Technical Project Lead (TPL) Review: SE0002807, SE0002808, SE0002811, SE0002812, SE0002815, SE0002816, SE0002817, SE0002818, SE0002819, SE0002820, and SE0002821

SE0002807: USA Gold Blue 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	47%
Characterizing Flavor	None
SE0002808: USA Gold Blue 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	47%
Characterizing Flavor	None
SE0002811: USA Gold Gold 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	18%
Characterizing Flavor	None
SE0002812: USA Gold Gold 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	18%
Characterizing Flavor	None
SE0002815: USA Gold Menthol Dark Green 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	6%
Characterizing Flavor	Menthol

SE0002816: USA Gold Menthol Dark Green 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	6%
Characterizing Flavor	Menthol
SE0002817: USA Gold Menthol Dark Green King Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	14%
Characterizing Flavor	Menthol
SE0002818: USA Gold Menthol Dark Green King Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	14%
Characterizing Flavor	Menthol
SE0002819: USA Gold Menthol Green 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	18%
Characterizing Flavor	Menthol
SE0002820: USA Gold Menthol Green 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	18%
Characterizing Flavor	Menthol

SE0002821: USA Gold Menthol Green King Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	18%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Commonwealth Brands, Inc.
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.08.22 12:08:58 -04'00'

Kenneth M. Taylor, 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: 2019.08.22 14:40:09 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002807: USA Gold Blue 100s Box	
Product Name	USA Gold Ultra Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	47%
Characterizing Flavor	None
SE0002808: USA Gold Blue 100s Soft Pack	
Product Name	USA Gold Ultra Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	47%
Characterizing Flavor	None
SE0002811: USA Gold Gold 100s Box	
Product Name	USA Gold Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	22%
Characterizing Flavor	None
SE0002812: USA Gold Gold 100s Soft Pack	
Product Name	USA Gold Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	22%
Characterizing Flavor	None

SE0002815: USA Gold Menthol Dark Green 100s Box	
Product Name	USA Gold Full Flavor Menthol 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	6%
Characterizing Flavor	Menthol
SE0002816: USA Gold Menthol Dark Green 100s Soft Pack	
Product Name	USA Gold Full Flavor Menthol 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	6%
Characterizing Flavor	Menthol
SE0002817: USA Gold Menthol Dark Green King Box	
Product Name	USA Gold Full Flavor Menthol Kings Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Ventilation	6%
Characterizing Flavor	Menthol
SE0002818: USA Gold Menthol Dark Green King 5oft Pack	
Product Name	USA Gold Full Flavor Menthol Kings Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Ventilation	6%
Characterizing Flavor	Menthol

SE0002819: USA Gold Menthol Green 100s Box	
Product Name	USA Gold Menthol Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	22%
Characterizing Flavor	Menthol
SE0002820: USA Gold Menthol Green 100s Soft Pack	
Product Name	USA Gold Menthol Lights 100s Box
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	22%
Characterizing Flavor	Menthol
SE0002821: USA Gold Menthol Green King Soft Pack	
Product Name	USA Gold Menthol Lights Kings Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Ventilation	14%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 21, 2011, FDA received 11 SE Reports from Commonwealth Brands, Inc. On April 6, 2011, FDA received a resubmission of all 11 SE Reports as a result of the original submission disc being password protected (TC0000093). FDA issued Acknowledgement letters to the applicant on September 7, 2011. On August 20, 21, and 25, 2012, FDA completed a Public Health Impact (PHI) review; these STNs were assigned to PHI Tier 2. FDA issued Advice/Information (A/I) Request letters for SE0002807, SE0002808, SE0002811, SE0002812, and SE0002815-SE0002817 on February 15, 2013, and for SE0002818-SE0002821 on February 20, 2013. On March 22, 2013, FDA received responses to the A/I Request letters (SE0007938, SE0007939, SE0007897, SE0007898, SE0007901, SE0007902, SE0007903, SE0007904, SE0007905 and SE0007906). On April 11, 2017, FDA issued a Notification letter to inform the applicant that scientific review of their SE Reports would commence on May 26, 2017. On May 23, 2017, FDA received a response

to the Notification letter (SE0014104). On April 10, 2018, FDA issued an A/I Request letter. On April 19, 2018, FDA received an Extension Request (SE0014633) for 90 days to respond to the A/I Request letter. On May 10, 2018, FDA received an amended Extension Request (SE0014713) for responding to the A/I Request letter dated April 10, 2018. On May 18, 2018, FDA issued an Extension Granted letter extending the due date to September 5, 2018. On May 24, 2018, FDA received a Clarification Request (requesting clarification on FDA's statements and requests) for responding to the A/I Request letter (SE0014734). On June 1, 2018, FDA provided responses to the applicant's clarification request by email. On September 5, 2018, FDA received a response to the A/I Request letter dated April 10, 2018 (SE0014866). On November 5, 2018, FDA issued a Preliminary Finding (PFind) letter for SE0002807, SE0002808, SE0002811, SE0002812, and SE0002815 - SE0002821. On May 1, 2019, FDA received a response to the PFind letter (SE0015212).

Product Name	SE Report	Amendments
USA Gold Blue 100s Box	SE0002807	SE0007938 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Blue 100s Soft Pack	SE0002808	SE0007939 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Gold 100s Box	SE0002811	SE0007897 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Gold 100s Soft Pack	SE0002812	SE0007898 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212

Product Name	SE Report	Amendments
USA Gold Menthol Dark Green 100s Box	SE0002815	SE0007901 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Menthol Dark Green 100s Soft Pack	SE0002816	SE0007902 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Menthol Dark Green King Box	SE0002817	SE0007903 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Menthol Dark Green King Soft Pack	SE0002818	SE0007904 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Menthol Green 100s Box	SE0002819	SE0007905 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212
USA Gold Menthol Green 100s Soft Pack	SE0002820	SE0007906 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212

Product Name	SE Report	Amendments
USA Gold Menthol Green King Soft Pack	SE0002821	SE0007907 SE0014104 SE0014633 SE0014713 SE0014734 SE0014866 SE0015212

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 Gregory Bissonette on September 7, 2011, Stephanie Durkin on February 15, 2013, and Tamara Brewton on June 5, 2013.

The reviews conclude that the SE Reports are not administratively complete because the following information was not included in the SE Reports:

1. Unique identification of the new and predicate tobacco products

This information was provided during the scientific review process. Therefore, 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 as of February 15, 2007). The OCE reviews dated June 19, 2017, 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. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Sharyn Miller on August 24, 2017 and by Jiu Ai on October 23, 2018 and June 24, 2019.

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

SE0002807 and SE0002808

- Tobacco Blend:
  - 21% decreases in (b) (4) tobacco
  - 76% increase in (b) (4)
  - 2% decrease in total tobacco

- Ingredients added to tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decreases in all other ingredients

- Cigarette paper ingredients:
  - Removal of (b) (4)
  - 94% increase in (b) (4)
  - 40% decrease in (b) (4)
  - Removal of (b) (4)

- Filter tow ingredients:
  - 9.3% decrease in all ingredients

- Plug wrap ingredients:
  - 3.7% decrease in all ingredients

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

SE0002811 and SE0002812

- Tobacco blend:
  - 21% decrease in (b) (4) tobacco
  - 29% increase in (b) (4) tobacco
  - 81% increase in (b) (4)
  - 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decreases in all other ingredients

- Cigarette paper ingredients:
  - Removal of (b) (4)
  - 94% increase in (b) (4)
  - 40% decrease in (b) (4)

- Addition of (b) (4)

- Filter tow ingredients:
  - 16% decrease in (b) (4)
  - 19% decrease in (b) (4)
  - 119% increase in (b) (4)
  - 71% increase in (b) (4)

- Plug wrap ingredients:
  - 10% decrease in (b) (4)
  - Addition of (b) (4)
  - Removal of (b) (4)

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

SE0002815 and SE0002816

- Tobacco blend:
  - 22% decrease in (b) (4) tobacco
  - 21% decrease in (b) (4) tobacco
  - 29% increase in (b) (4) tobacco
  - 81% increase in (b) (4)
  - 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decrease in all other ingredients

- Cigarette paper ingredients:
  - 11%-12% increase in (b) (4)
  - 72% increase in (b) (4)
  - 42% decrease in (b) (4)
  - Addition of (b) (4)

- Filter tow ingredients:
  - 11% decrease in all ingredients

- Plug wrap ingredients:
  - 10% decrease in (b) (4)
  - Removal of (b) (4)
  - Addition of (b) (4)
    (b) (4)

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

SE0002817 and SE0002818

- Tobacco blend:
  - 24% decrease in (b) (4) tobacco
  - 25% increase in (b) (4) tobacco
  - 76% increase in (b) (4)
  - 2% decrease in total tobacco

- Ingredients added in tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decrease of all other ingredients

- Cigarette paper ingredients:
  - 11%-12% increase in (b) (4)
  - 107% increase in (b) (4)
  - 40% decrease in (b) (4)
  - Addition of (b) (4)

- Filter tow ingredients:
  - 16% decrease in (b) (4)
  - 118% increase in (b) (4)
  - 5% increase in (b) (4)
  - 67% increase in (b) (4)

- Plug wrap ingredients:
  - 10% decrease in (b) (4)
  - Addition of (b) (4)
  - Removal of (b) (4)

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

SE0002819 and SE0002820

- Tobacco blend:
  - 22% decrease in (b) (4) tobacco
  - 21% decrease in (b) (4) tobacco
  - 29% increase in (b) (4) tobacco
  - 81% increase in (b) (4)
  - 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decrease of all other ingredients

- Cigarette paper ingredients:
  - 11%-12% increase in (b) (4)
  - 72% increase in (b) (4)
  - 42% decrease in (b) (4)
  - Addition of (b) (4)

- Filter tow ingredients:
  - 16% decrease in (b) (4)
  - 19% decrease in (b) (4)
  - 119% increase in (b) (4)
  - 71% increase in (b) (4)

- Plug wrap ingredients:
  - 10% decrease in (b) (4)
  - Addition of (b) (4)
  - Removal of (b) (4)

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

SE0002821

- Tobacco blend:
  - 24% decreases in (b) (4) tobaccos
  - 25% increase in (b) (4) tobacco
  - 76% increase in (b) (4) tobacco
  - 2% decrease in total tobacco

- Ingredients added to tobacco blend:
  - Removal of (b) (4)
  - 11-21% decreases in all non-tobacco ingredients

- Cigarette paper ingredients
  - 11-12% increases in (b) (4)
  - 108% increase in (b) (4)
  - 39% decrease in (b) (4)
  - Addition of (b) (4)

- Filter tow ingredients:
  - 16% decrease in (b) (4)
  - 19% decrease in (b) (4)
  - 119% increase in (b) (4)
  - 71% increase in (b) (4)

- Plug wrap ingredients:
  - 10% decrease in (b) (4) 10% lower

- Addition of (b) (4)
- Removal of (b) (4)

- Tipping paper ingredients:
  - 11% decrease in (b) (4)
  - 23% decrease in (b) (4)
  - Removal of (b) (4)

The new tobacco products have changes in the tobacco blend, which include decreases in (b) (4) (b) (4) tobaccos; and increases in both (b)(4) tobacco and (b) (4) Overall, there are nominal differences (1% increases or 2% decreases) in the total amount of tobacco contained in the new products. Except for the increased amounts of (b) (4) the tobacco blend changes should not adversely affect HPHCs. Similarly, the ingredients added to the tobacco filler in the new products are either reduced or removed and should not adversely affect smoke chemistry because any related pyrolysis products would be less. The cigarette papers of the new tobacco products have multiple ingredient changes which may affect smoke chemistry. For example, increases in (b) (4) (b) (4) all can adversely affect the amounts of acetaldehyde and benzene in the smoke of the new tobacco products. However, the removal of (b) (4) and (b) (4) which also produce acetaldehyde and benzene as pyrolysis products, may be offsetting. Furthermore, the increases in the burn rate modifier (b) (4) are greater than and appear to offset the decreases in (b) (4) another burn rate modifier. HPHC data provided by the applicant showed that TNCO and other related HPHCs, including acetaldehyde, formaldehyde, and benzene are either lower or analytically equivalent in the new tobacco products compared to the corresponding predicate tobacco products for both non-intense and intense smoking regimens. Therefore, the ingredient changes in the cigarette papers of the new tobacco products do not cause concerns. The chemistry review also notes ingredient changes in the filter tows, plug wraps, and tipping papers of the new tobacco products. However, since these are non-combusted components, smoke chemistry is not anticipated to be affected by these changes.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by James Roche on August 28, 2017 and by Robert Meyer on October 23, 2018.

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

- **SE0002807 and SE0002808**
  - 15% decrease in band porosity
  - 14% decrease in band width

- 22% decrease in filter denier per filament
- 10% decrease in filter density
- 5% decrease in cigarette mass

- **SE0002811 and SE0002812**
  - 5% decrease in puff count
  - 15% decrease in band porosity
  - 14% decrease in band width
  - 17% decrease in total denier
  - 14% decrease in filter denier per filament
  - 5% decrease in filter density
  - 9% decrease in pressure drop
  - 18% decrease in ventilation

- **SE000281S and SE0002816**
  - 10% decrease in draw resistance
  - 12% increase in base paper basis weight
  - 50% increase in base paper porosity
  - 11% decrease in filter denier per filament
  - 10% decrease in filer density
  - 15% decrease in pressure drop

- **SE0002817 and SE0002818**
  - 7% decrease in draw resistance
  - 6% decrease in filler mass
  - 15% increase in band porosity
  - 14% increase in band width
  - 17% decrease in total denier
  - 14% decrease in filter denier per filament
  - 14% decrease in filter density
  - 8% decrease in pressure drop
  - 133% increase in ventilation
  - 6% decrease in cigarette mass

- **SE0002819 and SE0002820**
  - 5% decrease in draw resistance
  - 12% increase in base paper basis weight
  - 50% increase in base paper porosity
  - 17% decrease in total denier
  - 14% decrease in filter denier per filament
  - 15% decrease in filer density
  - 8% decrease in filer density
  - 18% increase in ventilation

- **SE0002821**
  - 7% decrease in puff count
  - 10% decrease in draw resistance
  - 5% decrease in filler mass

- 15% increase in band porosity
- 14% increase in band width
- 17% decrease in total denier
- 14% decrease in filter denier per filament Filter density (↓20%)
- 11% decrease in pressure drop
- 29% increase in ventilation
- 7% decrease in cigarette mass

The new tobacco products have multiple design changes that can impact smoke constituent yields. The decreases in cigarette mass do not cause concerns because less tobacco is burned and will cause smoke constituent yields to also decrease. Increases in base paper basis weight may increase smoke constituent yields, however this is likely to be offset by the increase in base paper porosity. Decreases in filter density and filter pressure drop decrease filter efficiency and cause smoke constituent yields to increase. Similarly, the overall changes in total denier and denier per filament suggest that the filters in the new tobacco products may be less efficient and increase smoke constituent yields. The decreases in cigarette paper band porosity are offset by the decreases in the band width; and the 1% differences between these design parameters are anticipated to have undetectable effects on smoke constituents. Conversely, increases in ventilation may reduce smoke constituent yields. While the cumulative effects of all design changes on smoke constituents cannot be determined, the most relevant differences appear to be in the filters of the new tobacco products and reduced filter efficiency, which would negatively impact smoke constituent yields. The engineering review does not conclude the overall effects of the design changes in the new tobacco products and defers evaluation of HPHC data to the chemistry review.

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

4.3. TOXICOLOGY

Toxicology reviews were completed by Carmine Leggett on August 29, 2017 and October 31, 2018 and Sang Ki Park on June 21, 2019.

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

- Increases in (b) (4) tobacco and (b) (4)
- Ingredient changes in the structural components

The toxicology review considered HPHC data to evaluate the changes in structural components in the new tobacco products. No measured HPHCs are increased in the new products beyond analytical equivalence levels for both ISO or CI smoking regimens. As a result, the structural ingredient differences in the new tobacco products do not cause concerns.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports (SE0002807, SE0002808, SE0002811, SE0002812, SE0002815, SE0002816, SE0002817, SE0002818, SE0002819, SE0002820, and SE0002821) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an 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 predicate tobacco products:

SE0002807 and SE0002808

- Tobacco Blend:
  - o 21% decreases in (b) (4) tobacco
  - o 76% increase in (b) (4)
  - o 2% decrease in total tobacco
- Ingredients added to tobacco blend:
  - o Removal of (b) (4)
  - o 11%-21% decreases in all other ingredients
- Cigarette paper ingredients:
  - o Removal of (b) (4)
  - o 94% increase in (b) (4)
  - o 40% decrease in (b) (4)
  - o Removal of (b) (4)
- Filter tow ingredients:
  - o 9.3% decrease in all ingredients
- Plug wrap ingredients:
  - o 3.7% decrease in all ingredients
- Tipping paper ingredients:
  - o 15% increase in (b) (4)
  - o Removal of (b) (4)
- 15% decrease in band porosity
- 14% decrease in band width

- 22% decrease in filter denier per filament
- 10% decrease in filter density
- 5% decrease in cigarette mass

SE0002811 and SE0002812

- Tobacco blend:
  - 21% decrease in (b) (4) tobacco
  - 29% increase in (b) (4) tobacco
  - 81% increase in (b) (4)
  - 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - Removal of (b) (4)
  - 11%-21% decreases in all other ingredients

- Cigarette paper ingredients:
  - Removal of (b) (4)
  - 94% increase in (b) (4)
  - 40% decrease in (b) (4)
  - Addition of (b) (4)

- Filter tow ingredients:
  - 16% decrease in (b) (4)
  - 19% decrease in (b) (4)
  - 119% increase in (b) (4)
  - 71% increase in (b) (4)

- Plug wrap ingredients:
  - 10% decrease in (b) (4)
  - Addition of (b) (4)
  - Removal of (b) (4)

- Tipping paper ingredients:
  - 15% increase in (b) (4)
  - Removal of (b) (4)

- 5% decrease in puff count
- 15% decrease in band porosity
- 14% decrease in band width
- 17% decrease in total denier
- 14% decrease in filter denier per filament
- 5% decrease in filter density
- 9% decrease in pressure drop
- 18% decrease in ventilation

SE0002815 and SE0002816

- Tobacco blend:
  - o 22% decrease in (b) (4) tobacco
  - o 21% decrease in (b) (4) tobacco
  - o 29% increase in (b) (4) tobacco
  - o 81% increase in (b) (4)
  - o 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - o Removal of (b) (4)
  - o 11%-21% decrease in all other ingredients

- Cigarette paper ingredients:
  - o 11%-12% increase in (b) (4)
  - o 72% increase in (b) (4)
  - o 42% decrease in (b) (4)
  - o Addition of (b) (4)

- Filter tow ingredients:
  - o 11% decrease in all ingredients

- Plug wrap ingredients:
  - ○ 10% decrease in (b) (4)
  - ○ Removal of (b) (4)
  - ○ Addition of (b) (4)
    (b) (4)

- Tipping paper ingredients:
  - o 15% increase in (b) (4)
  - o Removal of (b) (4)

- 10% decrease in draw resistance
- 12% increase in base paper basis weight
- 50% increase in base paper porosity
- 11% decrease in filter denier per filament
- 10% decrease in filer density
- 15% decrease in pressure drop

SE0002817 and SE0002818

- Tobacco blend:
  - o 24% decrease in (b) (4) tobacco
  - o 25% increase in (b) (4) tobacco
  - o 76% increase in (b) (4)
  - o 2% decrease in total tobacco

- Ingredients added in tobacco blend:
  - o Removal of (b) (4)
  - o 11%-21% decrease of all other ingredients

- Cigarette paper ingredients:
  - o 11%-12% increase in (b) (4)
  - o 107% increase in (b) (4)
  - o 40% decrease in (b) (4)
  - o Addition of (b) (4)

- Filter tow ingredients:
  - o 16% decrease in (b) (4)
  - o 118% increase in (b) (4)
  - o 5% increase in (b) (4)
  - o 67% increase in (b) (4)

- Plug wrap ingredients:
  - o 10% decrease in (b) (4)
  - o Addition of (b) (4)
  - o Removal of (b) (4)

- Tipping paper ingredients:
  - o 15% increase in (b) (4)
  - o Removal of (b) (4)

- 7% decrease in draw resistance
- 6% decrease in filler mass
- 15% increase in band porosity
- 14% increase in band width
- 17% decrease in total denier
- 14% decrease in filter denier per filament
- 14% decrease in filter density
- 8% decrease in pressure drop
- 133% increase in ventilation
- 6% decrease in cigarette mass

SE0002819 and SE0002820

- Tobacco blend:
  - o 22% decrease in (b) (4) tobacco
  - o 21% decrease in (b) (4) tobacco
  - o 29% increase in (b) (4) tobacco
  - o 81% increase in (b) (4)
  - o 1% increase in total tobacco

- Ingredients added in tobacco blend:
  - o Removal of (b) (4)
  - o 11%-21% decrease of all other ingredients

- Cigarette paper ingredients:
  - o 11%-12% increase in (b) (4)
  - o 72% increase in (b) (4)
  - o 42% decrease in (b) (4)
  - o Addition of (b) (4)

- Filter tow ingredients:
  - o 16% decrease in (b) (4)
  - o 19% decrease in (b) (4)
  - o 119% increase in (b) (4)
  - o 71% increase in (b) (4)

- Plug wrap ingredients:
  - o 10% decrease in (b) (4)
  - o Addition of (b) (4)
  - o Removal of (b) (4)

- Tipping paper ingredients:
  - o 15% increase in (b) (4)
  - o Removal of (b) (4)

- 5% decrease in draw resistance
- 12% increase in base paper basis weight
- 50% increase in base paper porosity
- 17% decrease in total denier
- 14% decrease in filter denier per filament
- 15% decrease in filer density
- 8% decrease in filer density
- 18% increase in ventilation

SE0002821

- Tobacco blend:
  - o 24% decreases in (b) (4) tobaccos
  - o 25% increase in (b) (4) bacco
  - o 76% increase in (b) (4) tobacco
  - o 2% decrease in total tobacco

- Ingredients added to tobacco blend:
  - o Removal of (b) (4)
  - o 11-21% decreases in all non-tobacco ingredients

•Cigarette paper ingredients
  - o 11-12% increases in (b) (4)
  - o 108% increase in (b) (4)
  - o 39% decrease in (b) (4)
  - o Addition of (b) (4)

• Filter tow ingredients:
  - o 16% decrease in (b) (4)
  - o 19% decrease in (b) (4)
  - o 119% increase in (b) (4)
  - o 71% increase in (b) (4)

• Plug wrap ingredients:
  - o 10% decrease in (b) (4) 10% lower
  - o Addition of (b) (4)
  - o Removal of (b) (4)

• Tipping paper ingredients:
  - o 11% decrease in (b) (4)
  - o 23% decrease in (b) (4)
  - o Removal of (b) (4)

- 7% decrease in puff count
- 10% decrease in draw resistance
- 5% decrease in filler mass
- 15% increase in band porosity
- 14% increase in band width
- 17% decrease in total denier
- 14% decrease in filter denier per filament Filter density (↓20%)
- 11% decrease in pressure drop
- 29% increase in ventilation
- 7% decrease in cigarette mass

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. All SE Reports have new tobacco products which have changes in tobacco and non-tobacco ingredients and changes in physical design parameters to structural components. All of the changes can impact smoke constituents. The applicant provided HPHC data for tobacco filler and smoke yields for both ISO and Canadian Intense smoking regimens. The smoke yields for the new tobacco products do not have analytically significant increases in HPHCs. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

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

SE order letters should be issued for the new tobacco products in SE0002807, SE0002808, SE0002811, SE0002812, and SE0002815 - SE0002821, as identified on the cover page of this review.