Technical Project Lead (TPL) Review: SE0014879

SE0014879: Black & Mild® Wood Tip	
Package Type	Cello (Polypropylene plastic wrap)
Package Quantity	One cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood tip
Characterizing Flavor	None
Attributes of SE Report	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigar
Product Sub-Category	Unfiltered, Sheet-wrapped
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Shixia Feng -S
Date: 2019.05.17 09:23:53 -04'00'

Shixia Feng, 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: 2019.05.22 08:42:12 -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:

GF1602166: Black & Mild	
Product Name	Black & Mild
Package Type	Cello (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 a sheet-wrapped, unfiltered cigar manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one SE report on October 1, 2018, and subsequently issued an acknowledgement letter on October 18, 2018. The applicant submitted an amendment (SE0014994) to the environmental assessment, which FDA received on December 4, 2018. FDA issued an Advice and Information Request letter on December 7, 2018. The applicant submitted a response (SE0015094), which FDA received on February 26, 2019.

Product Name	SE Report	Amendments
Black & Mild® Wood Tip	SE0014879	SE0014994 SE0015094

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 Shireen Fotelargias on October 18, 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 November 4, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 26, 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 Jianping Gong on November 15, 2018, and Lida Oum on April 8, 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:

- Decrease in total tobacco weight (5%)
- Decrease in (b) (4) (4%) and (b) (4) (9%) tobacco
- Addition of (b) (4) to the cigar wrapper (b) (4)) and cigar binder (b) (4) mg/cigar) to replace (b) (4)
- Increase in (b) (4) (33%) to replace (b) (4) in the cigar binder
- Decrease of 4-19% in all measured HPHCs in the tobacco filler
- Increase of 3-14% in tar and 4-22% in nicotine mainstream smoke

The chemistry review concludes that the differences in characteristics in the new product compared to the predicate product do not raise different questions of public health in regard to product composition. The new product has lower amounts of total tobacco weight (5%), (b) (4) (4%), and (b) (4) (9%) compared to the predicate product. The lower amounts of (b) (4) and total tobacco weight in the filler are expected to result in lower NNN, NNK and PAH smoke yields. (b) (4) was added to the cigar binder to replace (b) (4) (b) (4) due to safety concerns with handling (b) (4) . While there is an increase of (b) (4) l in the cigar binder by 33% in the new product, the total (b) (4) quantity decreased by (b) (4) compared to the predicate product. Thus, acrolein and TPM yields are not expected to increase. (b) (4) was added to the cigar wrapper and binder in the new product to replace (b) (4) in the predicate product. However, the amount added is less than 0.1%, relative to the total cigar weight. Therefore, the differences in tobacco blends and ingredients in the new product compared to the predicate product are not expected to raise different questions of public health.

All measured HPHCs (ammonia, arsenic, cadmium, nicotine, NNN, and NNK) in the cigar tobacco filler decreased by 4-19% in the new product compared to the predicate product. The applicant provided TNCO mainstream smoke data for the new and predicate product but did not provide detailed quantitative testing protocols or validation reports or any pertinent information to demonstrate that the analytical methods used to generate the data are suitable for the intended purpose. While the mainstream smoke yield of tar is increasing up to 14% and nicotine is increasing up to 22%, based on the analytical variability data provided for similar types of products, the statistical analysis performed using a two one-sided t-test (TOST) indicates that the TNCO yields between the new and predicate tobacco products are analytically equivalent. Thus, from a chemistry perspective, the differences in TNCO smoke yields and HPHCs in the cigar tobacco filler of new and predicate product are not expected to cause the new 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 a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Morgan Lee on November 15, 2018, and April 3, 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 by 6%
- Decrease in wrapper moisture by 17%
- Decrease in binder moisture by 23%
- Decrease in overall tobacco mass cut at (b) (4) by 9%

Decreases in tobacco mass are expected to reduce the amount of tobacco that is available to be burned, therefore, reduce the HPHC smoke yields. A decrease in the wrapper and binder moisture may affect puff count and, in turn, may affect smoke constituent yields. As such, the effect of the decreases in wrapper and binder moisture target specifications were deferred to chemistry to evaluate smoke yields.

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 related to product engineering.

4.3. TOXICOLOGY

Toxicology reviews were completed by Juan Crespo-Barreto on November 30, 2018, and Chad Brocker on April 12, 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) in the binder and wrapper
- Increase of (b) (4) to substitute for (b) (4)
- Replacement of a plastic tip with a wood tip (serves as a mouthpiece)
- Decreases of filler HPHCs (ammonia, arsenic, cadmium, nicotine, NNK, and NNN)

(b) (4) was added to the new tobacco product as a substitute for (b) (4) (b) (4) level represents less than 0.1% of the finished product in the new tobacco product and is not expected to increase benzene yield. (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) the burned region of the cigar is lower in the new tobacco product compared to the predicate tobacco product. The wood tip serves as a mouthpiece, does not filter the smoke, and is not burned during smoking. The components listed for the wood tip (b) (4)) are not intended to be inhaled or ingested. The filler HPHCs (ammonia, arsenic, cadmium, nicotine, NNK, and NNN) are decreased in the new product compared to the predicate tobacco product. The TNCO yields in the mainstream smoke did not indicate analytically important increases.

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 a toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Mehran Niazi on November 14, 2018, and March 28, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 23, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 23, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Decrease in total tobacco weight (5%)
- Decrease in (b) (4) (4%) and (b) (4) (9%) tobacco
- Decrease in tobacco filler mass by 6%
- Decrease in overall tobacco mass cut at (b) (4) CPI by 9%
- Addition of (b) (4) to the cigar wrapper ((b) (4) mg/cigar) and cigar binder (b) (4) mg/cigar) to replace
- Increase in (b) (4) (33%) to replace (b) (4) in the cigar binder

- Decrease in wrapper moisture by 17%
- Decrease in binder moisture by 23%
- Decrease of 4-19% in all measured HPHCs in the tobacco filler (ammonia, arsenic, cadmium, nicotine, NNK, and NNN)
- Increase of 3-14% in tar and 4-22% in nicotine mainstream smoke

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 lower amount of tobaccos than the predicate tobacco product, which is expected to reduce the HPHC smoke yields. (b) (4) (less than 0.1% of the finished tobacco product) was added to replace (b) (4) and is not expected to increase benzene yield. (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 is lower in the new tobacco product compared to the predicate tobacco product. The wood tip serves as a mouthpiece, does not filter the smoke, and is not burned during smoking. HPHC analysis of the 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. Furthermore, while smoke yield of tar increased up to 14% and nicotine increased up to 22%, the statistical analysis performed using a two one-sided t-test (TOST) indicates that in this case, TNCO yields are analytically equivalent based on the analytical variances recorded for similar types of tobacco products. 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 SE0014879, as identified on the cover page of this review.