

Technical Project Lead (TPL) Review:

SE0015034

SE0015034: Black & Mild® Wood Tip	
Package Type	Cellophane
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood tip
Characterizing Flavor	None
Additional Property	Wood Tip 2
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet Wrapped Cigar
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.03.08 10:36:06 -05'00'

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: 2019.03.11 07:18:28 -04'00'

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:

SE0015034: Black & Mild	
Product Name	Black & Mild
Package Type	Cellophane (Polypropylene plastic wrap)
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic tip
Characterizing Flavor	None

The predicate tobacco product is an unfiltered, sheet-wrapped cigar manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received an SE Report submitted by Altria Client Services LLC on behalf of John Middleton Co. on December 19, 2018. FDA issued an Acknowledgement letter to the applicant on December 26, 2018. On March 4, 2019, the applicant submitted an unsolicited amendment (SE0015108) providing corrected information for the cigar tip of the new tobacco product.

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 Elizabeth Harrod on December 26, 2018. The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated January 22, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated February 14, 2019, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW¹

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

4.1. CHEMISTRY

The chemistry review was completed by Jiu Ai on February 7, 2019².

The 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:

- (b) (4) (6.4%) decrease target cigar filler weight
- (b) (4) (4.4%) decrease target tobacco weight (without non-tobacco ingredients)
- 8.7% decrease in (b) (4) tobacco
- Removal of ingredients
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
- Decreases in all non-tobacco ingredients in cigar filler
- Replacement of (b) (4)(b) (4) with (b) (4)(b) (4) in the wrapper and binder
- 33 % increase in (b) (4)
- 9.7% decrease in wrapper weight
- 11.2% decrease in binder weight

¹ Scientific reviews were completed prior to receipt of Amendment SE0015108. The amendment provides corrected information for the new tobacco tip mass and ingredients. The corrected values show a heavier mass for the tip overall and decreases in all tip ingredients except (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4), which is increased. These changes do not affect the scientific reviews, this TPL review, and overall conclusions because the tip is not burned during use of the new tobacco product.

² The chemistry review identifies several requests for information that are unnecessary to make a determination with respect to substantial equivalence. This TPL review does not capture the requests.

- Cigar tip:
 - Replacement of a (b) (4)(b) (4) with (b) (4)
 - Addition of (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (solvent)
 - Removal of (b) (4)(b) (4)(b) (4)(b) (4)

The wrapper and binder of the new tobacco product are reformulated with (b) (4)(b) (4) replacing (b) (4)(b) (4) in the wrapper and binder of the predicate tobacco product; and additional (b) (4) replaces the (b) (4) in the binder of the predicate tobacco product. The total quantity of (b) (4)(b) (4) in the wrapper and binder of the new tobacco product is approximately (b) (4)/cigar, which is less than 0.1% of the tobacco rod weight and is not anticipated to affect smoke chemistry. Although the binder has 33% more (b) (4) the new tobacco product overall has (b) (4)/cigar less (b) (4) than the predicate tobacco product. The overall decrease in (b) (4) is not anticipated to adversely affect the harmful and potentially harmful constituent (HPHC) smoke yields of the new tobacco product. The new tobacco product also has a birch wood tip with different ingredients, but since the tip is a non-combusted component, smoke chemistry is not anticipated to be affected.

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

The engineering review was completed by Drew Katherine on February 9, 2019.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- 3% decrease in overall cigar rod length
- 1% decrease in overall cigar diameter
- 6% decrease in tobacco filler mass
- 3% decrease in tobacco rod density
- 3% increase in tobacco rod moisture
- 17% decrease in wrapper moisture
- 23% decrease in binder moisture
- 1% increase in tip length
- 4% decrease in tip inner diameter
- 1.3% decrease in overall cigar mass
- 3% decrease in (b) (4) tobacco processed at (b) (4)
- 3% increase in (b) (4) tobacco processed at (b) (4)
- 1% decrease in (b) (4) tobacco processed at (b) (4)
- 1% increase in (b) (4) tobacco processed at (b) (4)

³ Cuts per inch

Of the design parameter changes, only the decrease in diameter and the increase in tobacco rod moisture may adversely affect smoke TNCO; the decrease in tobacco rod density may increase smoke carbonyls. The changes to the other design parameters are likely offsetting because they are anticipated to reduce TNCO smoke yields and HPHCs like benzo- α -pyrene. Smoke data for TNCO and other HPHCs was not provided to confirm these predicted effects on smoke chemistry. However, this data is not necessary because the new tobacco product is smaller than the predicate tobacco product and there is less tobacco available for combustion.

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 related to product engineering.

4.3. MICROBIOLOGY

The microbiology review was completed by David Craft on February 5, 2019.

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

- 8% and 15% decreases in NNN and NNK, respectively
- Addition of (b) (4)(b) (4)(b) (4) , a preservative, in the wrapper and binder
- Removal of (b) (4)(b) (4)(b) (4) , a preservative, in the wrapper and binder
- 5% decrease in total (b) (4) content in the finished cigar
- 7% and 5% decreases in the target contents of (b) (4)(b) (4)(b) (4) , respectively, as humectants, in the tobacco filler

Stability data during the storage duration of the new and predicate tobacco products was not provided. However, the total moisture content of both tobacco products is less than 15%, which is insufficient to support fungal growth; and comprehensive data to support bacterial growth at this concentration have not been substantiated. Additionally, the new and predicate tobacco products do not have any fermented tobacco and have identical container closure systems. Therefore, the lack of stability data for the new and predicate tobacco products is not a concern from a microbiology perspective. Additionally, NNN and NNK of the finished new tobacco product are decreased. Based on the lack of fermented tobacco, the container closure system, the decreases in NNN and NNK, and the low moisture content (<15%) of the new tobacco product, the differences in humectants and preservatives do not cause the new tobacco product to raise different questions of public health from a microbiological perspective.

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 microbiology perspective.

4.4. TOXICOLOGY

The toxicology review was completed by Kamau Peters on February 8, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to toxicology 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:

- Addition of the complex flavor, (b) (4)(b) (4) to replace (b) (4)(b) (4) (b) (4)(b) (4) in the tobacco filler
- Addition of (b) (4)(b) (4) in the binder and wrapper
- 33% increase in (b) (4) in the binder
- Addition of a wood tip to replace the plastic tip as a mouthpiece

The new tobacco product has ingredient changes that do not cause concerns. The complex flavor (b) (4)(b) (4) has the same ingredients, but at lower amounts, as (b) (4) (b) (4)(b) (4)(b) (4). (b) (4) is substituted for (b) (4)(b) (4) and increased in the binder and wrapper of the new product, but its overall amount is lower compared to the predicate product. The added (b) (4)(b) (4) represents less than 0.1% of the finished new tobacco product and are unlikely to increase benzene yields. The wood tip does not function as a filter and is not burned. The HPHCs ammonia, arsenic, cadmium, nicotine, NNK, and NNN are decreased in the freeze-ground cigar tobacco rods (wrapper, binder, and filler) in the new product compared to the predicate product.

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 toxicology perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 1, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 1, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- (b) (4) (6.4%) decrease target cigar filler weight
- (b) (4) (4.4%) decrease target tobacco weight (without non-tobacco ingredients)
- 8.7% decrease in (b) (4) tobacco
- Replacement of (b) (4)(b) (4) with (b) (4)(b) (4) in the wrapper and binder
- 9.7% decrease in wrapper weight
- 11.2% decrease in binder weight

- Cigar tip:
 - Replacement of a (b) (4)(b) (4) with (b) (4)
 - Addition of (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (solvent)
 - Removal of (b) (4) and (b) (4)(b) (4)
- 3% decrease in overall cigar rod length
- 1% decrease in overall cigar diameter
- 6% decrease in tobacco filler mass
- 3% decrease in tobacco rod density
- 3% increase in tobacco rod moisture
- 17% decrease in wrapper moisture
- 23% decrease in binder moisture
- 1% increase in tip length
- 4% decrease in tip inner diameter
- 1.3% decrease in overall cigar mass
- 3% decrease in (b) (4) tobacco processed at (b) (4)
- 3% increase in (b) (4) tobacco processed at (b) (4)
- 1% decrease in (b) (4) tobacco processed at (b) (4)
- 1% increase in (b) (4) tobacco processed at (b) (4)
- 8% and 15% decreases in NNN and NNK, respectively
- 5% decrease in total (b) (4) content in the finished cigar
- 7% and 5% decreases in the target contents of (b) (4)(b) (4) and (b) (4), respectively, as humectants, in the tobacco filler

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The new tobacco product is smaller than the predicate product, with decreases in target tobacco filler mass, cigar length, and cigar diameter. There are also reductions in non-tobacco ingredients overall. HPHC analysis of the freeze-ground cigar tobacco rods (wrapper, binder, and filler) show decreases in ammonia, arsenic, cadmium, nicotine, NNK, and NNN in the new tobacco product compared to the predicate tobacco product. Although the applicant did not provide smoke chemistry, the reductions in tobacco HPHCs and overall product design parameters suggest that TNCO and other smoke HPHCs should be reduced in the new tobacco product relative to the predicate product. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined to be a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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

An SE order letter should be issued for the new tobacco product in SE0015034, as identified on the cover page of this review.