FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014857

SE0014857: Black & Mild®	
Package Type	Cellophane (polypropylene plastic wrap)
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Melissa Mcculloch -S

Digitally signed by Melissa Mcculloch -S
Date: 2019.04.05 11:02:10 -04'00'

Melissa McCulloch, Ph.D.
Senior Regulatory Scientist
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: 2019.04.08 06:45:09 -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:

SE0014857: 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
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 22, 2018, FDA received one SE Report from John Middleton Co. FDA issued an Acknowledgement letter to the applicant on August 27, 2018. FDA issued an Advice and Information (A/I) Request letter on October 30, 2018. On January 15, 2019, FDA received the response to the A/I Request letter (SE0015060).

Product Name	SE Report	Amendment
Black & Mild	SE0014857	SE0015060

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 Keyur Patel on August 27, 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 September 17, 2018, 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 April 3, 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 Selvin Edwards on October 9, 2018, and Jiu Ai on March 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:

- Decrease in target tobacco filler weight of (b) (4) mg/cigar (6.4%)
  - Decrease in ingredient (b) (4) weight of (b) (4) mg/cigar (4.3%)
  - Decrease in (b) (4) of (b) (4) /cigar (8.7%)
- Several non-tobacco ingredients have been removed
- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder
- Decrease of the weight of the wrapper (9.8%)
- Decrease of the weight of the binder (11.2%)
- Decrease in binder moisture (22.6%)[1]
- Decrease in wrapper moisture (17.2%)[1]

The tobacco blend of the cigar filler for the new tobacco product contains lower quantities of (b) (4) and identical quantities of (b) (4) compared to the predicate tobacco product, which is expected to reduce HPHC smoke yields. Therefore, the tobacco blend differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health. Since several non-tobacco ingredients have been removed from the new tobacco product, the non-tobacco ingredients added to the cigar filler of the new tobacco product are lower than those in the predicate tobacco product. The non-tobacco ingredient differences in the cigar fillers between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health. The wrapper and binder of the new tobacco product are reformulated with (b) (4) replacing (b) (4) in the wrapper and binder of the predicate tobacco product and additional (b) (4) to replace (b) (4) in the

[1] This difference is noted in the engineering reviews and discussed in the 1st chemistry review, dated October 9, 2018.

binder of the predicate tobacco product. However, the total quantity of (b) (4) in all the combusted components (wrapper, binder and seam adhesive) in the new tobacco product is approximately (b) (4) mg/cigar, which is less than (b) (4) of the tobacco rod weight of the cigar and it is not expected to influence the smoke chemistry. Although the (b) (4) quantity in the binder of the new tobacco product is 33% higher than that of the predicate product, the total quantity of the (b) (4) in the tobacco rod of the new tobacco product is (b) (4) mg/cigar lower than of the predicate tobacco product. Additionally, the decreased weight and moisture for the binder and wrapper between the new and corresponding predicate tobacco products are both expected to generate lower amounts of HPHC smoke yields. Therefore, the differences in ingredients, decreased weight and decreased moisture between the new and predicate tobacco products do 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

Engineering reviews were completed by Raymond Williamson on October 18, 2018, and Jim Melchiors on March 5, 2019.

The final 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 (6.4%)
- Decrease in cigar mass (5.5%)
- Decrease in binder moisture (22.6%)
- Decrease in wrapper moisture (17.2%)
- Decrease in (b) (4) tobacco processed at (b) (4) (5.4%)
- Increase in (b) (4) tobacco processed at (b) (4) (6.8%)

The new tobacco product has 5.5% less mass than the predicate tobacco product. This decreased mass is due to the new tobacco product containing 6.4% less tobacco filler and the removal of several non-tobacco ingredients. A decrease in tobacco mass is expected to reduce HPHC smoke yields. Therefore, the differences in tobacco filler and overall cigar mass do not cause the new tobacco product to raise different questions of public health. The new tobacco product uses a different wrapper and binder than the predicate tobacco product. For both the wrapper and binder used on the new tobacco product, the moisture decreased compared to the wrapper and binder used on the predicate tobacco product. A decrease in the binder moisture and wrapper moisture may reduce puff count and is expected to reduce HPHC smoke yields. Therefore, the decrease in binder and wrapper moisture does not cause the new tobacco product to raise different questions of public health. For tobacco cut size, the new tobacco product used 5.4% less (b) (4) tobacco at (b) (4) and 6.8% more (b) (4) tobacco (b) (4) when compared to the predicate tobacco product.

The applicant was asked to provide additional information on the tobacco cut size including upper and lower range limits, test data, test protocols, and acceptance criteria for the new and predicate tobacco products. The applicant amended their report to verify that the same machine settings were used for the new and predicate tobacco products and submitted that they do not measure tobacco cut size for the production of their cigar products and, therefore, do not have test data, test protocols, or acceptance criteria for the new or predicate tobacco products. Since the applicant established that there are no differences between the new and predicate tobacco products with respect to tobacco cut size, the differences in tobacco cut size discussed above do not cause the new tobacco product to raise different questions of public health.

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

4.3. TOXICOLOGY

Toxicology reviews were completed by Ana Depina on October 19, 2018, and February 26, 2019.

The final 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:

- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder

(b) (4) was added to the new tobacco product as a substitute for (b) (4) at less than 0.1% of the total product mass. The (b) (4) increase in the new product is not expected to result in increased HPHC smoke yields, and thus does not cause the new tobacco product to raise different questions of public health. (b) (4) was used as a substitute for (b) (4) and is increased in the binder of the new product, but the overall amount of (b) (4) in the burned region of the cigar is lower in the new tobacco product compared to the predicate tobacco product. Therefore, increased (b) (4) in the binder 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Dilip Venugopal on October 3, 2018, and February 20, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 6, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 6, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Decrease in target tobacco filler weight of (b) (4) mg/cigar (6.4%)
  - Decrease in ingredient free tobacco weight of (b) (4) mg/cigar (4.3%)
  - Decrease in (b) (4) of (b) (4) mg/cigar (8.7%)
- Several non-tobacco ingredients have been removed
- (b) (4) is added to the wrapper and binder to replace (b) (4)
- (b) (4) increased 33% to replace (b) (4) in the wrapper and binder
- Decrease of the weight of the wrapper (9.8%)
- Decrease of the weight of the binder (11.2%)
- Decrease in binder moisture (22.6%)
- Decrease in wrapper moisture (17.2%)
- Decrease in (b) (4) tobacco processed at (b) (4) inch (5.4%)
- Increase in (b) (4) tobacco processed at (b) (4) inch (6.8%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The total mass, as well as the mass of several components of the new tobacco product, decrease compared to the predicate tobacco product. The decrease in mass is due to the new tobacco product containing 6.4% less tobacco filler and the removal of several non-tobacco ingredients. A decrease in tobacco mass is expected to reduce HPHC smoke yields. Therefore, the decreased mass does not cause the new tobacco product to raise different questions of public health. The new tobacco product uses a different wrapper and binder than the predicate tobacco product. For both the wrapper and binder used on the new tobacco product, the moisture decreased compared to the wrapper and binder used on the predicate tobacco product. A decrease in the binder moisture and wrapper moisture may reduce puff count and is expected to reduce HPHC smoke yields. Therefore, the decrease in binder and wrapper moisture does not cause the new tobacco product to raise different questions of public health. For tobacco cut size, the new tobacco product used 5.4% less (b) (4) tobacco at (b) (4) and 6.8% more (b) (4) tobacco (b) (4) when compared to the predicate tobacco product. The applicant established that there are no differences between the new and predicate tobacco products with respect to tobacco cut size; therefore, the differences in tobacco cut size do not cause the new tobacco product to raise different questions of public health. (b) (4) was added to the new tobacco product as a substitute for (b) (4) at less than 0.1% of the total product mass. The (b) (4) increase in the new tobacco product is not expected to result in increased HPHC smoke yields. (b) (4) was used as a substitute for (b) (4) and is increased in the binder of the new tobacco product, but the overall amount of (b) (4)

in the burned region of the cigar are lower in the new tobacco product compared to the predicate tobacco product. Therefore, the addition of (b) (4) and the increased (b) (4) in the binder 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 product 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 tobacco 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 product 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 this 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 SE0014857, as identified on the cover page of this review.