Technical Project Lead (TPL) Review:

SE0001889 - SE0001893, SE0003304 - SE0003306

SE0001889: Traditions, King Size, "Full Flavor"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor	None
SE0001890: Traditions, King Size, "High Air"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	None
SE0001891: Traditions, King Size, "Ultra High Air"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter[1]	7.8 mm
Ventilation	30%
Characterizing Flavor	None
SE0001892: Traditions, King Size, "Menthol"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter[1]	7.8 mm
Ventilation	None
Characterizing Flavor	Menthol

[1] The applicant submitted the circumference which allowed for a calculation for diameter

SE0001893: Traditions, 100's, "Full Flavor"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor	None
SE0003304: Traditions, 100's, "High Air"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	None
SE0003305: Traditions, 100's, "Ultra High Air"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.8 mm
Ventilation	30%
Characterizing Flavor	None
SE0003306: Traditions, 100's, "Menthol"	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.8 mm
Ventilation	None
Characterizing Flavor	Menthol

Common Attributes of SE Reports	
Applicant	Skookum Creek Tobacco Company
Report Type	Provisional
Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Not Substantially Equivalent (NSE) orders	

Technical Project Lead (TPL):

Digitally signed by Shixia Feng -S
Date: 2018.10.04 15:30:58 -04'00'

Shixia Feng, Ph.D.
Chemistry Branch Chief
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: 2018.10.05 07:19:44 -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:

SE0001889: Traditions, King Size, "Full Flavor"	
Product Name	Complete, King Size, "Full Flavor"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor	None
SE0001890: Traditions, King Size, "High Air"	
Product Name	Complete, Kings Size, "High Air"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	None
SE0001891: Traditions, King Size, "Ultra High Air"	
Product Name	Complete, King Size, "Ultra High Air"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter[1]	7.8 mm
Ventilation	30%
Characterizing Flavor	None
SE0001892: Traditions, King Size, "Menthol"	
Product Name	Complete, King Size, "Menthol"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter[1]	7.8 mm
Ventilation	None
Characterizing Flavor	Menthol

SE0001893: Traditions, 100's, "Full Flavor"	
Product Name	Complete, 100's, "Full Flavor"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor	None
SE0003304: Traditions, 100's, "High Air"	
Product Name	Complete, 100's, "High Air"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	25%
Characterizing Flavor	None
SE0003305: Traditions, 100's, "Ultra High Air"	
Product Name	Complete, 100's, "Ultra High Air"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.8 mm
Ventilation	30%
Characterizing Flavor	None
SE0003306: Traditions, 100's, "Menthol"	
Product Name	Complete, 100's, "Menthol"
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.8 mm
Ventilation	None
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 SE Reports from Skookum Creek Tobacco Company Inc. (Skookum Creek) on March 22, 2011. FDA issued Acknowledgement letters on August 23, 2011. FDA issued an Advice/Information Request (A/I) letter on April 5, 2013. In response, FDA received

amendments (SE0008406 and SE0008408) on May 3, 2013 and May 8, 2013, respectively. FDA issued another A/I letter on May 10, 2013 and received an amendment (SE0009680) on September 3, 2013. CTP classified all the SE Reports as PHI Tier 2.

On September 26, 2013, FDA held a teleconference with the applicant to clarify discrepancies identified in the new tobacco product name in amendment SE0009680. FDA issued a Notification letter on March 11, 2015, indicating that scientific review was expected to begin on April 25, 2015. On June 15, 2015, FDA issued a Preliminary Finding letter. In response, FDA received an amendment (SE0012188) on July 15, 2015. FDA received amendments on July 22, 2015, (SE0012203), August 4, 2015, (SE0012247), and August 5, 2015, (SE0012248) containing information for OCE's review of predicate eligibility.

On December 16, 2015, FDA issued an A/I letter with deficiencies based on scientific reviews. The applicant did not respond to this letter. Therefore, on April 27, 2016, FDA issued a Preliminary Finding (PFind) letter with the same deficiencies identified in the A/I letter. On May 27, 2016, FDA received the applicant's response (SE0013397) to request an extension of at least 90 days to complete data collection and testing. Additionally, amendment SE0013397 indicated that Appendix B included an enclosed compact disc (CD); however, a CD was not included with the amendment. On June 8, 2016, FDA held a teleconference with the applicant to request the CD that was not included with amendment SE0013397. On June 9, 2016, FDA received an amendment (SE0013422) with the requested CD. On June 9, 2016, FDA issued an extension denial letter. On March 20, 2017, FDA received a late amendment (SE0014018) to further respond to April 27, 2016, PFind letter. Although FDA received this amendment after the response due date, FDA reviewed the late amendment in conjunction with the Technical Project Lead's (TPL) review of all information submitted by the applicant as the review of this amendment (received in March 2017) does not further delay FDA's continued review of these SE Reports. FDA developed addendums to the final scientific reviews to incorporate information contained within the late amendment.

Product Name	SE Report	Amendments
Traditions, King Size, "Full Flavor"	SE0001889	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, King Size, "High Air"	SE0001890	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, King Size, "Ultra High Air"	SE0001891	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, King Size, "Menthol"	SE0001892	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018

Product Name	SE Report	Amendments
Traditions, 100's, "Full Flavor"	SE0001893	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, 100's, "High Air"	SE0003304	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, 100's, "Ultra High Air"	SE0003305	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018
Traditions, 100's, "Menthol"	SE0003306	SE0008406 SE0008408 SE0009680 SE0012188 SE0012203 SE0012247 SE0012248 SE0013397 SE0013422 SE0014018

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 Jonathan Kwan on June 6, 2013; Charmaine Flotildes on June 15, 2015; Jessica Kiser on April 26, 2016 and June 9, 2016; and Nabanita Nag on August 9, 2017.

The final review concludes 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 August 17, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, eligible predicate tobacco products.

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 Selvin Edwards on October 13, 2015, and by Jiu Ai on July 28, 2016.

An addendum, dated May 21, 2018, contains additional chemistry review of the late amendment (SE0014018) and concludes that the new tobacco products for SE0001889, SE0001890, SE0001893, and SE0003304 have different characteristics related to product chemistry 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.[2] The applicant failed to provide a response to the chemistry deficiencies noted in the September 16, 2015, A/I letter and April 27, 2016, PFind letter for SE0001891, SE0001892, SE0003305 and SE0003306, and these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product chemistry between the new and corresponding predicate tobacco products.

[2] For SE0001889, SE0001890, SE0001893, and SE0003304, although the chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products and that the SE Reports lack sufficient information to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health, the chemistry review did not recommend any deficiencies for these SE Reports because they deferred their concern about the increases in B[a]P, NNK, and NNN yields that may result from differences in tobacco blend and total tobacco quantity to toxicology review.

The chemistry addendum concludes that the following deficiencies that have *not* been adequately resolved:

1. SE0001891, SE0001892, SE0003305 and SE0003306 provide information about tobacco and ingredients added to tobacco in the new and corresponding predicate products. However, your SE Reports and amendments provide contradictory tobacco blend information and do not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new products. Your SE Reports include tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of [redacted] tobacco in the new and predicate products but do not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, all of your SE Reports lack the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the [redacted][3] Without this information, we cannot determine the difference in characteristics between the predicate and new products. We need any other information you may have that uniquely identifies the tobacco composition used in the predicate and new products. This is the information that you rely on to ensure that the tobacco used in the predicate and new products is identical for both products.[4] 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 predicate and new products. Similarly, other ingredients are reported as "less than" ("<") results. It would be helpful to know the grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients in all four SE Reports. Examples include the following complex ingredients:

   [redacted]
   e. All adhesive glues

   Provide a detailed list including:

   a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the [redacted] tobacco blend)
   b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
   c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate product. Report all quantities in mass-per-unit of product use (e.g.,

[3] "All" SE Reports refer to SE0001891, SE0001892, SE0003305 and SE0003306.

[4] This sentence is written in error, as the standard for FDA finding a new tobacco product to be SE to a predicate product is not that the tobacco products be "identical," but rather that the new tobacco product be found to have the same characteristics as the predicate tobacco product, or found to have different characteristics and the information submitted demonstrates that the new tobacco product does not raise different questions of public health.

milligrams/cigarette) and in accordance with FDA's Guidance for Industry Listing of Ingredients in Tobacco Products.

d. Give justification for reporting "less than" quantities

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

2. SE0001891, SE0001892, SE0003305 and SE0003306 state that the new and corresponding predicate products contain (b) (4)(b) (4)(b) (4)(b) (4) flavoring that are listed as (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4) However, only in SE0001892 and SE0003306 are the products distinctly identified as menthol-flavored new and predicate products. For this reason, provide clarification of the amounts of menthol in SE0001891 and SE0003305. In addition, provide menthol levels in mainstream smoke under both ISO and Canadian Intense smoking regimens for both the new and corresponding predicate products. If there is a difference in mainstream smoke quantities of menthol between the new and corresponding predicate products, provide evidence and a scientific rationale why this difference in menthol content does not cause the new products to raise different questions of public health.[5]

3. SE0001891, SE0001892, SE0003305 and SE0003306 indicate that you submitted HPHC data to FDA under separate cover, but do not explain how or the reason that the HPHC data may have been submitted. Nevertheless, HPHC data must be submitted as part of the SE Report for each product and cannot be cross referenced to a separate submission to FDA.[6] Your response to the Preliminary Finding letter only provides smoke yields of tar, nicotine and carbon monoxide (TNCO) for four of your new and corresponding predicate products.[7] For

[5] The rationale for this chemistry deficiency is that per information provided in the SE Reports, both the new and corresponding predicate tobacco products in SE0001891 and SE0003305 contain menthol ingredients although menthol is not identified as characterizing flavor for these products. However, in order to make a finding of substantial equivalence, FDA's scientific review of SE Reports focuses on whether the characteristics are the same or different for the new and corresponding predicate tobacco products, and if different, whether the differences do not cause the new tobacco products to raise different questions of public health. In this case, both the new and corresponding predicate tobacco products contain the same menthol ingredients. Thus, this deficiency should not be the basis for an NSE order and should not be conveyed to the applicant.

[6] This sentence is written in error. The sentence was not intended to imply that HPHC data is definitively needed for all SE Reports or that an applicant cannot reference other submissions to the agency. Rather, it should instead read that if the applicant relies on HPHC data from a different submission, it should clearly state which submission it is referencing. Additionally, submitting all information as part of the SE Report can be useful to facilitate FDA's review.

[7] The "four" SE Reports refer to SE0001889, SE0001890, SE0001893, and SE0003304.

each SE Report, submit data for the following HPHC smoke yields for the new and corresponding predicate products:

a. Tar[8]
b. Nicotine
c. Carbon monoxide (CO)
d. NNN
e. NNK
f. Benzo[a]pyrene

If there is a difference in mainstream smoke quantities of these HPHCs between the new and corresponding predicate products, provide evidence and a scientific rationale in each case why this difference does not cause the new products to raise different questions of public health.[9]

Therefore, for SE0001889, SE0001890, SE0001893, and SE0003304, the review concludes that the applicant did not demonstrate that the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The applicant failed to provide a response to the chemistry deficiencies noted in the 12/16/15 A/I letter and 4/27/16 PFind letter for SE0001891, SE0001892, SE0003305 and SE0003306 and these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product chemistry between the new and corresponding predicate tobacco products.

4.2. ENGINEERING

Engineering reviews were completed by Beth Tirio on October 20, 2015 and August 8, 2016.

[8] Tar is not on the FDA's HPHC list, but it serves as an indicator of total particulate HPHCs except nicotine and therefore, is included in this chemistry deficiency. The letter-ready deficiencies reflect this fact.

[9] For SE0001891, SE0001892, SE0003305 and SE0003306, because there is insufficient information to determine whether there are ingredient or tobacco blend changes between the new and corresponding predicate tobacco products that may cause the new tobacco products to raise different questions of public health, this deficiency is not conveyed to the applicant as a standalone letter-ready deficiency, but rather, is combined with chemistry Deficiency 1 into a single letter-ready deficiency. That letter-ready deficiency concludes that: the applicant has provided insufficient information to determine whether there are any ingredient or tobacco blend changes between the new and corresponding predicate tobacco products that may cause the new tobacco products to raise different questions of public health (for the reasons discussed in chemistry Deficiency 1); and if there are any ingredient or tobacco blend changes that may cause the new tobacco products to raise different questions of public health, one way to show that these differences do not cause the new tobacco products to raise different questions of public health is to provide relevant HPHC data and provide a rationale for why any differences in HPHC yields do not cause the new tobacco products to raise different questions of public health.

Addendums, dated May 29, 2018, July 5, 2018,[10] and August 15, 2018, contain additional engineering review of the late amendment (SE0014018). The July 5, 2018 and August 15, 2018 addendums conclude that for SE0001889, SE0001890, SE0001893, and SE0003304, the new tobacco products have same characteristics related to product engineering compared to the corresponding predicate tobacco products. However, for SE0001891, SE0001892, SE0003305 and SE0003306, these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product engineering between the new and corresponding predicate tobacco products. The August 15, 2018 engineering addendum concludes that the following deficiencies have *not* been adequately resolved:

1. SE0001891 provides some information on the design parameters for the new and predicate products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products include the target specifications and range limits for the design parameters listed below. Noted parameters also require test data to demonstrate the products can be manufactured within the stated range limits:[11]

    a. Overall Cigarette Length (range limit only)
    b. Overall Cigarette Puff Count (test data only)
    c. Overall Cigarette Draw Resistance (test data only)
    d. Tobacco Filler Mass (test data only)
    e. Tobacco Moisture (test data only)
    f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
    g. Cigarette Paper Porosity (test data only)
    h. Cigarette Paper Band Porosity (test data only)
    i. Cigarette Paper Band Width (range limits only)
    j. Cigarette Paper Band Space (range limits only)
    k. Filter Efficiency (target specifications, range limits, and test data)
        i. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
    l. Filter Pressure Drop (test data only)
    m. Filter Length (range limits only)
    n. Filter Ventilation (range limits and test data only)
    o. Tipping Paper Length (range limits only)

    If the materials in the new product are identical to the materials used to manufacture the predicate product corresponding with SE0001891, adequate evidence such as procurement information (e.g., the Bill of Materials that demonstrates the materials for the new and predicate products are identical) would be acceptable for demonstrating substantial equivalence.[12] Otherwise,

[10] The engineering addendum dated July 5, 2018, supersedes the engineering addendum dated May 29, 2018.
[11] The test data are needed to demonstrate that the products measured are representative of the production batch.
[12] As indicated above, the standard for SE is not "identical." Therefore, this sentence should be clarified in the letter-ready comments to read: If, like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one way to satisfy this deficiency would be to provide a Listing

target specifications, range limits, and test data for the design parameters listed above are necessary for evaluation.

2. SE0001892 provides some information on the design parameters for the new and predicate products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products include the target specifications and range limits for the design parameters listed below. Noted parameters also require test data to demonstrate the products can be manufactured within the stated range limits:

    a. Overall Cigarette Length (range limit only)
    b. Overall Cigarette Puff Count (test data only)
    c. Overall Cigarette Draw Resistance (test data only)
    d. Tobacco Filler Mass (test data only)
    e. Tobacco Moisture (test data only)
    f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
    g. Cigarette Paper Porosity (test data only)
    h. Cigarette Paper Band Porosity (test data only)
    i. Cigarette Paper Band Width (range limits only)
    j. Cigarette Paper Band Space (range limits only)
    k. Filter Efficiency (target specifications, range limits, and test data)
        i. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
    l. Filter Pressure Drop (test data only)
    m. Filter Length (range limits only)
    n. Tipping Paper Length (range limits only)

    If the materials in the new product are identical to the materials used to manufacture the predicate product corresponding with SE0001892, adequate evidence such as procurement information (e.g., the Bill of Materials that demonstrates the materials for the new and predicate products are identical) would be acceptable for demonstrating substantial equivalence. Otherwise, target specifications, range limits, and test data for the design parameters listed above are necessary for evaluation.

3. SE0003305 provides some information on the design parameters for the new and predicate products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products include the target specifications and range limits for the design parameters listed below. Noted parameters also require test data to demonstrate the products can be manufactured within the stated range limits:

of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. This applies to all engineering deficiencies in this review.

a. Overall Cigarette Length (range limit only)
b. Overall Cigarette Puff Count (test data only)
c. Overall Cigarette Draw Resistance (range limits and test data only)
d. Tobacco Filler Mass (test data only)
e. Tobacco Moisture (test data only)
f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
g. Cigarette Paper Porosity (test data only)
h. Cigarette Paper Band Porosity (test data only)
i. Cigarette Paper Band Width (range limits only)
j. Cigarette Paper Band Space (range limits only)
k. Filter Efficiency (target specifications, range limits, and test data)
    i. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Filter Ventilation (range limits and test data only)
o. Tipping Paper Length (range limits only)

If the materials in the new product are identical to the materials used to manufacture the predicate product corresponding with SE0003305, adequate evidence such as procurement information (e.g., the Bill of Materials that demonstrates the materials for the new and predicate products are identical) would be acceptable for demonstrating substantial equivalence. Otherwise, target specifications, range limits, and test data for the design parameters listed above are necessary for evaluation.

4. SE0003306 provides some information on the design parameters for the new and predicate products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products include the target specifications and range limits for the design parameters listed below. Noted parameters also require test data to demonstrate the products can be manufactured within the stated range limits:

    a. Overall Cigarette Length (range limit only)
    b. Overall Cigarette Puff Count (test data only)
    c. Overall Cigarette Draw Resistance (range limits and test data only)
    d. Tobacco Filler Mass (test data only)
    e. Tobacco Moisture (test data only)
    f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
    g. Cigarette Paper Porosity (test data only)
    h. Cigarette Paper Band Porosity (test data only)
    i. Cigarette Paper Band Width (range limits only)
    j. Cigarette Paper Band Space (range limits only)

k. Filter Efficiency (target specifications, range limits, and test data)
    i. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Tipping Paper Length (range limits only)

If the materials in the new product are identical to the materials used to manufacture the predicate product corresponding with SE0003306, adequate evidence such as procurement information (e.g., the Bill of Materials that demonstrates the materials for the new and predicate products are identical) would be acceptable for demonstrating substantial equivalence. Otherwise, target specifications, range limits, and test data for the design parameters listed above are necessary for evaluation.

Therefore, for SE0001891, SE0001892, SE0003305 and SE0003306, these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product engineering between the new and corresponding predicate tobacco products.

4.3. TOXICOLOGY

A Toxicology review was completed by Sang Ki Park on May 24, 2018.

The final toxicology review concludes that for SE0001889, SE0001890, SE0001893, and SE0003304, the new tobacco products have different characteristics related to product toxicity 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. For SE0001891, SE0001892, SE0003305, and SE0003306, these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product toxicity between the new and corresponding predicate tobacco products.

The review identifies the following deficiencies that have *not* been adequately resolved:

1. SE0001889, SE0001890, SE0001893, and SE0003304 indicate that the smoke yields of B[a]P,[13] NNN, and NNK are significantly increased in the mainstream smoke of the new tobacco products compared to the corresponding predicate tobacco products. B[a]P,[13] NNN, and NNK are carcinogenic to humans. Provide evidence or scientific rationale that the increases in B[a]P,[13] NNN, and NNK yields do not cause the new products to raise different questions of public health.

[13] I, as the TPL, analyzed the data and concluded that changes in B[a]P yields between the new and corresponding predicate tobacco products are smaller than the expected analytical variability of the analytical method. Therefore, the differences in B[a]P between the new and predicate tobacco products do not cause the new tobacco products to raise difference questions of public health. The letter-ready deficiency does not include B[a]P.

2. SE0001891, SE0001892, SE0003305, and SE0003306 provide information about tobacco and ingredients added to tobacco in the predicate and new products. However, your SE Reports and amendments provide contradictory tobacco blend information and do not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new products. Provide a detailed list including:

    a. Uniquely identifying information for all tobaccos (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
    b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
    c. Composition information for all complex ingredients
    d. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate product. Report all quantities in mass-per-unit of product use (e.g., milligrams/cigarette) and in accordance with FDA's Guidance for Industry Listing of Ingredients in Tobacco Products.
    e. Give justification for reporting "less than" quantities

    If a difference exists between the new and corresponding predicate products, provide a rationale for each difference with evidence and a scientific discussion for why the difference does not cause the new product to raise different questions of public health.[14]

3. SE0001891, SE0001892, SE0003305, and SE0003306 indicate that the total amount of tobacco filler was increased in the new products compared to the corresponding predicate products. The new products of these SE Reports also contain increased amounts of (b) (4) (b) (4) (b) (4)(b) (4) tobaccos compared to the corresponding predicate products.[15] These changes in the total tobacco weight and tobacco composition can increase the smoke yields of TSNAs and PAHs. For each SE Report, submit data for the following HPHC smoke yields for the new and corresponding predicate products:

    a. Tar[16]
    b. Nicotine
    c. Carbon monoxide (CO)
    d. NNN
    e. NNK
    f. Benzo[a]pyrene

[14] Because this toxicology deficiency overlaps with the chemistry Deficiency 1, which provides more specific information, only the chemistry Deficiency 1 is conveyed to the applicant.

[15] The first two sentences of this toxicology deficiency were written in error. The applicant provided—and failed to clarify despite OS's requesting it do so—contradictory tobacco blend information for SE0001891, SE0001892, SE0003305, and SE0003306. In an amendment received on September 3, 2013, the applicant indicated that the new tobacco products contain (b) (4) However, this information conflicts with the tobacco blend information reported in the original SE Reports for SE0001891, SE0001892, SE0003305, and SE0003306 as well as information provided in another amendment (received on August 5, 2015), both of which appear to indicate that the new and corresponding tobacco products have the same tobacco blend.

[16] Tar is not on the FDA's HPHC list, but it serves as an indicator of total particulate HPHCs except nicotine and therefore, is included in this toxicology deficiency.

If there is a difference in mainstream smoke quantities of these HPHCs between the new and corresponding predicate products, provide evidence and a scientific rationale in each case why this difference does not cause the new products to raise different questions of public health.[17]

Therefore, the review concludes that for SE0001889, SE0001890, SE0001893, and SE0003304, the applicant did not demonstrate that the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective. For SE0001891, SE0001892, SE0003305, and SE0003306, these SE Reports lack sufficient information to determine whether there are any differences in characteristics related to product toxicity between the new and corresponding predicate tobacco products.

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 RECOMMENDATION

The following are the key differences in characteristics between the new and corresponding predicate tobacco products for SE0001889, SE0001890, SE0001893, and SE0003304:

- (b) (4)(b) (4)(b) (4)
- (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
- Increased ISO and CI smoke yields of NNK and NNN
  - SE0001889: NNK was higher under both ISO (↑98%) and CI (↑137%); and NNN was higher under both ISO (↑29%) and CI (↑37%).
  - SE0001890: NNK was higher under both ISO (↑145%) and CI (↑152%); and NNN was higher under both ISO (↑38%) and CI (↑30%).
  - SE0001893: NNK was higher under both ISO (↑109%) and CI (↑135%); and NNN was higher under CI (↑38%).
  - SE0003304: NNK was higher under both ISO (↑153%) and CI (↑206%); and NNN was higher under both ISO (↑23%) and CI (↑33%).

For SE0001889, SE0001890, SE0001893, and SE0003304, the applicant has failed to demonstrate that the differences in characteristics do not cause the new tobacco products to raise different questions of public health. For these four SE Reports, the new tobacco products have (b) (4)

[17] For SE0001891, SE0001892, SE0003305 and SE0003306, because there is insufficient information to determine whether there are any ingredient or tobacco blend changes between the new and corresponding predicate tobacco products, this deficiency is not conveyed to the applicant as a standalone letter-ready deficiency. Instead, this deficiency, along with chemistry Deficiency 3 (*see supra* note 9), is combined with chemistry Deficiency 1 into a single letter-ready deficiency.

[18] Lower amount of (b) (4) tobacco and absence of (b) (4) tobacco do not raise concerns from a chemistry perspective.

than their corresponding predicate tobacco products and a significant change in the tobacco blend with an increase in (b) (4)(b) (4) tobacco. These changes in tobacco blend can affect smoke chemistry and HPHC yields such as B[a]P, NNK, and NNN. The applicant provided mainstream smoke yields for TNCO, B[a]P, NNK, and NNN tested under both the ISO and CI regimens for SE0001889, SE0001890, SE0001893, and SE0003304. The chemistry review concluded that there was sufficient information to determine that the data provided was accurate and reliable. The decrease in TNCO yields for the new tobacco products compared to the corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health. The chemistry review found increases in B[a]P, NNK, and NNN yields and deferred the increased HPHC data to the toxicology review, which agreed with the chemist's findings. However, neither the chemistry nor the toxicology review discussed statistical analysis. I, as the TPL, compared the data using a two-one sided t-test and determined that for each of these four SE Reports, NNK and NNN in the new tobacco product have higher mean mainstream smoke yields that exceeded the expected analytical variability of the analytical method (see the key differences above). However, changes in B[a]P yields between the new and corresponding predicate tobacco products are smaller than the expected analytical variability of the analytical method; therefore, the differences in B[a]P yields do not cause the new tobacco products to raise different questions of public health. However, the applicant did not provide any evidence or rationale to explain why the changes in tobacco blend composition and associated increased yields in NNK and NNN do not cause the new tobacco products to raise different questions of public health. Therefore, the applicant has not provided sufficient information to demonstrate that the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health for SE0001889, SE0001890, SE0001893, and SE0003304.

For SE0001891, SE0001892, SE0003305 and SE0003306, the applicant does not provide sufficient information to determine whether there are any differences in characteristics between the new and corresponding predicate tobacco products. The applicant provides contradictory tobacco blend information and does not provide adequate information on the quantities of tobacco and non-tobacco ingredients to determine whether there are differences between the new and corresponding tobacco products. For example, an amendment received on September 3, 2013 states that the new tobacco products contain higher percentages of (b) (4)(b) (4) tobacco than the corresponding predicate tobacco products. However, this conflicts with the information provided in the original SE Reports and another amendment (received on August 5, 2015) which appear to indicate that the new and corresponding tobacco products have the same tobacco blend. A change in tobacco blends such as (b) (4)(b) (4) tobaccos may affect the yields of mainstream smoke HPHCs such as B[a]P, NNN, and NNK, which may cause the new tobacco products to raise different questions of public health. The applicant states that HPHC data were submitted separately without specifying where, how, and for which HPHCs were data submitted. If there is a change in tobacco blends, one way to demonstrate that the differences between the new and predicate tobacco products do not cause the new products to raise different questions of public health would be analytical testing data for relevant smoke constituents. These concerns were conveyed to the applicant in FDA's A/I letter (dated December 16, 2015) and PFind letter (dated April 27, 2016). However, the applicant's responses to the A/I and PFind letters do not address the deficiencies related to these concerns. Furthermore, these SE Reports lack sufficient information regarding design characteristics for both the new and predicate tobacco products. Therefore, the applicant has not provided sufficient information to determine whether there are any differences in characteristics between the new and corresponding predicate tobacco products, and the applicant

failed to provide sufficient information to support a finding of substantial equivalence for SE0001891, SE0001892, SE0003305 and SE0003306.

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

For SE0001889, SE0001890, SE0001893, and SE0003304, the chemistry and toxicology reviews conclude that the new tobacco products have different characteristics 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. For SE0001891, SE0001892, SE0003305 and SE0003306, chemistry, engineering and toxicology reviews conclude that these SE Reports do not contain sufficient information to determine whether there are any differences in characteristics between the new and corresponding predicate tobacco products. I concur with these reviews and recommend that NSE order letters be issued. However, I disagree with the chemistry reviewer with respect to the menthol quantities and menthol smoke yields in SE0001891 and SE0003305 in Deficiency 2 of the chemistry review. In order to make a finding of substantial equivalence, FDA's scientific review of SE Reports focuses on whether the characteristics are the same or different between the new and corresponding predicate tobacco products, and if different, whether the differences do not cause the new tobacco products to raise different questions of public health. In this case, both the new and corresponding predicate tobacco products contain the same menthol ingredients in the same quantities. Thus, I do not believe the chemistry Deficiency 2 is a basis for an NSE order, and therefore, this deficiency should not be conveyed to the applicant.

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 determined 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 SE0001889, SE0001890, SE0001891, SE0001892, SE0001893, SE00003304, SE0003305, and SE0003306, as identified on the cover page of this review.

6.1. DEFICIENCIES FOR SE0001889

The NSE order letter for SE0001889 should cite the following deficiency:

1. Your SE Report indicates that the smoke yields of NNN (29% increase under ISO and 37% increase under CI) and NNK (98% increase under ISO and 137% increase under CI) are significantly increased in the mainstream smoke of the new tobacco product compared to the predicate tobacco product. NNN and NNK are carcinogenic to humans. However, your SE Report does not provide adequate scientific evidence and rationale that the increases in NNN and NNK yields do not cause the new tobacco product to raise different questions of public health.

6.2. DEFICIENCIES FOR SE0001890

The NSE order letter for SE0001890 should cite the following deficiency:

1. Your SE Report indicates that the smoke yields of NNN (38% increase under ISO and 30% increase under CI) and NNK (145% increase under ISO and 152% increase under CI) are significantly increased in the mainstream smoke of the new tobacco product compared to the predicate tobacco product. NNN and NNK are carcinogenic to humans. However, your SE Report does not provide adequate scientific evidence and rationale that the increases in NNN and NNK yields do not cause the new tobacco product to raise different questions of public health.

6.3. DEFICIENCIES FOR SE0001891

The NSE order letter for SE0001891 should cite the following deficiencies:

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report provides contradictory tobacco blend information and does not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new tobacco products. Your SE Report includes tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of (b) (4)(b) (4)(b) (4) (b) (4) tobacco in the new and predicate tobacco products but does not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, your SE Report lacks the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the (b) (4) tobacco sheets. FDA needs this information to determine whether the new and predicate tobacco products have differences in the tobacco ingredients. FDA needs any other information you may have that uniquely identifies the tobacco composition used in the predicate and new tobacco 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 predicate and new tobacco products. Similarly, other ingredients are reported as “less than” (“<”) results. It would be helpful to know the

grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients. Examples include the following complex ingredients:

(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)

e. All adhesive glues

Your SE Report does not provide a detailed list including:

a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate tobacco product
d. A justification for reporting "less than" quantities

If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed. For example, if there are increases in (b) (4), one way to show that the tobacco blend changes do not cause the new tobacco products to raise different questions of public health would be to provide HPHC (nicotine, CO, B[a]P, NNN, and NNK) and tar yields under both the ISO and Canadian Intense regimens and provide a rationale for why any differences in HPHC and tar yields do not cause the new products to raise different questions of public health.

2. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate tobacco products. The information needed to fully characterize the products includes the target specifications, range limits for the design parameters and test data. Information is needed for below design parameters:

a. Overall Cigarette Length (range limit only)
b. Overall Cigarette Puff Count (test data only)
c. Overall Cigarette Draw Resistance (test data only)
d. Tobacco Filler Mass (test data only)
e. Tobacco Moisture (test data only)
f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
g. Cigarette Paper Porosity (test data only)
h. Cigarette Paper Band Porosity (test data only)
i. Cigarette Paper Band Width (range limits only)
j. Cigarette Paper Band Space (range limits only)
k. Filter Efficiency (target specifications, range limits, and test data)

1. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)

l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Filter Ventilation (range limits and test data only)
o. Tipping Paper Length (range limits only)

If, like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one way to satisfy this deficiency would be to provide a Listing of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

6.4. DEFICIENCIES FOR SE0001892

The NSE order letter for SE0001892 should cite the following deficiencies:

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report provides contradictory tobacco blend information and does not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new tobacco products. Your SE Report includes tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of (b) (4)(b) (4)(b) (4) (b) (4) tobacco in the new and predicate tobacco products but does not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, your SE Report lacks the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the (b) (4) tobacco sheets. FDA needs this information to determine whether the new and predicate tobacco products have differences in the tobacco ingredients. FDA needs any other information you may have that uniquely identifies the tobacco composition used in the predicate and new tobacco 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 predicate and new tobacco products. Similarly, other ingredients are reported as "less than" ("<") results. It would be helpful to know the grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients. Examples include the following complex ingredients:

(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)

e. All adhesive glues

Your SE Report does not provide a detailed list including:

a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate tobacco product
d. A justification for reporting "less than" quantities

If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed. For example, if there are increases in (b) (4), one way to show that the tobacco blend changes do not cause the new tobacco products to raise different questions of public health would be to provide HPHC (nicotine, CO, B[a]P, NNN, and NNK) and tar yields under both the ISO and Canadian Intense regimens and provide a rationale for why any differences in HPHC and tar yields do not cause the new products to raise different questions of public health.

2. Your SE Report provides some information on the design parameters for the new and predicate products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products includes the target specifications and range limits for the design parameters listed below. Noted parameters also require test data:

a. Overall Cigarette Length (range limit only)
b. Overall Cigarette Puff Count (test data only)
c. Overall Cigarette Draw Resistance (test data only)
d. Tobacco Filler Mass (test data only)
e. Tobacco Moisture (test data only)
f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
g. Cigarette Paper Porosity (test data only)
h. Cigarette Paper Band Porosity (test data only)
i. Cigarette Paper Band Width (range limits only)
j. Cigarette Paper Band Space (range limits only)
k. Filter Efficiency (target specifications, range limits, and test data)
    1. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Tipping Paper Length (range limits only)

If like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one

way to satisfy this deficiency would be to provide a Listing of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

6.5. DEFICIENCIES FOR SE0001893

The NSE order letter for SE0001893 should cite the following deficiency:

1. Your SE Report indicates that the smoke yields of NNN (38% increase under CI) and NNK (109% increase under ISO and 135% increase under CI) are significantly increased in the mainstream smoke of the new tobacco product compared to the predicate tobacco product. NNN and NNK are carcinogenic to humans. However, your SE Report does not provide adequate scientific evidence and rationale that the increases in NNN and NNK yields do not cause the new tobacco product to raise different questions of public health.

6.6. DEFICIENCIES FOR SE0003304

The NSE order letter for SE0003304 should cite the following deficiency:

1. Your SE Report indicates that the smoke yields of NNN (23% increase under ISO and 33% increase under CI) and NNK (153% increase under ISO and 206% increase under CI) are significantly increased in the mainstream smoke of the new tobacco product compared to the predicate tobacco product. NNN and NNK are carcinogenic to humans. However, your SE Report does not provide adequate scientific evidence and rationale that the increases in NNN and NNK yields do not cause the new tobacco product to raise different questions of public health.

6.7. DEFICIENCIES FOR SE0003305

The NSE order letter for SE0003305 should cite the following deficiencies:

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report provides contradictory tobacco blend information and does not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new tobacco products. Your SE Report includes tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of (b) (4) [redacted] tobacco in the new and predicate tobacco products but does not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, your SE Report lacks the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the (b) (4) [redacted] tobacco sheets. FDA needs this information to determine whether the new and predicate tobacco products have differences in the tobacco ingredients. FDA needs any other information you may have that uniquely identifies the tobacco composition used in

the predicate and new tobacco 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 predicate and new products. Similarly, other ingredients are reported as "less than" ("<") results. It would be helpful to know the grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients. Examples include the following complex ingredients:

(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
(b) (4)

e. All adhesive glues

Your SE Report does not provide a detailed list including:

a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate product
d. A justification for reporting "less than" quantities

If a difference exists between the new and predicate products, scientific evidence and rationale for why the difference does not cause the new product to raise different questions of public health would be needed. For example, if there are increases in (b) (4), one way to show that the tobacco blend changes do not cause the new tobacco products to raise different questions of public health would be to provide HPHC (nicotine, CO, B[a]P, NNN, and NNK) and tar yields under both the ISO and Canadian Intense regimens and provide a rationale for why any differences in HPHC and tar yields do not cause the new products to raise different questions of public health.

2. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate products. The information needed to fully characterize the products includes the target specifications and range limits for the design parameters listed below. Noted parameters also require test data:

a. Overall Cigarette Length (range limit only)
b. Overall Cigarette Puff Count (test data only)
c. Overall Cigarette Draw Resistance (range limits and test data only)
d. Tobacco Filler Mass (test data only)
e. Tobacco Moisture (test data only)
f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
g. Cigarette Paper Porosity (test data only)
h. Cigarette Paper Band Porosity (test data only)
i. Cigarette Paper Band Width (range limits only)

j. Cigarette Paper Band Space (range limits only)
k. Filter Efficiency (target specifications, range limits, and test data)
    1. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Filter Ventilation (range limits and test data only)
o. Tipping Paper Length (range limits only)

If like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one way to satisfy this deficiency would be to provide a Listing of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.

6.8. DEFICIENCIES FOR SE0003306

The NSE order letter for SE0003306 should cite the following deficiencies:

1. Your SE Report provides information about tobacco and ingredients added to tobacco in the new and predicate tobacco products. However, your SE Report provides contradictory tobacco blend information and does not include sufficient and consistent details to fully identify the ingredients and tobacco composition of the predicate and new products. Your SE Report includes tobacco and ingredient quantities expressed as range of relative quantities (expressed as percentages) of [redacted] tobacco in the new and predicate products but does not include the actual amounts of each tobacco type or ingredients, expressed as mass-per-unit of use (e.g., milligram/cigarette) in each product. In addition, your SE Report lacks the grades or types of tobacco as well as the parts of tobacco (i.e., leaf lamina or stems) and additives in the [redacted] tobacco sheets. FDA needs this information to determine whether the new and predicate tobacco products have differences in the tobacco ingredients. FDA needs any other information you may have that uniquely identifies the tobacco composition used in the predicate and new 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 predicate and new products. Similarly, other ingredients are reported as "less than" ("<") results. It would be helpful to know the grade and purity of each ingredient, clarification for the term processing aid as well as the composition of complex ingredients. Examples include the following complex ingredients:

[redacted]

e. All adhesive glues

Your SE Report does not provide a detailed list including:

a. Uniquely identifying information for all tobacco (e.g., tobacco grading system, types of tobacco in the (b) (4) tobacco blend)
b. Uniquely identifying information for all ingredients (e.g., CAS # and grade/purity)
c. Side-by-side listing of all ingredients and additives for all tobacco and non-tobacco components for each new and corresponding predicate product
d. A justification for reporting "less than" quantities

If a difference exists between the new and predicate tobacco products, scientific evidence and rationale why the difference does not cause the new tobacco product to raise different questions of public health would be needed. For example, if there are increases in (b) (4), one way to show that the tobacco blend changes do not cause the new tobacco products to raise different questions of public health would be to provide HPHC (nicotine, CO, B[a]P, NNN, and NNK) and tar yields under both the ISO and Canadian Intense regimens and provide a rationale for why any differences in HPHC and tar yields do not cause the new products to raise different questions of public health.

2. Your SE Report provides some information on the design parameters for the new and predicate tobacco products. However, your SE Report lacks sufficient design characteristics information for both the new and predicate tobacco products. The information needed to fully characterize the products includes the target specifications and range limits for the design parameters listed below. Noted parameters also require test data:

a. Overall Cigarette Length (range limit only)
b. Overall Cigarette Puff Count (test data only)
c. Overall Cigarette Draw Resistance (range limits and test data only)
d. Tobacco Filler Mass (test data only)
e. Tobacco Moisture (test data only)
f. Cigarette Paper Base Paper Basis Weight (target specifications, range limits, and test data)
g. Cigarette Paper Porosity (test data only)
h. Cigarette Paper Band Porosity (test data only)
i. Cigarette Paper Band Width (range limits only)
j. Cigarette Paper Band Space (range limits only)
k. Filter Efficiency (target specifications, range limits, and test data)
    1. Alternatively, provide Total Denier (target specifications, range limits, and test data), Filter Denier Per Filament (target specifications, range limits, and test data), and Filter Density (target specifications, range limits, and test data)
l. Filter Pressure Drop (test data only)
m. Filter Length (range limits only)
n. Tipping Paper Length (range limits only)

If like SE0001889, SE0001890, SE0001893, and SE0003304, the materials relevant to the design parameters identified above are identical in the new and predicate products, one way to satisfy this deficiency would be to provide a Listing of Materials (similar to the Tables found in those SE reports) that adequately demonstrates this; you could also make this showing by providing procurement information, such as the Bill of Materials. If a difference exists between the new and predicate tobacco products, scientific evidence and rationale for why the difference does not cause the new tobacco product to raise different questions of public health would be needed.