FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015224

SE0015224: Black & Mild® Estate Blend	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	None[2]
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
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.	

[1] The applicant defines "cello" as a clear wrap. In this case, cello is composed of (b) (4) plastic wrap.

[2] The applicant uses the term (b) (4) A. In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.06.03 15:10:53 -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: 2020.06.03 15:21:00 -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:

SE0015224: Black & Mild® Estate Blend	
Product Name	Black & Mild Wine
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Wine[3]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 8, 2019, FDA received one SE Report from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgment letter to the applicant on May 13, 2019. FDA issued a Deficiency letter to the applicant on October 31, 2019. On November 12, 2019, FDA received an email from the applicant with requests for clarification to the Deficiency letter. On November 21, 2019, FDA received an amendment (SE0015574) responding to the Deficiency letter.

Product Name	SE Report	Amendments
Black and Mild® Estate Blend	SE0015224	SE0015574

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 May 9, 2019.

The review concludes that the SE Report is administratively complete.

[3] 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.

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 June 6, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, 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 reviews dated July 30, 2019, January 29, 2020, and May 11, 2020, conclude that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

The new tobacco product has differences in characteristics compared to the predicate tobacco product, but the differences in the new tobacco product do not raise different questions of public health.

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

4.1. CHEMISTRY

A chemistry review was completed by An Vu on July 15, 2019, and an addendum on October 29, 2019. A second chemistry review was completed on May 1, 2020.

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:

- Smaller product size, which results in:
  - Decreases in rod length (↓2.8%) and rod diameter (↓0.5%)
  - Decrease in total product weight (↓11%)
  - Decreases in weight of many subcomponents including tobacco rod (↓14%), filler (↓15%), binder (↓11%), wrapper (↓9%), and seam adhesive (↓15%)
  - Decreases in total tobacco (↓2%) and most individual tobacco types (↓9-19%)
- Increase in (b) (4) tobacco (↑5%)
- Decrease in amount of most non-tobacco ingredients, including numerous flavor ingredients
- Removal of a number of other non-tobacco ingredients
- Minor reduction (↓1.3%) in total (b) (4) amount
- Addition of (b) (4) mg of (b) (4) as a new cigar tip (b) (4)

The new tobacco product is smaller than the predicate tobacco product. This product size reduction results in decreases in the weights of the total product, tobacco rod, filler, binder,

wrapper, seam adhesive, as well as rod length and diameter and the amount of total tobacco and most individual tobacco types. There are also decreases in the amount of most non-tobacco ingredients, including numerous flavor ingredients, as well as removal of a number of other non-tobacco ingredients. These decreases are expected to lower HPHC quantities for the new tobacco product. In contrast, there is a 5% increase in filler (b) (4) of new tobacco product which could increase nicotine and TSNA smoke deliveries. However, evaluation of the reported HPHC amounts shows slightly lower quantities of tobacco rod nicotine, NNK, NNN, arsenic, and cadmium for the new tobacco product compared to the predicate tobacco product. These HPHC decreases do not cause the new tobacco product to raise different questions of public health. There is a minor 1.3% reduction in total (b) (4) amount which is unlikely to increase smoke yields of NNN, NNK, and 4-aminobiphenyl of the new tobacco product given the expected overall decrease in mainstream smoke HPHCs due to changes in product design parameters, decreases in total tobacco and most individual tobacco types and most non-tobacco ingredients, and removal of a number of other non-tobacco ingredients. Therefore, the minor reduction in total (b) (4) does not cause the new tobacco product to raise different questions of public health. There is an addition of (b) (4) mg of (b) (4) on the tip of the new tobacco product that is absent in the predicate tobacco product. However, there is a lack of specific scientific evidence to demonstrate that adding (b) (4) to the cigar tip would increase cigar initiation and/or enhance cigar appeal. Thus, at this time, the addition of (b) (4) (b) (4) to the new cigar tip does not cause the new tobacco product to raise different questions of public health.

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 July 11, 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:

- Decrease in tobacco filler mass (14.5%) and overall cigar mass (11.2%)
- Decrease in tobacco rod density (10.4%)
- Decrease in tobacco rod moisture (9.3%), wrapper moisture (14.3%), and binder moisture (22.6%)
- Change in tobacco cut size (CPI[4])
    - Elimination of (b) (4) and (b) (4) processed at (b) (4) and (b) (4) CPI
    - Addition of (b) (4) and (b) (4) processed at (b) (4) CPI
    - Increase in (b) (4) (13.8%) and (b) (4) (23.5%) tobacco processed at (b) (4) CPI

[4] Cuts per inch

- Increase in (b) (4) (5.9%), (b) (4) (11.7%), and (b) (4) (52.4%) tobacco processed at (b) (4) CPI

Taken together, the decreases in tobacco filler mass and overall cigar mass, tobacco rod density, tobacco rod moisture, wrapper moisture, and binder moisture, and the changes in tobacco cut size may affect smoke TNCO and smoke carbonyls. HPHC data was submitted only for tobacco filler, and evaluation of smoke TNCO and HPHCs was deferred to Chemistry. Although the changes in density, moisture, and mass are anticipated to decrease smoke TNCO, FDA is not aware of any peer-reviewed scientific literature that could be used to make an assessment regarding whether these specific changes to tobacco cut size would decrease or increase TNCO. Therefore, we do not know the overall impact of all of these design changes on TNCO. Smoke carbonyls are anticipated to increase as a result of the decreased tobacco rod density. However, because the new tobacco product has reduced tobacco filler mass and the measured tobacco filler HPHC amounts are analytically equivalent between the new and predicate products per the Chemistry review, in this case, we currently find that smoke TNCO and HPHC testing and evaluation of TNCO and HPHC yields are not necessary.

Therefore, in this case 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 Wen Lin on July 11, 2019.

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

- 15% lower moisture content (16.62% vs. 19.60%, respectively)
- 2% lower NNN and 7% lower NNK levels
- 5% decrease in (b) (4), 55% decrease in (b) (4), and 25% decrease in (b) (4), all humectants in the tobacco filler
- 22% decrease in (b) (4) content, a humectant in the finished cigar
- Removal of preservatives, (b) (4) g/cigar) and (b) (4) g/cigar), in the tobacco filler
- Removal of (b) (4) g/cigar) in the wrapper and binder[5]
- Addition of (b) (4) g/cigar) to the wrapper and binder
- 10% decreases in (b) (4) and (b) (4) in the seam adhesive

The new and predicate tobacco products differ in both humectant and preservative content, which could potentially affect the microbial stability of the product over the storage time of the product. 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

[5] I note that (b) (4) was also removed from the binder. Removal of ingredients do not raise different questions of public health.

(% oven volatiles), NNN, and NNK content of the finished new and predicate tobacco products. Based on the low moisture content of the new tobacco product (< 17%), lower NNN (2%) and NNK (7%) content of the new tobacco product compared to the predicate tobacco product, identical container closure systems, and lack of (b) (4) in the new tobacco product, the differences in humectant and preservative content of the new tobacco product compared to the predicate tobacco product 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

A toxicology review was completed by Kimberly Stratford on July 11, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product 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 (b) (4) with (b) (4) in the wrapper and the binder
- Addition of (b) (4) to replace (b) (4) in binder
- Addition of (b) (4) (i.e., (b) (4)) as a sweetener to the cigar tip

(b) (4) was added to the new tobacco product and represents less than 0.1% of the total cigar rod weight of the new tobacco product and is not expected to increase benzene yields in the new tobacco product when compared to the predicate tobacco product. (b) (4) was added to substitute for (b) (4) (b) (4) and is increased in the binder of the new tobacco product, but the total amount of (b) (4) from all components was decreased in the new tobacco product compared to the predicate tobacco product. (b) (4) [6] was added to the cigar tip at a concentration that does not raise different questions of public health from a toxicology perspective because if the product is used as intended, the sweetener will be ingested rather than inhaled and is unlikely to become combusted.

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.

[6] (b) (4)

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on June 3, 2019, and an addendum on October 4, 2019. A second environmental review was completed on December 18, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 10, 2019. The FONSI was supported by an environmental assessment prepared by FDA on July 10, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Removal of (b) (4) and addition of (b) (4) to the binder and wrapper
- Removal of (b) (4) and addition of (b) (4) to the binder
- Addition of (b) (4) as a sweetener to the cigar tip
- Smaller product size, which results in:
  - Decrease in rod length (↓2.8%) and rod diameter (↓0.5%)
  - Decrease in tobacco rod density (10.4%)
  - Decrease in tobacco filler mass (14.5%) and overall cigar mass (11.2%)
  - Decrease in tobacco rod moisture (9.3%), wrapper moisture (14.3%), and binder moisture (22.6%)
  - Decrease in weight of many subcomponents including tobacco rod (↓14%), filler (↓15%), binder (↓11%), wrapper (↓9%), and seam adhesive (↓15%)
  - Decrease in total tobacco (↓2%) and most individual tobacco types (↓9-19%)
- Decrease in amount of most non-tobacco ingredients including numerous ingredients within complex ingredients
- Removal of a number of other non-tobacco ingredients
- Minor reduction (↓1.3%) in total (b) (4) amount
- Change in tobacco cut size (CPI) and increase in (b) (4) (↑5%)
  - Elimination of (b) (4) and (b) (4) processed at (b) (4) and (b) (4) CPI
  - Addition of (b) (4) and (b) (4) processed at (b) (4) CPI
  - Increase in (b) (4) (13.8%) and (b) (4) (23.5%) tobacco processed at (b) (4) CPI
  - Increase in (b) (4) (5.9%), (b) (4) (11.7%), and (b) (4) (52.4%) tobacco processed at (b) (4) CPI
- 15% lower moisture content
- 5% decrease in (b) (4) 55% decrease in (b) (4) and 25% decrease in (b) (4) all humectants in the tobacco filler
- 22% decrease in (b) (4) content, a humectant in the finished cigar
- 10% decreases in (b) (4) and (b) (4) in the seam adhesive

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Although there is a 5% increase in (b) (4) in the filler of the new tobacco product, evaluation of the HPHC data in tobacco filler shows slightly lower quantities of tobacco rod nicotine, NNK, NNN, arsenic, and cadmium for the new tobacco product as compared to the predicate tobacco product. Therefore, the 5% increase

in the filler [redacted] is not anticipated to cause a measurable increase in nicotine and TSNA smoke deliveries. [redacted] was added as a preservative to the new tobacco product and represents less than 0.1% of the total cigar rod weight of the new tobacco product and is not expected to increase benzene yields in the new tobacco product when compared to the predicate tobacco product. [redacted] was added to substitute for [redacted] and is increased in the binder of the new tobacco product, but the total amount of [redacted] from all components was decreased in the new tobacco product compared to the predicate tobacco product. [redacted] was added to the cigar tip at a concentration that is likely to be ingested rather than inhaled. Because the [redacted] is placed on the tip of the cigar, it is unlikely to become combusted; therefore, the addition of [redacted] to the cigar tip is not expected to adversely affect smoke chemistry. In this case, although we do not know the overall impact of tobacco cut size on TNCO, taking together all of the changes to the new tobacco product discussed above, and given that the HPHC filler data did not raise different questions of public health, it is not likely that the change in tobacco cut size would have a measurable impact on smoke constituents. Lastly, the reduction in total [redacted] amount is unlikely to increase smoke yields of NNN, NNK, and 4-aminobiphenyl of the new tobacco product given the expected overall decrease in mainstream smoke HPHCs due to changes in product design parameters, decreases in total tobacco and most individual tobacco types and most non-tobacco ingredients, and removal of a number of other non-tobacco ingredients.

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.

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 SE0015224, as identified on the cover page of this review.