

**Technical Project Lead (TPL) Review: SE0015364, SE0015365, SE0015366, and SE0015367**

<b>SE0015364: Black &amp; Mild® White Label</b>	
Package Type	Cello <sup>1</sup>
Package Quantity	1 Cigar
Characterizing Flavor	None <sup>2</sup>
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
<b>SE0015365: Black &amp; Mild® Red Label Wood Tip</b>	
Package Type	Cello <sup>1</sup>
Package Quantity	1 Cigar
Characterizing Flavor	None <sup>2</sup>
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood Tip
<b>SE0015366: Black &amp; Mild® Autumn</b>	
Package Type	Cello <sup>1</sup>
Package Quantity	1 Cigar
Characterizing Flavor	None <sup>2</sup>
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
<b>SE0015367: Black &amp; Mild® Red Label</b>	
Package Type	Cello <sup>1</sup>
Package Quantity	1 Cigar
Characterizing Flavor	None <sup>2</sup>
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip

<sup>1</sup> The applicant defines “cello” as a clear wrap. In this case, cello is composed of polypropylene plastic wrap.

<sup>2</sup> The applicant uses the term (b) (4)

In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

Common Attributes of SE Reports	
<b>Applicant</b>	John Middleton Co.
<b>Report Type</b>	Regular
<b>Product Category</b>	Cigars
<b>Product Sub-Category</b>	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Samantha Spindel -S3  
Date: 2020.06.05 16:27:59 -04'00'

Samantha Spindel, Ph.D., M.Eng.  
CDR, US Public Health Service  
Engineering 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: 2020.06.05 17:18:05 -04'00'

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

## TABLE OF CONTENTS

<b>1. BACKGROUND .....</b>	<b>4</b>
1.1. PREDICATE TOBACCO PRODUCTS .....	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	5
1.3. SCOPE OF REVIEW .....	5
<b>2. REGULATORY REVIEW .....</b>	<b>5</b>
<b>3. COMPLIANCE REVIEW .....</b>	<b>5</b>
<b>4. SCIENTIFIC REVIEW .....</b>	<b>6</b>
4.1. CHEMISTRY.....	6
4.2. ENGINEERING .....	7
4.3. MICROBIOLOGY.....	8
4.4. TOXICOLOGY.....	9
<b>5. ENVIRONMENTAL DECISION.....</b>	<b>10</b>
<b>6. CONCLUSION AND RECOMMENDATION .....</b>	<b>11</b>

## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

<b>SE0015364: Black &amp; Mild® White Label</b>	
<b>Product Name</b>	Black & Mild Cream
<b>Package Type</b>	Cello <sup>1</sup>
<b>Package Quantity</b>	1 Cigar
<b>Characterizing Flavor</b>	Cream <sup>3</sup>
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip
<b>SE0015365: Black &amp; Mild® Red Label Wood Tip</b>	
<b>Product Name</b>	Black & Mild Cream
<b>Package Type</b>	Cello <sup>1</sup>
<b>Package Quantity</b>	1 Cigar
<b>Characterizing Flavor</b>	Cream <sup>3</sup>
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip
<b>SE0015366: Black &amp; Mild® Autumn</b>	
<b>Product Name</b>	Black & Mild Apple
<b>Package Type</b>	Cello <sup>1</sup>
<b>Package Quantity</b>	1 Cigar
<b>Characterizing Flavor</b>	Apple <sup>4</sup>
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip

<sup>3</sup> The applicant uses the term (b) (4)

. In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

<sup>4</sup> The applicant uses the term (b) (4)

. In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

<b>SE0015367: Black &amp; Mild® Red Label</b>	
<b>Product Name</b>	Black & Mild Cream
<b>Package Type</b>	Cello <sup>1</sup>
<b>Package Quantity</b>	1 Cigar
<b>Characterizing Flavor</b>	Cream <sup>3</sup>
<b>Length</b>	126.9 mm
<b>Diameter</b>	9.62 mm
<b>Tip</b>	Plastic Tip

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 19, 2019, FDA received four SE Reports from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on July 26, 2019. FDA issued a Deficiency letter to the applicant on September 25, 2019. On February 10, 2020, FDA received an email from the applicant with requests for clarification to the Deficiency letter. On March 20, 2020, FDA received an amendment (SE0015780) responding to the Deficiency letter for all reports.

<b>Product Name</b>	<b>SE Report</b>	<b>Amendments</b>
Black & Mild® White Label	SE0015364	SE0015780
Black & Mild® Red Label Wood Tip	SE0015365	
Black & Mild® Autumn	SE0015366	
Black & Mild® Red Label	SE0015367	

### 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 Anikah Salim on July 26, 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 as of February 15, 2007). The OCE reviews dated August 6, 2019, 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 review dated May 27, 2020, concludes 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

Chemistry reviews were completed by Jikun Liu on September 5, 2019, and May 1, 2020.

The final 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:

- Tobacco Blend Changes
  - (b) (4) ((b) (4) mg/cigar) lower amount of (b) (4)
  - (b) (4) (b) (4) mg/cigar) lower amount of (b) (4)
  - (b) (4) (b) (4) mg/cigar) decrease in burley leaf in SE0015364, SE0015365, and SE0015367
  - (b) (4) (b) (4) mg/cigar) increase in (b) (4) in SE0015366
- Binder and Wrapper Changes
  - (b) (4) ((b) (4) mg/cigar) lower amount of (b) (4) content in binder and wrapper
  - Deletion of (b) (4) and addition of (b) (4) in binder and wrapper
  - Deletion of (b) (4) in binder
  - Deletion of (b) (4) and (b) (4) and addition of (b) (4) in wrapper of SE0015365 and SE0015367
  - Composition of the (b) (4) content in the binder and wrapper in SE0015364–SE0015367
- Tip Changes
  - Deletion of (b) (4) in SE0015365
  - Addition of (b) (4) in SE0015365
  - Addition of (b) (4) to tip of SE0015364 and SE0015366
- Seam Adhesive Change
  - (b) (4) (b) (4) mg/cigar) decrease in (b) (4)
- Tobacco Filler Ingredient Changes
 

SE0015364–SE0015367

  - Deletion of (b) (4) for (b) (4) (b) (4)
  - Deletion of (b) (4)

SE0015364, SE0015365, and SE0015367

- Deletion of (b) (4)
- Deletion of (b) (4)
- Deletion of (b) (4)
- Deletion of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- (b) (4) ((b) (4) mg/cigar) decrease in total (b) (4)
- (b) (4) (b) (4) mg/cigar) decrease in (b) (4)
- 12–14% (b) (4) mg/cigar) decrease in (b) (4)
- Deletion of (b) (4)
- (b) (4) (b) (4) mg/cigar) decrease in (b) (4)

SE0015366

- Deletion of (b) (4)

Initially, SE0015364–SE0015367 lacked sufficient information about the composition of complex ingredients (e.g., (b) (4) (b) (4) ) and the tobacco content of the binder and wrapper. A (b) (4) decrease in total (b) (4) (e.g., (b) (4) ) was noted for the new tobacco products compared to the predicate tobacco products and a deficiency was issued regarding mainstream (MSS) yields of (b) (4) (b) (4) to elucidate the impact of the ingredient change on smoke chemistry for the new tobacco products. The deficiency also included (b) (4) ) due to changes in tobacco cut size (deferred from engineering). Additionally, all SE Reports lacked detailed information for ALCS method (b) (4) and full validation reports for Altria Client Services (ALCS) methods (b) (4) . The applicant provided sufficient information (i.e., unique identifying name/code, function, grade, target quantities, boundary values) for (b) (4) (b) (4) , and (b) (4) , and clarified that the binder and wrapper tobacco contents between the new and predicate tobacco products were identical. Additionally, the applicant justified that the differences in total sugars and tobacco cut size between the new and predicate tobacco products will not induce significant increases in the mainstream smoke yields of (b) (4) (b) (4) and TNCO, and submitted detailed information about ALCS method (b) (4) together with full validation reports for ALCS methods (b) (4) and (b) (4) . The applicant clarified that ALCS method (b) (4) is an official method listed in the Federal Register and therefore, the validation report 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 Rashele Moore on September 18, 2019.

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:

- SE0015364 and SE0015367
  - (b) (4) decrease in (b) (4)
  - (b) (4) increase in (b) (4)
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - Changes in tobacco cut size (CPI)
- SE0015365
  - (b) (4) decrease in (b) (4)
  - (b) (4) increase in (b) (4)
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - Changes in tobacco cut size (CPI)
- SE0015366
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - Changes in tobacco cut size (CPI)

A decrease in (b) (4) reduces the amount of tobacco that is burned and is anticipated to decrease smoke TNCO yields. A decrease in the (b) (4) and (b) (4) may reduce puff count and, in turn, decrease smoke (b) (4) yields. A decrease in (b) (4) (b) (4) reflects a decrease in the amount of tobacco in a cigar, which could result in less particulate matter and smoke (b) (4) yields. A difference in tobacco cut size may alter the size of the tobacco pieces, which may result in more particulate matter and, in turn, affect smoke constituent yields. The overall effect of the changes in (b) (4), (b) (4) on smoke TNCO yields was evaluated by Chemistry. Chemistry determined that these changes may not have a significant impact on smoke HPHCs.

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 David Craft on September 6, 2019.

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

- Change in preservatives
  - Addition of (b) (4) to the binder (b) (4) mg/cigar) and wrapper (b) (4) mg/cigar)
  - Removal of (b) (4) from the filler
  - (b) (4) decrease of (b) (4) in the seam adhesive
  - Removal of (b) (4) from the binder (b) (4) mg) and wrapper (b) (4) (b) (4) mg)
- Change in humectants
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - (b) (4) to (b) (4) change in (b) (4)

These differences in preservative and humectant content between the new and corresponding predicate tobacco products could affect the microbial stability of the products during storage. The applicant did not provide stability data over the storage duration of the new and predicate tobacco products to address this concern. However, the applicant provided moisture (OV%), (b) (4) and (b) (4) content of the finished new and predicate tobacco products. The total moisture content of the new and predicate tobacco products is (b) (4) which is insufficient to support fungal growth. And, scientific evidence indicating that bacterial growth can occur in tobacco at moisture contents of (b) (4) is not currently available. Based on the low moisture content of the new tobacco products, analytically equivalent (b) (4) and (b) (6) content, lack of (b) (6) and (b) (4) the differences in humectants and preservatives 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

Toxicology reviews were completed by Theresa Thekkudan on September 17, 2019, and May 4, 2020.

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:

- SE0015364–SE0015367
  - Reduction in total (b) (4) % ↓)
  - Changes in tobacco cut size
- SE0015364, SE0015365, and SE0015367
  - Increase in (b) (4), (b) (4) (b) (4) ↑), (b) (4) (94% ↑), (b) (4) (14% ↑), (b) (4) (15% ↑), and (b) (4) (9% ↑)

Initially, toxicology postulated that the changes to the new tobacco products in comparison to the corresponding predicate tobacco products may increase smoke HPHC yields of (b) (4), (b) (4) and (b) (4) during product use. However, Chemistry determined that these changes are not expected to have a measurable impact on the smoke HPHCs because total sugars between the new and predicate tobacco products were less than (b) (4) relative to the tobacco filler weight, which will not cause significant impacts on the smoke HPHC levels of the new tobacco products. Moreover, the overall changes in design features and overall cigar mass may reduce the smoke yields of (b) (4) for the new tobacco products compared to the corresponding predicate tobacco products. Therefore, in all SE Reports, changes in total sugar quantities and tobacco cut size in the new tobacco products are unlikely to raise different questions of public health.

In SE0015364, SE0015365, and SE0015367, increases in five tobacco filler flavor ingredients may increase smoke HPHC yields of (b) (4), and (b) (4). The applicant provided a comparison of the total quantity of these increased ingredients (b) (4) mg/cigar) to the total quantity of decreased and removed ingredients (b) (4) mg/cigar) in the new tobacco products compared to the predicate tobacco product. These decreased and removed ingredients, upon combustion, are known to form multiple HPHCs, which are (b) (4) (b) (4), and (b) (4) or (b) (4). Therefore, given the toxicity and the HPHCs associated with the decreased and removed ingredients, the reduction and removal of ingredients likely offsets any potential toxicity due to the increases in the absolute values of (b) (4)

Moreover, any potential HPHC changes due to the ingredient increases (b) (4) mg/cigar, or (b) (4) w/w) are likely to be analytically equivalent using current analytical methods for cigars. Therefore, ingredient increases may not have a significant impact on HPHC yields and 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

Environmental reviews were completed by Susana Addo Ntim on August 21, 2019, and May 5, 2020.

A finding of no significant impact (FONSI) was signed by Luis G. Valerio Jr., Ph.D., ATS on May 6, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 5, 2020.

## 6. CONCLUSION AND RECOMMENDATION

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

- Tobacco Blend Changes
  - (b) (4) (b) (4) mg/cigar lower amount of (b) (4)
  - (b) (4) (b) (4) mg/cigar lower amount of (b) (4)
  - (b) (4) (b) (4) mg/cigar decrease in (b) (4) in SE0015364, SE0015365, and SE0015367
  - (b) (4) (b) (4) mg/cigar increase in (b) (4) in SE0015366
- Binder and Wrapper Changes
  - (b) (4) (b) (4) 5 mg/cigar lower amount of (b) (4) in binder and wrapper
  - Deletion of (b) (4) (b) (4) in binder
  - Deletion of (b) (4) and (b) (4) and addition of (b) (4) of SE0015365 and SE0015367
  - (b) (4) in the binder and wrapper in SE0015364–SE0015367
- Tip Changes
  - Deletion of (b) (4) in SE0015365
  - Addition of (b) (4) in SE0015365
  - Addition of (b) (4) to (b) (4) of SE0015364 and SE0015366
- Seam Adhesive Change
  - (b) (4) (b) (4) mg/cigar decrease in (b) (4)
- Tobacco Filler Ingredient Changes
 

SE0015364–SE0015367

  - Deletion of (b) (4) for (b) (4)
  - Deletion of (b) (4) (b) (4) (b) (4) mg/cigar decrease in total sugars (b) (4) (b) (4) )
  - (b) (4) ((b) (4) mg/cigar decrease in (b) (4)
  - (b) (4) (b) (4) mg/cigar decrease in (b) (4)

SE0015364, SE0015365, and SE0015367

  - Deletion of (b) (4)
  - Deletion of (b) (4)
  - Deletion of (b) (4)
  - Deletion of (b) (4)
  - Addition of (b) (4)
  - Addition of (b) (4)
  - Addition of (b) (4)
  - Addition of (b) (4)
  - (b) (4) (b) (4) mg/cigar decrease in (b) (4)
  - (b) (4) e in (b) (4) ↑), (b) (4) (94% ↑), (b) (4) 14% ↑), (b) (4) (b) (4) (15% ↑), and (b) (4) (9% ↑)

SE0015366

  - Deletion of (b) (4)

- Preservative Changes
  - Addition of (b) (4) to the binder (b) (4) mg/cigar) and wrapper (b) (4) mg/cigar)
  - Removal of (b) (4) from the filler
  - (b) (4) decrease of (b) (4) in the seam adhesive
  - Removal of (b) (4) from the binder (b) (4) mg) and wrapper (b) (4) (b) (4) mg)
- Humectant Changes
  - (b) (4) decrease in (b) (4)
  - (b) (4) decrease in (b) (4)
  - (b) (4) change in (b) (4)
- Design Changes
  - SE0015364 and SE0015367
    - (b) (4) decrease in (b) (4)
    - (b) (4) increase in (b) (4)
    - (b) (4) decrease in (b) (4)
    - (b) (4) decrease in (b) (4)
    - (b) (4) decrease in (b) (4)
    - Changes in tobacco cut size (CPI)
  - SE0015365
    - (b) (4) decrease in (b) (4)
    - (b) (4) increase in (b) (4)
    - (b) (4) decrease in (b) (4)
    - (b) (4) decrease in (b) (4)
    - Changes in tobacco cut size (CPI)
  - SE0015366
    - (b) (4) decrease in (b) (4)
    - (b) (4) decrease in (b) (4)
    - Changes in tobacco cut size (CPI)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. All non-tobacco ingredients with quantities greater than 1 mg/cigar noted above are either absent from the new tobacco products, or their levels in the new tobacco products are lower than those in the predicate tobacco products. An analysis of HPHCs in the filler (b) (4) shows the HPHC level changes are all analytically equivalent. Although the (b) (4) is replaced with a (b) (4) and (b) (4) (b) (4) is added to the tip, the tip is a non-combusted part of the tobacco products and therefore is not expected to affect HPHC levels. The decrease in total sugars (e.g., (b) (4) (b) (4)) are not expected to induce measurable increases in the mainstream smoke yields of (b) (4), (b) (4) and (b) (4) because the amount of total sugars between the new and predicate tobacco products were less than 5% relative to the tobacco filler weight. Moreover, the overall changes in design features and overall cigar mass may reduce the smoke yields of (b) (4) for the new tobacco products compared to the corresponding predicate tobacco products. In addition, in SE0015364, SE0015365, and SE0015367, five tobacco filler flavor ingredients (i.e., (b) (4) (b) (4)) are increased in the new tobacco products compared to their predicate tobacco product. Although such changes may increase some smoke HPHC yields, the applicant provided a comparison of the total quantity of these increased ingredients to the total quantity of other decreased and removed ingredients in the

new tobacco products compared to the corresponding predicate tobacco products. These decreased and removed ingredients, upon combustion, are known to form multiple HPHCs, which are (b) (4), and (b) (4) or (b) (4). (b) (4) Given the toxicity and the HPHCs associated with the decreased and removed ingredients, the reduction and removal of ingredients likely offsets the toxicity due to the increases in (b) (4). Moreover, the HPHC changes due to the ingredient increases are likely to be analytically equivalent using current analytical methods for cigars.

The new tobacco products have preservative and humectant changes compared to the corresponding predicate products. Although the applicant did not provide stability data over the storage duration of the new and predicate tobacco products, the applicant provided moisture (OV%), (b) (4) and (b) (4) content. The total moisture content of the new and predicate tobacco products is (b) (4), which is insufficient to support fungal growth, and scientific evidence that indicates bacterial growth can occur in tobacco at moisture contents of (b) (4) is not currently available. Based on the low moisture content of the new tobacco products, analytically equivalent (b) (4) and (b) (4) content, lack of (b) (4) and (b) (4), the differences in humectants and preservatives of the new tobacco products when compared to the corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

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 SE0015364, SE0015365, SE0015366, and SE0015367 as identified on the cover page of this review.