

Technical Project Lead (TPL) Review: SE0015084

SE0015084: Black & Mild® Shorts	
Package Type	Cellophane ¹
Package Quantity	1 cigar
Length	88.9 mm
Diameter	9.57 mm
Tip	Plastic
Characterizing Flavor	None
Attributes of the SE Report	
Applicant	John Middleton Company
Report Type	Regular
Product Category	Cigar
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue Substantially Equivalent (SE) order.	

¹ The applicant identified the package type as cello, which is a clear wrap comprised of polypropylene.

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.08.06 10:54:55 -04'00'

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: 2019.08.06 11:15:10 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND	4
1.1. PREDICATE TOBACCO PRODUCT	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	4
1.3. SCOPE OF REVIEW	4
2. REGULATORY REVIEW	4
3. COMPLIANCE REVIEW	4
4. SCIENTIFIC REVIEW	5
4.1. CHEMISTRY.....	5
4.2. ENGINEERING	6
4.3. MICROBIOLOGY	6
4.4. TOXICOLOGY.....	7
5. ENVIRONMENTAL DECISION.....	8
6. CONCLUSION AND RECOMMENDATION	8

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015084: Black & Mild® Shorts	
Product Name	Black & Mild
Package Type	Cellophane ¹
Package Quantity	1 cigar
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 13, 2019, FDA received an SE Report from Altria Client Services, LLC on behalf of John Middleton Company. On February 19, 2019, FDA issued an Acknowledgement Letter to the applicant. On April 12, 2019, FDA issued an Advice/ Information (A/I) Request letter to the applicant. On May 8, 2019, FDA received the applicant's response to the A/I request letter (SE0015226).

Product Name	SE Report	Amendments
Black & Mild® Shorts	SE0015084	SE0015226

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

Regulatory review was completed by Elizabeth Harrod on February 14, 2019.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated March 14, 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated July 8, 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 Stephanie Daniels on April 04, 2019 and July 17, 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:

- 40% lower in tobacco quantity (b) (4) /cigar)
- 40%, 37%, and 42% lower in (b) (4) quantities, respectively
- Removal of (b) (4) (cigarette) in the cigar wrapper
- Removal of (b) (4) /cigarette) and (b) (4) (cigarette) in the cigar binder
- Addition of (b) (4) in the cigar wrapper (b) (4) /cigarette) and binder (0.0033 mg/cigarette)
- 38% – 47% lower yields for ammonia, arsenic, cadmium, nicotine, N-nitrosornicotine (NNN), and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)
- 23% and 17% lower binder and wrapper moisture target specifications, respectively

The new tobacco product is slightly smaller with a shorter tobacco rod length (↓39%) and rod diameter (↓2%) compared to the predicate tobacco product. The overall tobacco blend quantity of the new tobacco product is (b) (4) /cigar lower than the predicate tobacco product (↓40%), except for (b) (4) that has been deferred to toxicology. Smoke data was requested for tar, nicotine, carbon monoxide, formaldehyde, acetaldehyde, and crotonaldehyde; however, the applicant did not provide the information. The smoke data (i.e., TNCO and carbonyls) would have been helpful in determining if the new product is substantially equivalent to the predicate product; however, it is currently not a requirement. The applicant instead provided extraction data for ammonia, arsenic, cadmium, nicotine, NNN, and NNK for the rod (wrap, binder, and filler). The changes in the tobacco blend and physical parameters likely attributed to the 38% - 47% lower ammonia, arsenic, cadmium, nicotine, NNN, and NNK in the tobacco rod of the new tobacco product compared to the predicate tobacco product. The applicant has provided sufficient information from a chemistry perspective to determine that the differences 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

An engineering review was completed by Drew Katherine on April 04, 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:

- 39% lower overall cigar rod length
- 41% lower tobacco filler mass
- 15% lower in the lower range limits for tobacco rod density

The overall cigar rod length decreases 39%, tobacco filler mass decreases 41%, and tobacco rod density lower range limits decreases 15%. A shorter cigar rod length may lead to less tobacco available to be burned and a reduced pressure drop that can lead to a decrease in TNCO yields. A decrease in tobacco filler mass reduces the amount of tobacco that is burned and decreases TNCO yields. Therefore, both changes in cigar rod length and tobacco filler mass will not cause the new product to raise different question about public health. The lower range limits for tobacco rod density for the new product was 15% smaller than the lower range limits for the predicate product, even though the differences in target specifications for tobacco rod density was minimal. A decrease in tobacco rod density may cause more air to flow through the tobacco rod, leading to a decrease in TNCO while increasing carbonyls. Therefore, the decreases in tobacco rod density lower range limits are deferred to chemistry for evaluation of the yield of TNCO and carbonyls for the new and predicate 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 and engineering perspective.

4.3. MICROBIOLOGY

A microbiology review was completed by David Craft on March 26, 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:

- Lower NNN (41%) and NNK (47%) content
- Addition of (b) (4) a preservative, in the wrapper and binder
- Lower (b) (4) in the cigar seam adhesive
- Removal of (b) (4), a preservative, in the wrapper and binder
- Lower total (b) (4) content (41%) in the finished cigar
- Lower target contents of (b) (4) (41%), and (b) (4) r (42%), as humectants, in the tobacco filler

The new tobacco product has an addition of (b) (4) to the wrapper and binder, and removal of (b) (4), both preservatives. Additionally, the new tobacco product has decreases in the content of (b) (4) (43%) in the seam adhesive, and the humectants, (b) (4) (41%), (b) (4) (41%), and (b) (4) (42%). The applicant did not provide stability data over the storage duration of the new and predicate tobacco products. However, the total moisture content of the new and predicate tobacco products is less than 15% which is insufficient to support fungal growth and comprehensive data to support bacterial growth at this concentration have not been substantiated. Additionally, the new and predicate tobacco products do not include any (b) (4) and have identical container closure systems. Therefore, the lack of stability data for the new and predicate tobacco products is not a concern from a microbiology perspective. Additionally, the NNN, and NNK content of the finished new tobacco product are lower by 41% and 47%, respectively, when compared to the predicate tobacco product. Based on the lack of (b) (4), the container closure system, the decreases in NNN and NNK, and the low moisture content (<15%) of the new tobacco product, the differences in humectants and preservatives of the new tobacco product when compared to the predicate tobacco product does not cause the new tobacco product to raise different questions of public health from a microbiological perspective.

4.4. TOXICOLOGY

A toxicology review was completed by Cissy X. Li on April 03, 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:

- Addition of (b) (4) to the wrapper and binder

The applicant provided ingredients for all cigar components for the new and predicate products. The cigar rod length was shortened from 106.00 mm in the predicate product to 65.00 mm in the new product, and the rod diameter was slightly decreased from 9.62 mm in the predicate product to 9.57 mm in the new product. These changes in design features resulted in decreased weights of the final cigar, the rod, and all components of the rod (i.e. filler, binder, wrapper,

seam adhesive). Thus, the ingredients in the new product were nearly all decreased relative to the predicate product when compared on a per cigar basis. (b) (4) was the only ingredient that was net increased in the new product, as it was added to the wrapper and binder as a replacement for (b) (4). (b) (4) levels represent less than 0.1% of the finished product in the new product and are unlikely to increase benzene yields when compared to the predicate product. The reported six HPHCs (ammonia, arsenic, cadmium, nicotine, NNK, and NNN), measured following (b) (4) from (b) (4) cigar tobacco rods (containing wrapper, binder, and filler), were decreased in the new product compared to the predicate product. Therefore, the ingredient changes and the HPHC yields do not cause the new tobacco product to raise different questions of public health.

5. ENVIRONMENTAL DECISION

Environmental science reviews were completed by Shannon Hanna on March 26, 2019 and June 17, 2019.²

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 18, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 18, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 39% lower overall cigar rod length.
- 41% lower tobacco filler mass.
- 15% lower in the lower range limits for tobacco rod density
- 40%, 37%, and 42% lower in (b) (4) quantities, respectively
- Removal of (b) (4) /cigarette) in the cigar wrapper
- Removal of (b) (4) /cigarette) and (b) (4) (b) (4) cigarette) in the cigar binder
- Addition of (b) (4) in the cigar wrapper (b) (4) mg/cigarette) and binder (b) (4) /cigarette)
- 38% – 47% lower yields for ammonia, arsenic, cadmium, nicotine, NNN, and NNK
- 23% and 17% lower binder and wrapper moisture target specifications, respectively
- Lower (b) (4) in the cigar seam adhesive
- Lower total (b) (4) content (41%) in the finished cigar
- Lower target contents of (b) (4) (41%), and (b) (4) (42%), as humectants, in the tobacco filler

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 39%

² Addendum to the environmental review was completed on July 16, 2019 to correct the STNs that is included in the 2nd environmental review. SE0015085 was withdrawn by the applicant on July 1, 2019 and no longer the subject of the 2nd environmental review.

smaller with a shorter tobacco rod length and a slightly smaller rod diameter (2%) compared to the predicate tobacco product. The overall filler mass is 41% lower in the new tobacco product, which results from 40%, 37%, and 42% less (b) (4), respectively. These differences in characteristics are expected to decrease TNCO. Therefore, smoke data is not necessary at this time. The applicant instead provided extraction data for ammonia, arsenic, cadmium, nicotine, NNN, and NNK for the rod (wrap, binder, and filler), which are 38% – 47% lower in the new tobacco product compared with the predicate tobacco product. In the new product, there is an addition of (b) (4) to the wrapper and binder, and removal of (b) (4). These are preservatives. Additionally, the new tobacco product has decreases in the content of (b) (4) (43%) in the seam adhesive, and the humectants, (b) (4) (41%), (b) (4) (41%), and (b) (4) (42%). This may impact fungal growth, but the total moisture content is less than 15% and is insufficient to support fungal growth. Also, the NNN, and NNK content of the finished new tobacco product are lower by 41% and 47%. 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 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 SE0015084 as identified on the cover page of this review.