

**Technical Project Lead (TPL) Review: SE0015598, SE0015599, SE0015601, SE0015602, SE0015603, and SE0015604**

<b>SE0015598: Black &amp; Mild® 808 Wood Tip</b>	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood
Characterizing Flavor	None
<b>SE0015599: Black &amp; Mild® Horizon Wood Tip</b>	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood
Characterizing Flavor	None
<b>SE0015601: Black &amp; Mild® Horizon</b>	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
<b>SE0015602: Black &amp; Mild® 808</b>	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
<b>SE0015603: Black &amp; Mild® Vinyl Wood Tip</b>	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood
Characterizing Flavor	None

SE0015604: Black & Mild® Vinyl	
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigar
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2020.04.21 11:59:47 -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: 2020.04.21 13:13:05 -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:

<b>SE0015598: Black &amp; Mild® 808 Wood Tip</b>	
Product Name	Black & Mild Apple
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Apple
<b>SE0015599: Black &amp; Mild® Horizon Wood Tip</b>	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Cherry Vanilla
<b>SE0015601: Black &amp; Mild® Horizon</b>	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Cherry Vanilla

<b>SE001602: Black &amp; Mild® 808</b>	
Product Name	Black & Mild Apple
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Apple
<b>SE0015603: Black &amp; Mild® Vinyl Wood Tip</b>	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Cherry Vanilla
<b>SE0015604: Black &amp; Mild® Vinyl</b>	
Product Name	Prince Albert Soft Cherry Vanilla
Package Type	Cello (polypropylene plastic wrap)
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	Cherry Vanilla

The predicate tobacco products are sheet wrapped unfiltered cigars manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 9, 2019, FDA received six SE Reports from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acceptance letter to the applicant on December 16, 2019.

### 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 Travelle Mason on December 16, 2019.

The reviews conclude that the SE Reports are administratively complete.

## **3. COMPLIANCE REVIEW**

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE reviews dated January 8, 2020, 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.

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE reviews dated February 4, 2020 and April 17, 2020 conclude that the new tobacco products are in compliance with the FD&C Act.

## **4. SCIENTIFIC REVIEW**

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

### **4.1. CHEMISTRY**

A chemistry review was completed by Jiu Ai on February 3, 2020.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the 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:

SE0015598 and SE0015602

• Tobacco blend

- 2.2% decrease in cigar filler weight
- 2.0% decrease in target tobacco weight
- 3.9% increase in (b) (4)
- 2.5% decrease in (b) (4)
- 3.8% decrease in (b) (4)

• Non-tobacco ingredients in cigar filler

- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- 2.3% decrease in (b) (4)
- 18.9% decrease in (b) (4)
- 13.9% decrease in (b) (4)
- 7.6% decrease in (b) (4)
- 23.0% decrease in (b) (4)
- 2.2% decrease in (b) (4)
- 14.9% decrease in (b) (4)
- 6.1% decrease in (b) (4)
- 8.2% decrease in (b) (4)
- 4.8% decrease in (b) (4)
- 23.2% decrease in (b) (4)
- 4.3% decrease in (b) (4)
- 72.6% decrease in (b) (4)
- 0.2% decrease in (b) (4)

• Ingredients in cigar wrapper

- 67% tobacco (b) (4) content
- 9.2% decrease in wrapper weight
- 9.4% decrease in tobacco content
- 8.5% decrease in (b) (4)
- 9.0% decrease in (b) (4)
- 9.3% decrease in (b) (4)
- 9.2% decrease in (b) (4)
- 9.7% decrease in (b) (4)
- Addition of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)

• Ingredients in cigar binder

- 67% tobacco (b) (4) content
- 11.2% decrease in binder weight

- 11.3% decrease in tobacco content
- 11.1% decrease in (b) (4)
- 11.0% decrease in (b) (4)
- 33.1% increase in (b) (4)
- Addition of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
  
- Ingredients in seam adhesive
  - 10.2% decrease in seam adhesive weight
  - 9.7% decrease in (b) (4)
  
- Ingredients in wood cigar tip (SE0015598)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- Ingredients in plastic cigar tip (SE0015602)
  - 1.0% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)

**SE0015599 and SE0015601**

- Non-tobacco ingredients in cigar filler
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - 81.1% decrease in (b) (4)
  - 76.2% decrease in (b) (4)
  - 67.8% decrease in (b) (4)
  - 21.2% decrease in (b) (4)
  - 6.5% decrease in (b) (4)
  - 10.6% decrease in (b) (4)
  - 13.4% decrease in (b) (4)
  - 13.3% decrease in (b) (4)
  - 53.6% decrease in (b) (4)
  - 68.5% decrease in (b) (4)
  - 87.1% decrease in (b) (4)
  - 7.6% decrease in (b) (4)
  - 97.5% decrease in (b) (4)



- 20.4% decrease in (b) (4)
- 88.6% decrease in (b) (4)
- 8.6% decrease in (b) (4)
- 59.7% decrease in (b) (4)
- 12.8% decrease in (b) (4)
- 22.1% decrease in (b) (4)
- 18.8% decrease in (b) (4)
- 17.9% decrease in (b) (4)
- 6.3% decrease in (b) (4)
- 8.5% decrease in (b) (4)
- 1.1% decrease in (b) (4)
  
- **Ingredients in cigar wrapper**
  - 67% tobacco (b) (4) content
  - 9.2% decrease in wrapper weight
  - 9.4% decrease in tobacco content
  - 8.5% decrease in (b) (4)
  - 9.0% decrease in (b) (4)
  - 9.3% decrease in (b) (4)
  - 9.2% decrease in (b) (4)
  
  - 9.7% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in cigar binder**
  - 67% tobacco (b) (4) content
  - 11.2% decrease in binder weight
  - 11.3% decrease in tobacco content
  - 11.1% decrease in (b) (4)
  - 11.0% decrease in (b) (4)
  - 33.1% increase in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in seam adhesive**
  - 10.2% decrease in seam adhesive weight
  - 9.7% decrease in (b) (4)
  
- **Ingredients in wood cigar tip (SE0015599)**
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) 5 mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)

- **Ingredients in plastic cigar tip (SE0015601)**

- 1.0% decrease in (b) (4)
- Addition of (b) (4) mg/cigar of (b) (4)

**SE0015603 and SE0015604**

- **Non-tobacco ingredients in cigar filler**

- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- 62.3% decrease in (b) (4)
- 7.2% decrease in (b) (4)
- 46.6% decrease in (b) (4)
- 21.2% decrease in (b) (4)
- 100.0% decrease in (b) (4)
- 10.6% decrease in (b) (4)
- 13.4% decrease in (b) (4)
- 13.3% decrease in (b) (4)
- 7.0% decrease in (b) (4)
- 68.5% decrease in (b) (4)
- 97.2% decrease in (b) (4)
- 7.6% decrease in (b) (4)
- 97.5% decrease in (b) (4)
- 22.0% decrease in (b) (4)
- 8.6% decrease in (b) (4)
- 94.1% decrease in (b) (4)
- 11.7% decrease in (b) (4)
- 22.1% decrease in (b) (4)
- 20.2% decrease in (b) (4)
- 17.9% decrease in specially (b) (4)
- 6.3% decrease in (b) (4)
- 8.9% decrease in (b) (4)
- 1.0% decrease in (b) (4)

- **Ingredients in cigar wrapper**

- 67% tobacco (b) (4) content
- 9.2% decrease in wrapper weight
- 9.4% decrease in tobacco content
- 8.5% decrease in (b) (4)

- 9.0% decrease in (b) (4)
  - 9.3% decrease in (b) (4)
  - 9.2% decrease in (b) (4)
  - 9.7% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
- Ingredients in cigar binder
    - 67% tobacco (b) (4) content
    - 11.2% decrease in binder weight
    - 11.3% decrease in tobacco content
    - 11.1% decrease in (b) (4)
    - 11.0% decrease in (b) (4)
    - 33.1% increase in (b) (4)
    - Addition of (b) (4) mg/cigar of (b) (4)
    - Removal of (b) (4) mg/cigar of (b) (4)
    - Removal of (b) (4) mg/cigar of (b) (4)
  - Ingredients in seam adhesive
    - 10.2% decrease in seam adhesive weight
    - 9.7% decrease in (b) (4)
  - Ingredients in wood cigar tip (SE0015603)
    - Addition of (b) (4) mg/cigar of (b) (4)
    - Addition of (b) (4) mg/cigar of (b) (4)
    - Addition of (b) (4) mg/cigar of (b) (4)
    - Addition of (b) (4) mg/cigar of (b) (4)
    - Removal of (b) (4) mg/cigar of (b) (4)
    - Removal of (b) (4) mg/cigar of (b) (4)
  - Ingredients in plastic cigar tip (SE0015604)
    - 1.0% decrease in (b) (4)
    - Addition of (b) (4)

The new tobacco products are slightly smaller than the corresponding predicate tobacco products, with general decreases in tobacco and either decreases or removal of non-tobacco ingredients. Such changes are typically favorable because they reduce smoke constituents that have toxicological significance. The new tobacco products of SE0015598 and SE0015602 have increased (b) (4) in the cigar filler. An increase in (b) (4) can raise TSNA levels, however the analytically equivalent tobacco filler amounts of NNN and NNK between the new and corresponding predicate products in the tobacco filler demonstrate that this tobacco blend change does not cause concerns. (b) (4) replaces (b) (4) (both preservatives) and (b) (4) is increased. Smoke chemistry is not anticipated to be affected by either of these changes because the (b) (4) quantity is less than (b) (4) of the tobacco rod weight of the cigar and the total amount of (b) (4)

mg/cigar lower in the new tobacco products compared to the corresponding predicate tobacco products. Finally, the new tobacco products use a (b) (4) tip whereas the corresponding predicate tobacco products use cigar tips of (b) (4). As the cigar tips are a non-combusted component, smoke chemistry is also not anticipated to be altered by this change. Smoke chemistry information was not provided. With the exception nicotine, on a unit of mass per gram of tobacco rod basis, arsenic, cadmium, NNK and NNN are analytically equivalent in the new tobacco products. Nicotine is increased 7-12% but does not cause concerns from a behavioral and clinical pharmacology perspective.<sup>1</sup> As a result, the harmful and potentially harmful constituents (HPHC) data submitted for tobacco filler is sufficient and smoke data is not needed.

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

An engineering review was completed by Jimin P. Kim on January 23, 2020.

The 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:

- 6-8% decreases in tobacco filler mass (SE0015599, SE0015601, SE0015603, SE0015604)
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- Increases in tobacco cut size (CPI)

Decreases in tobacco mass, moisture in wrapper and binder, and increases in tobacco cut size, are all generally associated with a reduction in TNCO yields. The engineering review deferred evaluation of TNCO to chemistry.

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. MICROBIOLOGY

A microbiology review was completed by Wen S. Lin on January 28, 2020.

The microbiology review concludes that the new tobacco products have different characteristics related to product microbiology compared to the corresponding predicate

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<sup>1</sup> CTP Memorandum: March 5, 2018, BCP Reviews of Characteristic Changes in SE Reports

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:

- $\leq 1\%$  decrease in (b) (4),  $\leq 20\%$  lower (b) (4)  $\leq 13\%$  lower (b) (4), and  $\leq 6\%$  lower (b) (4) (all humectants)
- Removal of (b) (4) as a preservative in the tobacco filler
- Replacement of (b) (4) with (b) (4) as a preservative in the wrapper and binder
- 10% decrease in (b) (4) in the seam adhesive

All new and corresponding predicate tobacco products differ in humectant and preservative content, which could potentially affect microbial stability of the products over the storage time of the products. The applicant did not provide stability data, but they provided moisture content (OV%), NNN and NNK content of the finished new and corresponding predicate tobacco products. The moisture content ( $< 16\%$ ) decrease in OV% ( $\leq 7\%$ ) and analytically equivalent NNN and NNK quantities demonstrate that the differences in humectants and preservatives in the new tobacco products are not a concern.

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 microbiology perspective.

#### 4.4. TOXICOLOGY

A toxicology review was completed by Daniel Beury on January 30, 2020.

The 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:

- Decreases in non-tobacco ingredient additives
- Decreases in target weights for the binder, wrapper, and seam adhesive, which results in concomitant decreases of the respective ingredients
- Substitution of (b) (4) and (b) (4) respectively
- Decreases in tobacco rod weight and the overall tobacco blends
- 3.9% increase in (b) (4) (SE0015598 and SE0015602)
- Change from a plastic tip to a wood tip (SE0015598, SE0015599, and SE0015603)
- Addition of artificial sweeteners (b) (4) (SE0015598, SE001599, and SE0015603) or just (b) (4) (SE0015601, SE0015602, and SE0015604) to the cigar tip

The change in ingredient levels do not present toxicological concerns because they are either reduced, do not affect HPHCs, or, in the cases of the artificial sweeteners, will be consumed in amounts that are less than those established by the Joint FAO/WHO Expert Committee on Food Additives Acceptable Daily Intake (JECFA ADI).

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

An environmental review was completed by William Brenner on January 23, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 12, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 12, 2020.

## 6. CONCLUSION AND RECOMMENDATION

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

### SE0015598 and SE0015602

- Tobacco blend
  - 2.2% decrease in cigar filler weight
  - 2.0% decrease in target tobacco weight
  - 3.9% increase in (b) (4) tobacco
  - 2.5% decrease in (b) (4) tobacco
  - 3.8% decrease in (b) (4)
  
- Non-tobacco ingredients in cigar filler
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of specially (b) (4)
  - 2.3% decrease in (b) (4)
  - 18.9% decrease in (b) (4)
  - 13.9% decrease in (b) (4)
  - 7.6% decrease in (b) (4)
  - 23.0% decrease in (b) (4)
  - 2.2% decrease in (b) (4)
  - 14.9% decrease in (b) (4)
  - 6.1% decrease in (b) (4)
  - 8.2% decrease in (b) (4)
  - 23.2% decrease in (b) (4)
  - 72.6% decrease in (b) (4)

- **Ingredients in cigar wrapper**
  - 67% tobacco (b) (4) content
  - 9.2% decrease in wrapper weight
  - 9.4% decrease in tobacco content
  - 8.5% decrease in (b) (4)
  - 9.0% decrease in (b) (4)
  - 9.3% decrease in (b) (4)
  - 9.2% decrease in (b) (4)
  - 9.7% decrease in (b) (4)
  
- **Ingredients in cigar binder**
  - 67% tobacco (b) (4) content
  - 11.2% decrease in binder weight
  - 11.3% decrease in tobacco content
  - 11.1% decrease in (b) (4)
  - 11.0% decrease in (b) (4)
  - 33.1% increase in (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in seam adhesive**
  - 9.7% decrease in (b) (4)
  
- **Ingredients in wood cigar tip (SE0015598)**
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in plastic cigar tip (SE0015602)**
  - 1.0% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)

**SE0015599 and SE0015601**

• **Non-tobacco ingredients in cigar filler**

- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
- 81.1% decrease in (b) (4)
- 76.2% decrease in (b) (4)
- 67.8% decrease in (b) (4)
- 21.2% decrease in (b) (4)
- 6.5% decrease in (b) (4)
- 10.6% decrease in (b) (4)
- 13.4% decrease in (b) (4)
- 13.3% decrease in (b) (4)
- 53.6% decrease in (b) (4)
- 68.5% decrease in (b) (4)
- 87.1% decrease in (b) (4)
- 7.6% decrease in (b) (4)
- 97.5% decrease in (b) (4)
- 20.4% decrease in (b) (4)
- 88.6% decrease in (b) (4)
- 8.6% decrease in (b) (4)
- 59.7% decrease in (b) (4)
- 22.1% decrease in (b) (4)
- 18.8% decrease in (b) (4)
- 17.9% decrease in (b) (4)
- 8.5% decrease in (b) (4)

• **Ingredients in cigar wrapper**

- 67% tobacco (b) (4) content
- 9.2% decrease in wrapper weight
- 9.4% decrease in tobacco content
- 8.5% decrease in (b) (4)
- 9.0% decrease in (b) (4)
- 9.3% decrease in (b) (4)
- 9.2% decrease in (b) (4)
- 9.7% decrease in (b) (4)

• **Ingredients in cigar binder**

- 67% tobacco (b) (4) content
- 11.2% decrease in binder weight
- 11.3% decrease in tobacco content



- 11.1% decrease in (b) (4)
- 11.0% decrease in (b) (4)
- 33.1% increase in (b) (4)
- Removal of (b) (4) mg/cigar of (b) (4)
  
- Ingredients in seam adhesive
  - 9.7% decrease in (b) (4)
  
- Ingredients in wood cigar tip (SE0015599)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- Ingredients in plastic cigar tip (SE0015601)
  - 1.0% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)

**SE0015603 and SE0015604**

- Non-tobacco ingredients in cigar filler
  - Removal (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - 62.3% decrease in (b) (4)
  - 7.2% decrease in (b) (4)
  - 46.6% decrease in (b) (4)
  - 21.2% decrease in (b) (4)
  - 100.0% decrease of (b) (4)
  - 10.6% decrease in (b) (4)
  - 13.4% decrease in (b) (4)
  - 13.3% decrease in (b) (4)
  - 7.0% decrease in (b) (4)
  - 68.5% decrease in (b) (4)
  - 97.2% decrease in (b) (4)
  - 7.6% decrease in (b) (4)
  - 97.5% decrease in (b) (4)
  - 22.0% decrease in (b) (4)

- 8.6% decrease in (b) (4)
- 94.1% decrease in (b) (4)
- 22.1% decrease in (b) (4)
- 20.2% decrease in red (b) (4)
- 17.9% decrease in (b) (4) (b) (4)
- 6.3% decrease in (b) (4)
- 8.9% decrease in (b) (4)
  
- **Ingredients in cigar wrapper**
  - 67% tobacco (b) (4) content
  - 9.2% decrease in wrapper weight
  - 9.4% decrease in tobacco content
  - 8.5% decrease in (b) (4)
  - 9.0% decrease in (b) (4)
  - 9.3% decrease in (b) (4)
  - 9.2% decrease in (b) (4)
  - 9.7% decrease in (b) (4)
  
- **Ingredients in cigar binder**
  - 67% tobacco (b) (4) content
  - 11.2% decrease in binder weight
  - 11.3% decrease in tobacco content
  - 11.1% decrease in (b) (4)
  - 11.0% decrease in (b) (4)
  - 33.1% increase in (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in seam adhesive**
  - 9.7% decrease in (b) (4)
  
- **Ingredients in wood cigar tip (SE0015603)**
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  - Removal of (b) (4) mg/cigar of (b) (4)
  
- **Ingredients in plastic cigar tip (SE0015604)**
  - 1.0% decrease in (b) (4)
  - Addition of (b) (4) mg/cigar of (b) (4)

## All SE Reports

- $\leq 1\%$  decrease in water,  $\leq 20\%$  lower (b) (4)  $\leq 13\%$  lower (b) (4) and  $\leq 6.3\%$  lower (b) (4) (all humectants)
- Removal of (b) (4) as a preservative in the tobacco filler
- Replacement of (b) (4) with (b) (4) as a preservative in the wrapper and binder
- 10.2% decrease in (b) (4) in the seam adhesive
- 6-8% decreases in tobacco filler mass (SE0015599, SE0015601, SE0015603, SE0015604)
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- Increases in tobacco cut size (CPI)
- Addition of artificial sweeteners (b) (4) and (b) (4) (SE0015598, SE0015599, and SE0015603) or just (b) (4) (SE0015601, SE0015602, and SE0015604) to the cigar tip of the new products.

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Decreases in tobacco and non-tobacco ingredient additives will not adversely affect smoke chemistry because less material is combusted. Similarly, the change to a (b) (4) cigar tip is not a concern since it is a non-combusted component. The differences in humectants, preservatives and tobacco blend (increase in (b) (4) tobacco) can affect microbial activity and related HPHCs like NNN and NNK. However, these HPHCs are analytically equivalent. The use of artificial sweeteners on the (b) (4) cigar tips is not a concern as exposure via dermal and oral routes are less than JECFA ADI established guidelines. 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). The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0015598, SE0015599, SE0015601, SE0015602, SE0015603, and SE0015604, as identified on the cover page of this review.