

Technical Project Lead (TPL) Review: SE0015410

SE0015410: Black & Mild Wine Shorts	
Package Type¹	Cello
Package Quantity	1 Cigar
Length	88.9 mm
Diameter	9.57 mm
Tip	Plastic tip
Characterizing Flavor	Wine
Common Attributes of SE Reports	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) order.	

¹ The applicant defines "cello" as a clear wrap. In this case, cello is composed of polypropylene plastic wrap.

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.11.22 15:16:56 -05'00'

Jeannie Jeong-Im, 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: 2019.11.22 15:42:58 -05'00'

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:

SE0015410: Black & Mild Wine Shorts	
Product Name	Black & Mild® Wine
Package Type ¹	Cello
Package Quantity	1 Cigar
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic tip
Characterizing Flavor	Wine

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 26, 2019, FDA received one SE Report (SE0015410) from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on August 28, 2019.

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 Anikah Salim on August 28, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015410 was determined to be substantially equivalent by FDA under SE0015142. Therefore, this product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 November 1, 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 Megan Mekoli on October 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:

- 36% (b) (4) decrease in tobacco weight
- Tobacco blends:
 - 36% (b) (4) decrease in (b) (4)
 - 36% (b) (4) decrease in (b) (4)
 - 37% (b) (4) decrease in (b) (4)
- Tobacco Filler HPHCs:
 - 26 – 34% (b) (4) decreased yields for nicotine, NNN, NNK, arsenic, and cadmium

The applicant submitted an SE Report for a new tobacco product that has a shorter tobacco rod length (↓ 37%) and identical rod diameter (b) (4) compared to the predicate tobacco product. Therefore, the new tobacco product in the SE Report has a lower tobacco weight (↓ 36%) compared to the predicate tobacco product. The lower tobacco weight results in a consistent 36 – 37% lower quantity of ingredients added to tobacco filler, binder, wrapper, and seam adhesive. Both new and predicate tobacco product contain tips which are identical in composition and are attached with tip adhesive that is identical in quantity and composition. Decreases in tobacco blend, composition of ingredients added to tobacco, cigar binder, and wrapper are expected to have lower HPHCs. The applicant provided nicotine and HPHCs (i.e., NNN, NNK, arsenic, and cadmium) in cigar filler, which are 26 – 34% lower in the new tobacco product. Therefore, these decreases in characteristics 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 Ryan Andress on October 8, 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:

- 37% decrease in overall cigar rod length
- 37% decrease in tobacco filler mass
- 37% decrease in overall cigar mass

The new tobacco product has a 37% decrease in overall cigar rod length, which corresponds to a 37% decrease in tobacco filler mass and a 37% decrease in overall cigar mass, compared to the predicate tobacco product. These differences are expected to reduce the smoke yields of TNCO. The evaluation of the yield of nicotine is deferred to chemistry. All other design parameters are identical between the new and predicate tobacco products. 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

Microbiology reviews were completed by Wen Lin on October 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:

- 36% decrease in (b) (4) and (b) (4)
- 37% decrease in glycerol and (b) (4)
- 37% decreases in (b) (4), a preservative
- 26% lower NNN and NNK levels

The new and predicate tobacco products differ in humectant and preservative content, which resulted from the reduction in tobacco rod weight and length. However, these differences in humectant and preservative levels could potentially affect the microbial stability of the products over the storage time of the products. 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 content (OV%), NNN, and NNK content of the finished new and predicate tobacco products. The total moisture content of the new and predicate tobacco products is < 17%, which is insufficient to support fungal growth, and scientific evidence that indicates bacterial growth can occur in tobacco at moisture contents of < 17% is not currently available. Based on the < 17% moisture content, lower NNN (26%) and NNK (26%) contents of the new tobacco product compared to the predicate tobacco product, identical container closure systems, and lack of fermented tobacco in the new tobacco product, the differences in humectant and preservative content of the new tobacco product when compared to the predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a microbiological perspective.

4.4. TOXICOLOGY

Toxicology reviews were completed by Ana DePina on October 11, 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:

- Cigar rod length was shortened from (b) (4) in the predicate product to (b) (4) in the new product.
- Ingredients all decreased when compared on a per cigar basis.
- HPHC data measured (arsenic, cadmium, nicotine, NNK, and NNN) from unburned tobacco rod following extraction from freeze-ground cigars (wrapper, binder, and filler) decreased.

The new product has a rod length that is (b) (4) shorter than the predicate product. Consequently, there are decreases in all components of the rod, and the final cigar length and weight are decreased in the new product. Also, arsenic, cadmium, nicotine, NNK, and NNN in ground tobacco all decreased. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on October 28, 2019.²

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 22, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 22, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 36% (b) (4) decrease in tobacco weight
- 37% decrease in overall cigar rod length
- 37% decrease in overall cigar mass
- Tobacco blends:
 - 36% (b) (4) decrease in (b) (4)
 - 36% (b) (4) decrease in (b) (4)
 - 37% (b) (4) decrease in (b) (4)
- Tobacco Filler HPHCs:

² An addendum was provided on November 13, 2019 to amend the 1st cycle review. The environmental concern has been resolved; therefore, environmental has all the information needed for an EA.

- 26 – 34% (b) (4) decreased yields for nicotine, NNN, NNK, arsenic, and cadmium

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 (b) (4) shorter (37% decrease) than the predicate tobacco product. Therefore, all of the ingredients have decrease proportionally except for the plastic tip and its adhesive to the cigar (which are the same as the predicate tobacco product). The applicant provided nicotine, NNN, NNK, arsenic, and cadmium yields in filler. All of the yields decreased by 26% - 34%. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0015142.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015410 was previously determined to be substantially equivalent by FDA under SE0015142. Comparison of the new tobacco product to the grandfathered product (Black & Mild Wine in SE005142) reveals that the new tobacco product has the following differences in characteristics from Black & Mild Wine, the grandfathered tobacco product:

- 39% decrease in overall cigar rod length
- 46% decrease in tobacco filler mass
- 10% decrease in tobacco rod density
- 9% decrease in tobacco rod moisture
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- 45% decrease in overall cigar mass
- Differences in tobacco cut size (CPI)
- 37% decrease in total tobacco
 - 33% decrease in (b) (4)
 - 48% decrease in (b) (4)
 - 46% decrease in (b) (4)
- Ingredients added to tobacco:
 - Deletion of (b) (4)
 - Addition of (b) (4)
 - 40 – 53% (b) (4)

- 60 – 99% (b) (4)
- Decrease in humectants:
 - 40% decrease in (b) (4)
 - 51% decrease in (b) (4)
 - 71% decrease in (b) (4)
 - 52% decrease in (b) (4)
- Change in preservatives:
 - Removal of (b) (4) from the cigar filler
 - Addition of (b) (4) to the cigar wrapper and binder
 - 43% lower (b) (4) in the seam adhesive
 - Removal of a (b) (4) from the cigar filler, wrapper and binder
- Decrease in ground cigar HPHCs:
 - 38% decrease in nicotine
 - 27% decrease in NNN
 - 31% decrease in NNK
 - 40% decrease in arsenic
 - 41% decrease in cadmium

The differences in characteristics listed above, other than the differences in cigar length and proportionally all ingredients except for the tip and tip adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco product in SE0015142. Therefore, these differences do not cause the new tobacco product in SE0015410 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in the cigar length, tobacco cut size, ingredients added to tobacco, humectants, and preservatives between the new tobacco product in SE0015410 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015410 to the predicate of grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

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 corresponding 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 SE order letters 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 SE0015410, as identified on the cover page of this review.