Technical Project Lead (TPL) Review: SE0015197

SE0015197: Black & Mild Estate Blend Wood Tip	
Package Type	Cellophane
Package Quantity	1Cigars
Characterizing Flavor[1]	None
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood
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.	

[1] The applicant states that there is no identifying flavor.

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.07.17 16:08:02 -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: 2019.07.18 08:31:30 -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:

SE0015197: Black & Mild Estate Blend Wood Tip	
Product Name	Black & Mild Wine
Package Type	Cellophane
Package Quantity	1 cigar
Characterizing Flavor	Wine
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 17, 2019, FDA received one SE Report from Altria Client Services on behalf of John Middleton Company. FDA issued an Acknowledgment letter to the applicant on April 23, 2019. No amendments were received.

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 Nicholas Hasbrouck on April 23, 2019.

The final review concludes that the SE Reports are 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 May 13, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated July 12, 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

A chemistry review was completed by Andrew Idzior on July 10, 2019.

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:

- 5% increase in (b) (4) Tobacco
- 34% decrease of all ingredients added to the cigar filler
- 33% increase in (b) (4) in the cigar binder
- 11% decrease of cigar binder weight, 9% decrease of cigar wrapper weight, and 10% decrease of seam adhesive weight
- Change in tobacco tip from polyethylene to wood ((b) (4)

The increase in (b) (4) is not a concern because the reported cigar rod HPHC amounts are analytically equivalent between the new and predicate product. Similarly, the decreases in non-tobacco ingredients and in the weights of the cigar binder, cigar wrapper, and seam adhesive do not raise concerns because smoke chemistry is not anticipated to be adversely affected in terms of pyrolytic byproducts because less material is burned. The change in cigar tip is also not a concern because it is a non-combusted component.

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.

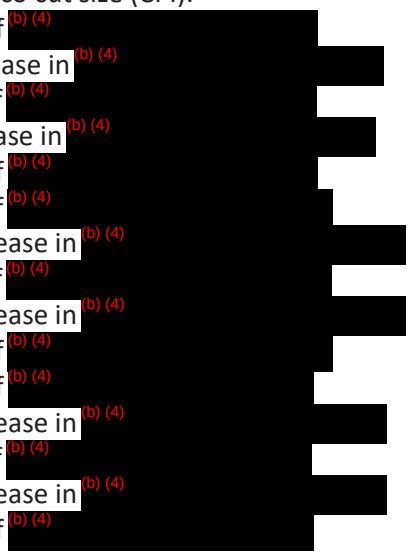
4.2. ENGINEERING

An engineering review was completed by Nashaat Rasheed on June 12, 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:

- 14.5% decrease in tobacco filler mass
- 10.4% decrease in tobacco rod density

- 9.3% decrease in tobacco rod moisture
- 14.3% decrease in wrapper moisture
- 22.6% decrease in binder moisture
- 6.9% decrease in overall cigar mass
- Changes in tobacco cut size (CPI):
  - Removal of (b) (4)
  - 4.3% decrease in (b) (4)
  - Addition of (b) (4)
  - 5.9% increase in (b) (4)
  - Removal of (b) (4)
  - Removal of (b) (4)
  - 13.8% increase in (b) (4)
  - Addition of (b) (4)
  - 11.7% increase in (b) (4)
  - Removal of (b) (4)
  - Removal of (b) (4)
  - 23.5% increase in (b) (4)
  - Addition of (b) (4)
  - 52.4% increase in (b) (4)
  - Removal of (b) (4)



A shorter cigar rod length and a decrease in tobacco filler mass may reduce smoke TNCO yields because there is less tobacco burned. A decrease in tobacco rod density may cause more air to flow through the tobacco rod, causing a decrease in the open draw resistance, which may also lead to a decrease in smoke TNCO yields while increasing smoke carbonyls. Decreases in tobacco rod, wrapper, and binder moisture may affect the temperature at which the coal burns, which in turn affects combustion and burn rate, and similarly result in a favorable decrease in smoke TNCO yields. An increase in tip length and decrease in tip inner diameter may lead to an increase in pressure drop, which may cause less air to flow through the cigar rod, thereby decreasing tar, nicotine, and benzo-α-pyrene yields. Tobacco cut size may alter the size of the tobacco pieces and affect smoke constituent yields. However, the overall effect of the change in tobacco cut size (CPI) on smoke TNCO yields is inconclusive because of the elimination of tobacco blend cut size (b) (4) and (b) (4), the addition of tobacco blend cut size (b) (4), and the overall increase in tobacco blend cut size (b) (4) and (b) (4).

The engineering review defers evaluation of smoke TNCO and other HPHCs to the chemistry review. However, HPHC data was submitted only for tobacco filler. Therefore, evaluation of smoke TNCO and HPHCs was not performed. However, since the new tobacco product has reduced tobacco filler mass and the measured tobacco filler HPHC amounts are analytically equivalent, evaluation of smoke TNCO and HPHC yields is not necessary.

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 Almaris Alonso-Claudio on June 3, 2019.

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

- Removal of the preservatives [redacted] g/cigar) and [redacted] g/cigar) from the tobacco filler
- Decreases in the humectants [redacted] (25%), [redacted] (55%), [redacted] (5%), and [redacted] (24%) in the tobacco filler
- Removal of [redacted] g) and addition of [redacted] g/cigar) in the wrapper
- 9 % decrease in [redacted] in the wrapper
- Removal of [redacted] g) and addition of [redacted] g/cigar) in the binder
- 33% increase in [redacted] in the binder
- 10% decreases in [redacted] and [redacted] in the seam adhesive
- 15% decrease in finished product moisture content 22% decrease in total [redacted] content
- 2% decrease in NNN and 7% decrease in NNK

The new tobacco product has changes to humectants and preservatives which could potentially affect the microbial stability of the product during storage. The applicant did not provide stability data over the storage duration of the new and predicate tobacco products. However, the applicant provided moisture (OV%), NNN and NNK content of the finished new and predicate tobacco products. Based on the moisture content of the new tobacco product (< 17%), which is not favorable for microbial growth, analytically equivalent NNN and NNK amounts (as noted in the chemistry review), identical container closure systems and the absence of fermented tobacco, the differences in humectants and preservatives are not anticipated to affect microbial activity.

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

A toxicology review was completed by Prince Kwaku Awuah on June 6, 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:

- Replacement of [redacted] with [redacted]
- Increase in [redacted] in the binder
- Replacement of the plastic tip with a wood tip ([redacted])

[redacted] represents less than 0.1% of the finished product in the new tobacco product and is not anticipated to increase benzene yields when compared to the predicate product. Even though [redacted] is a substitute for [redacted] and increased in the binder for the new products, the overall amount of [redacted] in the burned region of the cigar is less compared to the predicate product; and does raise different questions of public health from a toxicological perspective. The replacement of the plastic tip with a wood cigar tip [redacted] does not present any toxicology concerns because it is a non-combusted component and is not intended to be inhaled or ingested.

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

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on May 13, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 15, 2019. The FONSI was supported by an environmental assessment prepared by FDA on July 15, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 5% increase in [redacted]
- 14.5% decrease in tobacco filler mass
- 10.4% decrease in tobacco rod density
- 9.3% decrease in tobacco rod moisture
- 14.3% decrease in wrapper moisture
- 22.6% decrease in binder moisture
- 6.9% decrease in overall cigar mass
- Multiple changes in tobacco cut size
- Removal of the preservatives [redacted] g/cigar) and [redacted] g/cigar) from the tobacco filler
- Decreases in the humectants [redacted] (25%), [redacted] (55%), [redacted] r (5%), and [redacted] (24%) in the tobacco filler
- Removal of [redacted] g) and addition of [redacted] g/cigar) in the wrapper

- 9 % decrease in [redacted] in the wrapper
- Removal of [redacted] g) and addition of [redacted] g/cigar) in the binder
- 33% increase in [redacted] in the binder
- 10% decreases in [redacted] and [redacted] in the seam adhesive
- 15% decrease in finished product moisture content 22% decrease in total [redacted] content
- 2% decrease in NNN and 7% decrease in NNK
- Replacement of the plastic tip with a wood tip ([redacted])

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 has decreases in tobacco filler mass, tobacco rod density, and overall cigar mass which will should have a favorable effect on HPHCs due to less tobacco being burned. There are also decreases in moisture in the tobacco filler rod, binder, and wrapper, which is anticipated to increase the burn rate (lower the puff count) and reduce HPHC smoke yields. The tobacco blend of increased [redacted] and removal of the preservatives [redacted] and [redacted] in the tobacco filler in the new product could cause increases in NNK and NNN. However, HPHC tobacco filler data provided by the applicant was determined to be analytically equivalent between the new and predicate tobacco products, demonstrating that these changes do not cause concern. There are changes in humectants which could also affect microbial activity, however the microbiology review concluded that this was not a concern due to the analytical equivalence in NNK and NNN, low moisture content, and also that new tobacco products do not contain fermented tobacco. There are many changes to tobacco cut and the effects of these changes cannot be determined. However, the analytically equivalent values of HPHCs in tobacco filler and the overall reduced amount of tobacco suggest that this should not cause concerns. 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 that it 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 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 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 SE0015197, as identified on the cover page of this review.