Filter pressure drop (mm H_2O)

   For each of the above parameters, the necessary data should be provided on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

   Certificates of analysis from the material supplier may have satisfied this concern. If you choose to address this concern by providing certificates of analysis for any of the parameters listed above, the certificates of analysis 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

certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

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

If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, you should have provided test data as described above for filter efficiency.

7. Your SE Report indicates that the new and predicate tobacco products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) [redacted]" and sometimes as "(b) (4) [redacted]," indicating there may be two different cigarette base papers with different porosities used in one product.

   In accordance with section 910(a)(1)(B) of the FD&C Act, each tobacco product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette paper, tipping paper, filter tow, and plug wrap materials. You should either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

   a. Every unique material combination in the predicate tobacco product that was on the market as of February 15, 2007.
   b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. 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.

   For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, you needed to provide data generated from testing of design parameters and HPHCs. You state that you no longer manufacture the predicate tobacco 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 tobacco product and, if the characteristics are different, you needed to demonstrate that the new tobacco product does not raise different questions of public health. Some potential options for obtaining data on the predicate tobacco product include, but are not limited to:

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

- Submit design parameter data for a tobacco product other than the predicate tobacco product (referred to as a surrogate tobacco product) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco product could be submitted in place of data for the predicate tobacco product. Information and data would need to be provided to demonstrate that data for the surrogate tobacco product can be extrapolated to the predicate tobacco product. For example, the design parameters specifications for the predicate and surrogate tobacco products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products. Additionally, if a difference exists between the new and predicate product identified for each SE Report, scientific evidence and a rationale are needed for why the difference does not cause the new tobacco product to raise different questions of public health.

6.3. DEFICIENCIES FOR SE0003206

The NSE order letter for SE0003206 should cite the following deficiencies:

1. Your SE Report contains limited information and does not include sufficient detail to identify differences between the new and predicate tobacco products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 amendment, you provide evidence that several components changed:

    a. The adhesives changed from (b) (4) on 10/25/2007
    b. The tobacco blend changed from (b) (4) on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    You are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette can include changes in the ingredients and may potentially affect the smoke chemistry. A detailed list is needed clearly stating all of the component and ingredient differences between the new and predicate tobacco products. If there are differences between the components of the new and predicate tobacco product, scientific evidence and a rationale are needed as to why the differences do not cause the new tobacco product to raise different questions of public health.

2. Your SE Report contains limited tobacco blend information and does not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate tobacco product. For example, on page 90 of the July 2016 amendment, you provide a breakdown of a tobacco blend but do not identify to which product this blend pertains. Furthermore, the values for this tobacco blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However, you provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

We need any other information you may have that uniquely identifies the tobacco used in the new and predicate tobacco products. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate tobacco products. Additionally, your SE Report lists (b) (4) as a type of tobacco in your tobacco blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise different questions of public health. Information is needed on ingredient composition of the (b) (4) and *all* of the following for the new and predicate tobacco products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry by affecting the HPHC yields. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion is needed for why the difference does not cause the new product to raise different questions of public health.

3. Your SE Report provides information about ingredients added to the new and predicate tobacco products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate tobacco products. For example, your SE Report does not clearly list ingredients in all components of the new and predicate tobacco products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper. However, the cigarette paper ingredient differences between the new and predicate tobacco products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator, define the denominator, or the cigarette mass. Therefore, ingredient quantities cannot be compared.

   There appears to be many errors in the submitted ingredient listings. Most notably, quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear indication as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate product are substantially equivalent. A detailed side-by-side comparison of the new and predicate tobacco products is needed in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, including individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)

c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

If there are any differences in composition between the new and predicate tobacco products, scientific evidence and a rationale are needed for why each difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report lacks HPHC mainstream smoke data for the predicate tobacco product. You did provide ammonia, three aromatic amines, benzo[a]pyrene, carbon monoxide, four carbonyls, nicotine, NNN, NNK, and five volatiles yields under both the ISO and CI smoking conditions for the new product, but you did not provide these HPHC yields for the predicate tobacco product. As such, FDA is unable to determine the differences in characteristics between the new and predicate tobacco products. For example, you state that the cigarette paper changed from non-FSC to FSC, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper). You provided these HPHCs for the new tobacco product, however these HPHCs are also needed for the predicate tobacco product in order for FDA to compare any HPHC differences between the new and predicate tobacco products.

   These HPHC measurements would help determine whether significant changes cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. The following information about HPHC testing is also needed so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

   a. Reference product datasets (e.g., 1R6F)
   b. Quantitative test protocols and method used
   c. Testing laboratory and their accreditation(s)
   d. Length of time between date(s) of manufacture and date(s) of testing.
   e. Number of replicates
   f. Standard deviation(s)
   g. Complete data sets
   h. A summary of the results for all testing performed
   i. Storage conditions prior to initiating testing

   If your test methods are national or international test standards, you need to identify the standard(s) and any deviation(s) from those standards.

   It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate tobacco product is not available for testing, there are options which you may choose to try to demonstrate substantial equivalence.

Below are some options, though alternative options may be acceptable. For example, the predicate tobacco product could be manufactured 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, the mainstream smoke HPHC data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate tobacco product (referred to as surrogate tobacco products) that could be extrapolated to the new and predicate tobacco product. In this case, data for the surrogate tobacco products could be submitted in place of data for the new and predicate tobacco product; the data should demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in characteristics to the new and predicate tobacco product, and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate tobacco product should also be submitted.

5. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report does not include all of the design parameters necessary to fully characterize the new and predicate tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. Target specifications and upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products unless otherwise specified:

    a. Cigarette draw resistance (mm H_2O) (predicate product only)
    b. Tobacco filler mass (mg) (predicate product only)
    c. Tobacco rod density (g/cm^3) (predicate product only)
    d. Tobacco oven volatiles (OV) (%) (predicate product only)
    e. Tipping paper length (mm) (predicate product only)
    f. Cigarette paper base paper basis weight (g/m^2) (predicate product only)
    g. Cigarette paper base paper porosity (CU) (predicate product only)
    h. Cigarette paper band porosity (CU) (predicate product only)
    i. Cigarette paper band width (mm) (predicate product only)
    j. Cigarette paper band space (mm) (predicate product only)
    k. Filter efficiency (%) (predicate product only)
       [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    l. Filter length (mm) (predicate product only)
    m. Filter pressure drop (mm H_2O)

    Additionally, the upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    n. Cigarette length (mm) (predicate product only)

o. Cigarette circumference (mm) (predicate product only)
p. Filter ventilation (%) (predicate product only)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you need to state as such and provide a scientific rationale.

If a difference exists between the new and predicate tobacco product, a rationale is needed for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may have provided target specification and upper and lower range limits for filter efficiency.

6. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including **test protocols, quantitative acceptance criteria, data sets, and a summary of the results** are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

   a. Puff count
   b. Cigarette draw resistance (mm H_2O)
   c. Tobacco filler mass (mg)
   d. Tobacco oven volatiles (OV) (%)
   e. Filter ventilation (%)
   f. Cigarette paper base paper basis weight (g/m^2)
   g. Cigarette paper base paper porosity (CU)
   h. Cigarette paper band porosity (CU)
   i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
   j. Filter pressure drop (mm H_2O)

   For each of the above parameters, the necessary data should be provided on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

   Certificates of analysis from the material supplier may have satisfied this concern. If you choose to address this concern by providing certificates of analysis for any of the parameters listed above, the certificates of analysis 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

certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

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

If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, you should have provided test data as described above for filter efficiency.

7. Your SE Report indicates that the new and predicate tobacco products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) [redacted]" and sometimes as "(b) (4) [redacted]," indicating there may be two different cigarette base papers with different porosities used in one product.

   In accordance with section 910(a)(1)(B) of the FD&C Act, each tobacco product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette paper, tipping paper, filter tow, and plug wrap materials. You should either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

   a. Every unique material combination in the predicate tobacco product that was on the market as of February 15, 2007.
   b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. 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.

   For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, you needed to provide data generated from testing of design parameters and HPHCs. You state that you no longer manufacture the predicate tobacco 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 tobacco product and, if the characteristics are different, you needed to demonstrate that the new tobacco product does not raise different questions of public health. Some potential options for obtaining data on the predicate tobacco product include, but are not limited to:

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

- Submit design parameter data for a tobacco product other than the predicate tobacco product (referred to as a surrogate tobacco product) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco product could be submitted in place of data for the predicate tobacco product. Information and data would need to be provided to demonstrate that data for the surrogate tobacco product can be extrapolated to the predicate tobacco product. For example, the design parameters specifications for the predicate and surrogate tobacco products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products. Additionally, if a difference exists between the new and predicate product identified for each SE Report, scientific evidence and a rationale are needed for why the difference does not cause the new tobacco product to raise different questions of public health.

6.4. DEFICIENCIES FOR SE0003208

The NSE order letter for SE0003208 should cite the following deficiencies:

1. Your SE Report contains limited information and does not include sufficient detail to identify differences between the new and predicate tobacco products. You state that there are no differences in the ingredients, materials, heating source, composition and other features, yet, in your July 2016 amendment, you provide evidence that several components changed:

    a. The adhesives changed from (b) (4) on 10/25/2007
    b. The tobacco blend changed from (b) (4) on 6/18/2010
    c. The cigarette paper changed from non-FSC to FSC between 3/14/2008 and 3/31/2011

    You are responsible for all information pertaining to the products in these SE Reports.

    Component changes in a cigarette can include changes in the ingredients and may potentially affect the smoke chemistry. A detailed list is needed clearly stating all of the component and ingredient differences between the new and predicate tobacco products. If there are differences between the components of the new and predicate tobacco product, scientific evidence and a rationale are needed as to why the differences do not cause the new tobacco product to raise different questions of public health.

2. Your SE Report contains limited tobacco blend information and does not include sufficient detail to fully characterize the tobacco blend composition of the new and predicate tobacco product. For example, on page 90 of the July 2016 amendment, you provide a breakdown of a tobacco blend but do not identify to which product this blend pertains. Furthermore, the values for this tobacco blend are provided in relative quantities (i.e., percent) without providing the units for the numerator and denominator. Additionally, on page 90, you state that: “This blend contains casings and flavorings.” However, you provide the mass of only the tobaccos in the blend of one cigarette (i.e., mg/cig) without ingredients added to the tobacco.

We need any other information you may have that uniquely identifies the tobacco used in the new and predicate tobacco products. This is the information that you rely on to ensure that the tobacco used in the new and predicate tobacco products is identical for both products. For example, if you use a tobacco grading system, it would be helpful to know the tobacco grade (along with an explanation of the grading system) for each type of tobacco used in the new and predicate tobacco products. Additionally, your SE Report lists (b) (4) as a type of tobacco in your tobacco blend. However, you do not identify the tobacco or other ingredients in the (b) (4). It is important to know what ingredients, specifically, are included in the different (b) (4) in order to ensure that changes in (b) (4) do not raise different questions of public health. Information is needed on ingredient composition of the (b) (4) and *all* of the following for the new and predicate tobacco products:

a. All tobacco types used to manufacture the products
b. Quantities of all tobacco types expressed as mass per cigarette
c. Information to uniquely identify all tobacco (e.g., tobacco grading system)

Tobacco blend changes between the new and predicate tobacco products may potentially affect the smoke chemistry by affecting the HPHC yields. If there are any differences in tobacco blends between the new and predicate tobacco products, a rationale for each difference with evidence and a scientific discussion is needed for why the difference does not cause the new product to raise different questions of public health.

3. Your SE Report provides information about ingredients added to the new and predicate tobacco products. The information provided for ingredients does not include sufficient detail to fully characterize the composition of the new and predicate tobacco products. For example, your SE Report does not clearly list ingredients in all components of the new and predicate tobacco products. Furthermore, you state that the cigarette paper changed from non-FSC to FSC paper. However, the cigarette paper ingredient differences between the new and predicate tobacco products were not provided. Ingredient quantities are provided as percentages, grams, kg/g, ppm, and ranges of percentages, but you do not specify the original units of the numerator and denominator, define the denominator, or the cigarette mass. Therefore, ingredient quantities cannot be compared.

   There appears to be many errors in the submitted ingredient listings. Most notably, quantities appear to be placed in the incorrect row with the ingredient tables. Furthermore, you provided two different sets of ingredient data labeled “predicate product” and “grandfathered product” in addition to the “new product” data without clear indication as to which sets of data should be evaluated. Without complete, accurate, and clear ingredient information, we cannot determine whether the new and predicate product are substantially equivalent. A detailed side-by-side comparison of the new and predicate tobacco products is needed in a table organized by product and component including the following information:

   a. All ingredients used to manufacture the products, including individual ingredients in complex ingredients
   b. Quantities of all ingredients expressed as mass per cigarette (i.e., mg/cigarette)

c. Information to uniquely identify each ingredient (e.g., CAS #, grade/purity, and function)

If there are any differences in composition between the new and predicate tobacco products, scientific evidence and a rationale are needed for why each difference does not cause the new tobacco product to raise different questions of public health.

4. Your SE Report lacks HPHC mainstream smoke data for the predicate tobacco product. You did provide ammonia, three aromatic amines, benzo[a]pyrene, carbon monoxide, four carbonyls, nicotine, NNN, NNK, and five volatiles yields under both the ISO and CI smoking conditions for the new product, but you did not provide these HPHC yields for the predicate tobacco product. As such, FDA is unable to determine the differences in characteristics between the new and predicate tobacco products. For example, you state that the cigarette paper changed from non-FSC to FSC, and the combustion of sodium alginate (a component of banded FSC paper) may result in the formation of acetaldehyde and benzene. Additionally, acetaldehyde, formaldehyde, and benzene are potential pyrolysis products from cellulose, which is contained in flax fiber and wood pulp fiber (other components of banded FSC paper). You provided these HPHCs for the new tobacco product, however these HPHCs are also needed for the predicate tobacco product in order for FDA to compare any HPHC differences between the new and predicate tobacco products.

   These HPHC measurements would help determine whether significant changes cause the new tobacco product to raise different questions of public health. The measurement of HPHC quantities under both ISO and Canadian Intense smoking regimens would best characterize the delivery of constituents from these products. FDA recommends that appropriate measures be taken to minimize data variability and systematic bias. Such measures include, but are not limited to, using the same laboratory, the same type of smoking machine, the same methods, similar sample storage conditions and duration, and testing within similar timeframe. The following information about HPHC testing is also needed so that we can fully evaluate the differences in HPHC quantities between the new and predicate products:

   a. Reference product datasets (e.g., 1R6F)
   b. Quantitative test protocols and method used
   c. Testing laboratory and their accreditation(s)
   d. Length of time between date(s) of manufacture and date(s) of testing.
   e. Number of replicates
   f. Standard deviation(s)
   g. Complete data sets
   h. A summary of the results for all testing performed
   i. Storage conditions prior to initiating testing

   If your test methods are national or international test standards, you need to identify the standard(s) and any deviation(s) from those standards.

   It is an applicant's responsibility to provide appropriate scientific evidence and data for the predicate tobacco product. If your predicate tobacco product is not available for testing, there are options which you may choose to try to demonstrate substantial equivalence.

Below are some options, though alternative options may be acceptable. For example, the predicate tobacco product could be manufactured 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, the mainstream smoke HPHC data should be accompanied by documentation demonstrating that the manufacture of the predicate tobacco product at present day is reflective of the predicate tobacco product at the time of original manufacture. Another option would be to submit mainstream smoke HPHC data for products other than the new and predicate tobacco product (referred to as surrogate tobacco products) that could be extrapolated to the new and predicate tobacco product. In this case, data for the surrogate tobacco products could be submitted in place of data for the new and predicate tobacco product; the data should demonstrate that the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. In order to extrapolate such data, the HPHC smoke data should be produced from surrogate tobacco products as similar as possible in characteristics to the new and predicate tobacco product, and enough information should be provided to demonstrate that these comparisons are valid. In addition to the smoke data, information comparing the surrogate tobacco products to the new and predicate tobacco product should also be submitted.

5. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report does not include all of the design parameters necessary to fully characterize the new and predicate tobacco products. In order to adequately characterize the products, it is necessary to compare key design parameters. Target specifications and upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products unless otherwise specified:

    a. Cigarette draw resistance (mm H_2O) (predicate product only)
    b. Tobacco filler mass (mg) (predicate product only)
    c. Tobacco rod density (g/cm^3) (predicate product only)
    d. Tobacco oven volatiles (OV) (%) (predicate product only)
    e. Tipping paper length (mm) (predicate product only)
    f. Cigarette paper base paper basis weight (g/m^2) (predicate product only)
    g. Cigarette paper base paper porosity (CU) (predicate product only)
    h. Cigarette paper band porosity (CU) (predicate product only)
    i. Cigarette paper band width (mm) (predicate product only)
    j. Cigarette paper band space (mm) (predicate product only)
    k. Filter efficiency (%) (predicate product only)
       [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
    l. Filter length (mm) (predicate product only)
    m. Filter pressure drop (mm H_2O)

    Additionally, the upper and lower range limits are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

    n. Cigarette length (mm) (predicate product only)

o. Cigarette circumference (mm) (predicate product only)
p. Filter ventilation (%) (predicate product only)

For each of the above parameters, provide the necessary data on a per unit of product basis (e.g., tipping paper length should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you need to state as such and provide a scientific rationale.

If a difference exists between the new and predicate tobacco product, a rationale is needed for each difference in the target specification and range limits with evidence and a scientific discussion for why the difference does not cause the new tobacco product to raise different questions of public health.

Note that filter density, denier per filament, and total denier are necessary because filter efficiency (%) was not provided. As an alternative to submitting the information described above for filter density, denier per filament, and total denier, you may have provided target specification and upper and lower range limits for filter efficiency.

6. Your SE Report includes design parameter specifications but does not include data confirming that specifications are met. Test data (i.e., measured values of design parameters), including **test protocols, quantitative acceptance criteria, data sets, and a summary of the results** are needed for *all* of the following cigarette design parameters for the new and predicate tobacco products:

   a. Puff count
   b. Cigarette draw resistance (mm H_2O)
   c. Tobacco filler mass (mg)
   d. Tobacco oven volatiles (OV) (%)
   e. Filter ventilation (%)
   f. Cigarette paper base paper basis weight (g/m^2)
   g. Cigarette paper base paper porosity (CU)
   h. Cigarette paper band porosity (CU)
   i. Filter efficiency (%) [If no filter efficiency data is available for the products, include information sufficient to show that the cigarette filter is unchanged (e.g., denier per filament, total denier, and filter density)]
   j. Filter pressure drop (mm H_2O)

   For each of the above parameters, the necessary data should be provided on a per unit of product basis (e.g., filter pressure drop should be reported in mm per cigarette). If a design parameter is not applicable (e.g., band porosity if the cigarette paper does not contain bands), you needed to state as such and provide a scientific rationale.

   Certificates of analysis from the material supplier may have satisfied this concern. If you choose to address this concern by providing certificates of analysis for any of the parameters listed above, the certificates of analysis 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

certificate of analysis must be a complete, unaltered certificate of analysis from the material supplier.

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

If you choose to provide filter efficiency in place of filter density, denier per filament, and total denier, you should have provided test data as described above for filter efficiency.

7. Your SE Report indicates that the new and predicate tobacco products may use multiple materials including cigarette base paper, tipping paper, filter tow, and plug wrap materials. You state that you do not use multiple combinations of these materials, however you list multiple suppliers for cigarette base paper and in the listing of materials you provide multiple labels for each cigarette paper, tipping paper, filter tow, and plug wrap material. For example, cigarette base paper is named several times, sometimes as "(b) (4) " and sometimes as "(b) (4) ," indicating there may be two different cigarette base papers with different porosities used in one product.

   In accordance with section 910(a)(1)(B) of the FD&C Act, each tobacco product modification, including use of an alternate material, constitutes a new tobacco product. Each identified new and predicate tobacco product must consist of a single combination of cigarette paper, tipping paper, filter tow, and plug wrap materials. You should either reorganize your listing of materials to clarify the use of multiple materials or identify the following:

   a. Every unique material combination in the predicate tobacco product that was on the market as of February 15, 2007.
   b. Every unique material combination in the new tobacco product that was on the market between February 15, 2007 and March 22, 2011. 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.

   For each identified new and predicate product, based on each combination of cigarette paper, tipping paper, filter tow, and plug wrap materials, you needed to provide data generated from testing of design parameters and HPHCs. You state that you no longer manufacture the predicate tobacco 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 tobacco product and, if the characteristics are different, you needed to demonstrate that the new tobacco product does not raise different questions of public health. Some potential options for obtaining data on the predicate tobacco product include, but are not limited to:

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

- Submit design parameter data for a tobacco product other than the predicate tobacco product (referred to as a surrogate tobacco product) that can be extrapolated to the predicate products. In this case, data for the surrogate tobacco product could be submitted in place of data for the predicate tobacco product. Information and data would need to be provided to demonstrate that data for the surrogate tobacco product can be extrapolated to the predicate tobacco product. For example, the design parameters specifications for the predicate and surrogate tobacco products should be compared and an explanation provided for how each difference in specification would affect the extrapolation from the surrogate to predicate products. Additionally, if a difference exists between the new and predicate product identified for each SE Report, scientific evidence and a rationale are needed for why the difference does not cause the new tobacco product to raise different questions of public health.