

**Technical Project Lead (TPL) Review: SE0015126**

SE0015126: Black & Mild FT	
Package Type	Polypropylene plastic wrap
Package Quantity	1 Cigar <sup>1</sup>
Length	110 mm
Diameter	8.9 mm
Ventilation	0%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Filtered, Sheet-Wrapped Cigar
Recommendation	
Issue a Substantially Equivalent (SE) order.	

<sup>1</sup> Amendment SE0015350 (submitted July 11, 2019) states that the new and predicate tobacco products are all individually wrapped cigars that are co-packaged into different quantities. Therefore, there is no change in product quantity from Black & Mild FT – 5 pack (predicate tobacco product) and the package quantity is one cigar.

**Technical Project Lead (TPL):**

Digitally signed by Jeannie H. Jeong-im -S  
Date: 2019.12.06 13:52:46 -05'00'

Jeannie Jeong-Im, 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: 2019.12.06 14:01:44 -05'00'

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

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## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015126: Black & Mild FT – 5 Pack	
Product Name	Black & Mild FT – 5 Pack
Package Type	Polypropylene plastic wrap
Package Quantity	1 Cigar <sup>1</sup>
Length	110 mm
Diameter	8.9 mm
Ventilation	0%
Characterizing Flavor	None

The predicate tobacco product is a filtered, sheet-wrapped cigar manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 19, 2019, FDA received one SE Report from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on March 26, 2019. On May 21, 2019, FDA issued a Deficiency letter. On May 31, 2019 and July 11, 2019, FDA received unsolicited amendments (SE0015252 and SE0015350, respectively) and on September 12, 2019, FDA received the applicant's response to the deficiency letter (SE0015470).

Product Name	SE Report	Amendments
Black & Mild FT – 5 Pack	SE0015126	SE0015252 SE0015350 SE0015470

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

## 2. REGULATORY REVIEW

A regulatory review was completed by Nicholas Hasbrouck on March 26, 2019.

The review concludes that the SE Report is administratively complete.

### 3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015126 was determined to be substantially equivalent by FDA under SE0014625. Therefore, this product is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated November 19, 2019, concludes that the new tobacco product is 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 Robert F. Gahl on May 9, 2019 and November 1, 2019.

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

- 5% reduction in target rod length
- Removal of complex flavor ingredients (e.g., (b) (4))
- Addition of (b) (4) of complex ingredient (b) (4)
- Removal of (b) (4), a preservative, in wrapper<sup>2</sup>
- Addition of (b) (4), a preservative, in the wrapper
- Increase in filter length by 20 mm, and thus an increase in filter system materials (e.g., Cigar Filter Tow, Plug Wrap, Filter Seam Adhesive, Filter Anchor Adhesive, Tipping Adhesive, and Tipping Paper).

The final chemistry review found there is a 5% reduction in the rod length, and thus a reduction in target tobacco weight and ingredients added to the tobacco. Tobacco blends were reduced 1-10% or a 6% total tobacco content decrease. There are some flavor changes as well as replacement of (b) (4) with (b) (4) in the wrapper. These changes have all decreased or are all under 0.1% of the total finished product and are not expected to have an impact on tar, nicotine, or HPHCs. However, the filter length increased by 20 mm; therefore, there are increases in the cigar filter tow, plug wrap, filter seam adhesive, filter anchor adhesive, tipping adhesive, and tipping paper. The applicant provided smoke data for tar, nicotine, B[a]P, NNN, and NNK under the CI smoking regimen. NNN increased by 15%; however, NNN as well as the other constituents are analytically equivalent between the new and predicate tobacco

<sup>2</sup> The 1<sup>st</sup> chemistry review incorrectly stated that (b) (4) was removed from the wrapper. There is no (b) (4) in the new and predicate tobacco products.

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

#### **4.2. ENGINEERING**

An engineering review was completed by Mary Powell on May 8, 2019.

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

- Decrease in tobacco filler mass (7%)
- Increase in filter length (33%)
- Decrease in filter total denier (15%)
- Increase in filter denier per filament (6%)
- Decrease in filter density (9%)
- Increase in filter pressure drop (10%)
- Increase in cigar tipping paper length (23%)

The new tobacco product has 7% less tobacco filler mass than the predicate tobacco products. This is due to the new tobacco product having a shorter tobacco rod. A decrease in tobacco filler mass reduces the amount of tobacco that is available to be burned. Reduced tobacco weight may reduce TNCO smoke yields. The new tobacco product has a filter that has five key differences compared to the predicate tobacco product: filter length increased 33%; filter total denier decreased 15%; filter denier per filament increased 6%; filter density decreased 9%; and filter pressure drop increased 10%. The differences in filter design parameters may impact tar, nicotine, and B[a]P smoke yields. The filter differences between the new tobacco product compared to the predicate tobacco product are deferred to chemistry to evaluate the impact on tar, nicotine, and B[a]P smoke yields to determine whether the filter differences cause the new tobacco product to raise different questions of public health. The new tobacco product has 23% increased cigar tipping paper length compared to the predicate product. The increase in tipping paper length is consistent with the increase in filter length for the new tobacco product. A difference in cigar tipping paper length may impact tar and nicotine yields. Therefore, the increase in cigar tipping paper length is deferred to chemistry to evaluate the tar and nicotine yields. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

#### **4.3. MICROBIOLOGY**

A microbiology review was completed by David L. Craft on May 8, 2019.

The microbiology review concludes that the new tobacco product has different characteristics related to product microbiology compared to the corresponding predicate tobacco product, but

the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Decrease (1%) in average total moisture content [Oven volatiles (OV%) 14.72%] (comparison to predicate only)
- Decrease in NNN (4%) content (comparison to predicate only)
- Increase in NNK (2%) content (comparison to predicate only)
- Addition of (b) (4), a preservative, in the wrapper
- Decrease in (b) (4) in the cigar seam adhesive
- Removal of (b) (4), a preservative, in the wrapper
- Decreases in the target contents of (b) (4) (7%), (b) (4) (8%), and (b) (4) (9%), as humectants, in the finished cigar

The new tobacco product has an addition of (b) (4) to the wrapper, and removal of (b) (4) both preservatives. Additionally, the new tobacco product has decreases in the content of (b) (4) in the seam adhesive, and the humectants, (b) (4) (7%), (b) (4) (8%), and (b) (4) (9%). The applicant did not provide stability data over the storage duration of the new and predicate tobacco product. However, the total moisture content of the new and predicate tobacco product is less than 15% which is insufficient to support fungal growth and comprehensive data to support bacterial growth at this concentration has not been substantiated. The new and predicate tobacco product do not include any fermented tobacco and have identical container-closure systems. Additionally, the NNN, and NNK content of the finished new tobacco product is decreased by 4% and increased by 2%, respectively, when compared to the predicate tobacco product. Therefore, the lack of stability data for the new and predicate tobacco product is not a concern from a microbiology perspective. Based on the lack of fermented tobacco, identical container closure system, the minor changes in NNN and NNK, and the low moisture content (<15%) of the new tobacco product, the differences in humectants and preservatives of the new tobacco product when compared to the predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a microbiological perspective.

#### 4.4. TOXICOLOGY

A toxicology review was completed by Theresa Thekkudan on May 10, 2019.

The toxicology review did not identify any differences in characteristics between the new and corresponding predicate tobacco product that could cause the new tobacco product to raise different questions of public health from a toxicology perspective. Therefore, the differences in characteristics between the new and corresponding predicate tobacco product does not cause the new tobacco product to raise different questions of public health related to product toxicology.

## 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Mehran Niazi on May 1, 2019 and Ronald Edwards on September 25, 2019.<sup>3,4</sup>

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 18, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 18, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- Reduction in target rod length (5%)
- Removal of complex flavor ingredients (e.g., (b) (4), (b) (4) and (b) (4))
- Addition of (b) (4) of complex ingredient (b) (4)
- Removal of (b) (4), a preservative, in wrapper
- Addition of (b) (4), a preservative, in the wrapper
- Increase in filter length (33%)
- Decrease in filter total denier (15%)
- Increase in filter denier per filament (6%)
- Decrease in filter density (9%)
- Increase in filter pressure drop (10%)
- Increase in cigar tipping paper length (23%)
- Decreases in the target contents of (b) (4) (7%), (b) (4) (8%), and (b) (4) (9%), as humectants, in the finished cigar

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. There is a 5% reduction in the rod length, and thus a reduction in target tobacco weight and ingredients added to the tobacco. Tobacco blends were reduced 1-10% or a 6% total tobacco content decrease. There is no fermented tobacco in the tobacco blend. There are some flavor changes as well as replacement of (b) (4) with (b) (4) in the wrapper. These changes have all decreased or are all under 0.1% of the total finished product and are not expected to have an impact on tar, nicotine, or HPHCs. However, there are increases in the cigar filter tow, plug wrap, filter seam adhesive, filter anchor adhesive, tipping adhesive, and tipping paper that may affect tar, nicotine, B[a]P, NNN, and NNK. The applicant provided smoke data for tar, nicotine, B[a]P, NNN, and NNK under the CI smoking regimen and all were found to be analytically equivalent under TOST. Therefore, the differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health.

<sup>3</sup> An addendum review was completed on October 8, 2019 to communicate a noncompliance or a violation status of Resource Conservation and Recovery Act provisions.

<sup>4</sup> An addendum review was completed on November 15, 2019 to communicate that the noncompliance or violation status has been resolved and environmental has all the information it needs to complete their review.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0014625.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015126 was previously determined to be substantially equivalent by FDA under SE0014625. Comparison of the new tobacco product to the grandfathered product (Black & Mild FT - 7 Pack) in SE0014625 reveals that the new tobacco product has the following differences in characteristics from Black & Mild FT - 7 Pack, the grandfathered tobacco product:

- Reduction in target rod length (5%)
- Removal of complex flavor ingredients (e.g., (b) (4) [redacted])
- Addition of (b) (4) [redacted] of complex ingredient (b) (4) [redacted]
- Removal of (b) (4) [redacted] a preservative, in wrapper
- Addition of (b) (4) [redacted] a preservative, in the wrapper
- Increase in filter length (33%)
- Decrease in filter total denier (15%)
- Increase in filter denier per filament (6%)
- Decrease in filter density (9%)
- Increase in filter pressure drop (10%)
- Increase in cigar tipping paper length (23%)
- Decreases in the target contents of (b) (4) [redacted] (7%), (b) (4) [redacted] (8%), and (b) (4) [redacted] (9%), as humectants, in the finished cigar

The differences in characteristics listed above are the same differences in characteristics identified for the new and grandfathered tobacco product in SE0014625. Therefore, these differences do not cause the new tobacco product in SE0015126 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in rod length, flavors, filter length, and preservatives in the wrapper between the new tobacco product in SE0015126 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015126 to the predicate of grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

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

An SE order letter should be issued for the new tobacco product in SE0015126, as identified on the cover page of this review.