FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015277, SE0015278, SE0015279, SE0015284, and SE0015286

SE0015277: Black & Mild® Sweets Wood Tip	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	None[2]
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood Tip
SE0015278: Black & Mild® Cream	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Cream[3]
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
SE0015279: Black & Mild® Sweets	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	None[2]
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip

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

[2] 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] 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.

SE0015284: Black & Mild® Apple	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Apple[4]
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
SE0015286: Black & Mild® Select	
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	None[2]
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic Tip
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) orders.	

[4] 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.

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.06.24 12:24:09 -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: 2020.06.24 12:30:28 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015277: Black & Mild® Sweets Wood Tip	
Product Name	Black & Mild Cream
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Cream[5]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
SE0015278: Black & Mild® Cream	
Product Name	Black & Mild Cream
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Cream[5]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
SE0015279: Black & Mild® Sweets	
Product Name	Black & Mild Cream
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Cream[5]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip

[5] 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.

SE0015284: Black & Mild® Apple	
Product Name	Black & Mild Apple
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	Apple[6]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip
SE0015286: Black & Mild® Select	
Product Name	Black & Mild Mild
Package Type	Cello[1]
Package Quantity	1 Cigar
Characterizing Flavor	None[7]
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic Tip

The predicate tobacco products are unfiltered, sheet-wrapped cigars manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 28, 2019, FDA received five SE Reports from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on July 5, 2019.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Regulatory reviews were completed by Anikah Salim on July 5, 2019.

The reviews conclude that the SE Reports are administratively complete.

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

[7] The applicant uses the term (b) (4) [redacted]. 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 reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE review dated July 29, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are 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 reviews dated September 6, 2019, January 29, 2020, and April 30, 2020, conclude that the new tobacco products are 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 An Vu on August 16, 2019.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Smaller product size, which results in:
  - Decreases in rod length (3%), rod diameter (1%), rod weight (3–7%), filler weight (2–7%), and total product weight (2–6%)
  - Decreases in weight of combusted subcomponents, which include filler (2–7%), binder (11%), wrapper (9–10%), and seam adhesive (10%)
  - Decreases in total tobacco (1–7%) and most individual tobacco types (3–11%)
- Change from plastic tip to wood tip for SE0015277
- A small increase in (b) (4) [redacted] (4%) for SE0015284
- Decreases in amount of almost all non-tobacco ingredients including numerous flavor ingredients
- Removal of many other non-tobacco ingredients, including flavor ingredients
- Addition of three high-intensity sweetening ingredients to two new tips. These include (b) (4) [redacted] mg) and (b) (4) [redacted] mg) added to the new tip of SE0015277, and (b) (4) [redacted] mg) added to the new tip of SE0015279

The new tobacco products are smaller than the corresponding predicate tobacco products. This product size reduction is due to decreases in rod length, rod diameter, total product weight, tobacco rod, filler, binder, wrapper, seam adhesive, total tobacco and most individual tobacco types as well as decreases in the amount of most non-tobacco ingredients and removal of a number of other non-tobacco ingredients. These decreases are expected to lower harmful and potentially harmful constituents (HPHC) quantities for all the new tobacco products. There is a

small increase in (b) (4) filler for the new tobacco product of SE0015284 compared to the predicate tobacco product. However, the new tobacco product of SE0015284 has lower total tobacco and this minor (b) (4) increase is not expected to significantly impact smoke yields. There is a change from plastic tip to wood tip for the new tobacco product of SE0015277. However, cigar tips are not combusted during product use; thus, this cigar tip replacement is not a concern. The applicant tested and reported quantities of arsenic, cadmium, nicotine, 4-(methylnitrosoamino)-1-(3-pyridyl)-1-butanone (NNK), and N-nitrosonornicotine (NNN) in the tobacco rods of the new and corresponding predicate tobacco products. All HPHC quantities measured in the tobacco rods are analytically equivalent between the new and corresponding predicate tobacco products; therefore, the HPHC values do not cause the new tobacco products to raise different questions of public health when compared to the predicate tobacco products. The (b) (4) preservative ingredient in the predicate binders and wrappers is replaced with a lower amount of (b) (4) preservative in the corresponding new binders and wrappers. The applicant stated that the change was made because combustion of (b) (4) could generate extensive pyrolysis of the tobacco products. The applicant provided a toxicological evaluation for this preservative ingredient change, which was deferred to Toxicology. There are three high-intensity sweetening ingredients added to two new tips that are absent in two of the predicate tobacco product tips. These include (b) (4) mg) and (b) (4) mg), added to the new tip of SE0015277, and (b) (4) mg), added to the new tip of SE0015279. Although the plastic tip of these new tobacco products contains some different ingredients (i.e., sweeteners) as compared to the predicate tobacco product, because the tip is not combusted when the new tobacco products are used as intended. The addition of these ingredients to the tip is not anticipated to affect smoke chemistry. Thus, at present, the addition of these three high-intensity sweeteners to the new cigar tips does not appear to cause the new tobacco products of SE0015277 and SE0015279 to raise different questions of public health from a chemistry perspective. However, the addition of sweeteners to the cigar tips of the new tobacco products is deferred to Toxicology. By taking into account the outcome of the HPHC measurements in the tobacco roll rod (all tested constituents are analytically equivalent) as well as the information described above pertaining to changes in the tobacco and ingredients, which are not anticipated to affect smoke chemistry, in conjunction with the physical design parameter changes deferred by engineering, the chemist concluded that mainstream smoke yield data was not necessary.

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 chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Pritesh Darji on August 19, 2019.

The engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

SE0015277

- Tobacco filler mass (↓7.0%)
- Tobacco rod moisture (↑7.25%)
- Wrapper moisture (↓17.24%)
- Binder moisture (↓22.58%)
- Change in tobacco cut size (CPI):
  - (b) (4) CPI (↓43% absolute change), (b) (4) CPI (↑43% absolute change)
  - (b) (4) CPI (↓59% absolute change), (b) (4) CPI (↑60% absolute change)

SE0015278

- Tobacco filler mass (↓7.0%)
- Tobacco rod moisture (↑7.25%)
- Wrapper moisture (↓17.24%)
- Binder moisture (↓22.58%)
- Overall cigar mass (↓5.96%)
- Change in tobacco cut size (CPI):
  - (b) (4) CPI (↓43% absolute change), (b) (4) CPI (↑43% absolute change)
  - (b) (4) CPI (↓59% absolute change), (b) (4) CPI (↑60% absolute change)

SE0015279

- Tobacco filler mass (↓7.0%)
- Tobacco rod moisture (↑7.25%)
- Wrapper moisture (↓17.24%)
- Binder moisture (↓22.58%)
- Overall cigar mass (↓5.96%)
- Change in tobacco cut size (CPI):
  - (b) (4) CPI (↓43% absolute change), (b) (4) CPI (↑43% absolute change)
  - (b) (4) CPI (↓59% absolute change), (b) (4) CPI (↑60% absolute change)

SE0015284

- Wrapper moisture (↓14.28%)
- Binder moisture (↓22.58%)
- Change in tobacco cut size (CPI):
  - (b) (4) CPI (↓43% absolute change), (b) (4) CPI (↑41% absolute change)
  - (b) (4) CPI (↓66% absolute change), (b) (4) CPI (↑67% absolute change)

SE0015286

- Tobacco filler mass (↓6.73%)
- Wrapper moisture (↓14.28%)
- Binder moisture (↓22.58%)
- Overall cigar mass (↓5.07%)

An increase in tobacco rod moisture may cause an increase in tar, nicotine, and carbon monoxide (TNCO) yields. The change in tobacco cut size may also affect TNCO yields. However, all other product design parameter changes are anticipated to decrease TNCO yields. Thus, differences in the product design parameters would likely lead to an overall decrease in TNCO yields. All differences were deferred to chemistry. Per the chemistry review, any potential increase in TNCO yields caused by an increase in tobacco rod moisture or change in tobacco cut size or both is likely to be counterbalanced by a decrease in TNCO yields due to decreases in the weight of the combusted subcomponents, decreases in the total tobacco and most individual tobacco types, and removal or decreases in the amount of almost all combusted ingredients.

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 an engineering perspective.

4.3. MICROBIOLOGY

A microbiology review was completed by Wen Lin on August 16, 2019.

The microbiology review concludes that the new tobacco products have different characteristics related to product microbiology compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- ≤ 5% lower moisture content
- ≤ 10% lower NNN (except 5% higher in SE0015278 and SE0015286) and ≤ 7% lower NNK (except 6% higher in SE0015278) levels
- ≤ 7% lower (b) (4) (except 0.1% higher in SE0015284), ≤ 4% lower (b) (4), ≤ 7% lower (b) (4) and ≤ 8% lower (b) (4) all humectants in the finished cigar
- Removal of (b) (4) mg/cigar), a preservative in the tobacco filler (except SE0015286)
- Removal of (b) (4) mg /cigar), a preservative in the wrapper and binder
- Addition of (b) (4) mg/cigar), a preservative to the wrapper and binder
- 10% lower (b) (4) in the seam adhesive

All new and corresponding predicate tobacco products differ in either humectant or preservative content, which could potentially affect the microbial stability of the tobacco products over storage time. The applicant did not provide stability data over the storage duration of the new and corresponding predicate tobacco products to address this concern. However, the applicant provided moisture (OV%), NNN and NNK contents of the new and corresponding predicate tobacco products. The moisture levels of the new tobacco products are insufficient to support fungal growth and comprehensive data to support bacterial growth at moisture contents of < 16% have not been substantiated. Therefore, the < 16% moisture content of the new tobacco products, equivalent NNN and NNK content of the new tobacco products compared to the corresponding predicate tobacco products, identical container-closure systems and lack of (b) (4) in the new tobacco products address any

potential microbial stability issues stemming from the differences in humectant and preservative contents of the new tobacco products compared to the corresponding predicate tobacco products.

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 microbiology perspective.

4.4. TOXICOLOGY

A toxicology review was completed by Matthew Savidge on August 16, 2019.

The toxicology review concludes that the new tobacco products have different characteristics related to toxicology compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- Increased amounts of (b) (4) incorporated into filler of new tobacco products in SE0015277–SE0015279
- Replacement of (b) (4) with (b) (4) in the wrapper and binder for new tobacco products
- Replacement of (b) (4) in the binder for new tobacco products
- Replacement of (b) (4) with (b) (4) in the new tobacco products in SE0015277 and SE0015279
- Addition o (b) (4) o the tip used in the new tobacco product of SE0015279
- Replacement of the plastic tip with a wood tip for the new tobacco product in SE0015277

In all SE Reports, the applicant provided ingredients for all cigar components for the new and corresponding predicate tobacco products. All product dimensions remain the same except for rod length and diameter, which were both decreased in the new tobacco products as compared to the corresponding predicate tobacco products. 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). For SE0015277–SE0015279, five ingredients were increased in the tobacco filler of the new tobacco products as compared to the corresponding predicate tobacco products. However, given these ingredients are added in relatively small amounts (< (b) (4) mg/cigar), their incorporation into the new tobacco products is unlikely to have a measurable increase on HPHC yields using current analytical methods (Pickworth et al., 2018) when compared to the predicate tobacco product. All other ingredients in the filler for all SE Reports were either removed or decreased in the new tobacco products as compared to the predicate tobacco products.

In all SE Reports, the binder and wrapper were reformulated to replace (b) (4) with a lesser amount of (b) (4) in the new tobacco products. Additionally, (b) (4) was removed from the binder of the corresponding predicate tobacco products and

replaced with 33% additional [redacted] however, the total inclusion weight of [redacted] in the burned region of the new tobacco products is lower than the corresponding predicate tobacco products. Two of the new tobacco products (SE015277 and SE0015279) replaced the [redacted] in the corresponding predicate tobacco product with the [redacted] in the wrapper. Notably, [redacted] was added in lower target inclusion levels than the pigment used in the corresponding predicate tobacco products. Additionally, the new tobacco product in SE0015277 uses a wood tip, replacing the plastic tip used in the predicate tobacco product, and the new tobacco product in SE0015279 contains a sweetener, which is added to the tip of the cigar. Cigar tips are not intended to be burned or inhaled and exposure to a sweetener is likely to only occur via oral exposure and thus is not expected to have a measurable impact on HPHC smoke yields. Therefore, these reported differences from the predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a toxicological perspective.

There were slight increases in measured NNN (SE0015278 and SE0015286), NNK (SE0015278), and nicotine (SE0015286) from the unburned tobacco rod in the new tobacco products compared to the corresponding predicate tobacco products. However, these HPHC measurements were determined to be analytically equivalent, and therefore the changes in NNN, NNK, and nicotine do not cause the new tobacco products to raise different questions of public health when compared to the predicate tobacco products from a toxicological perspective.

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

Environmental reviews were completed by Thomas Creaven on August 8, 2019. Addendum reviews were completed by Thomas Creaven on October 7, 2019, and December 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 13, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 13, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Smaller product size, which results in:
  - Decreases in rod length (3%), rod diameter (1%), rod mass (3–7%), and overall cigar mass (26%; SE0015278 and SE0015286 only)
- Decreases in weight of combusted subcomponents, which include filler mass (2–7%; except SE0015284), binder (11%), wrapper (9–10%), and seam adhesive (10%)
- Decreases in total tobacco (17%) and most individual tobacco types (3–11%), and a small increase in [redacted] (4%) for SE0015284

- Change in tobacco cut size (CPI) (except SE0015286):
  - o [redacted] CPI (↓ in absolute change), [redacted] CPI (↑ in absolute change)
  - o [redacted] CPI (↓ in absolute change), [redacted] CPI (↑ in absolute change)
- Decreases in amount of almost all non-tobacco ingredients
- Removal of many other non-tobacco ingredients including flavor ingredients
- Increase in tobacco rod moisture (SE0015277 and SE0015278 only), decrease in wrapper moisture, decrease in binder moisture, and ≤ 5% lower moisture content
- Change in humectants in the finished cigar: ≤ 7% lower [redacted] (except 0.1% higher in SE0015284), ≤ 4% lower [redacted], ≤ 7% lower [redacted] and ≤ 8% lower sucrose,
- Replacement of [redacted] preservative in binders and wrappers with a lower amount of [redacted] preservative
- 10% lower [redacted] in the seam adhesive
- Removal of [redacted] mg/cigar), a preservative in the tobacco filler (except SE0015286)
- Replacement of [redacted] in the binder for new tobacco products
- Addition of three high-intensity sweetening ingredients to two new tips. These include [redacted] mg) and [redacted] mg) added to the new tip of SE0015277, and [redacted] mg) added to the new tip of SE0015279
- Increased amounts of [redacted] incorporated into filler of the new tobacco products in SE0015277–SE0015279
- Replacement of [redacted] in the new tobacco products in SE0015277 and SE0015279
- Replacement of the plastic tip with a wood tip for the new tobacco product in SE0015277

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health compared to the predicate tobacco products.

The new tobacco products are smaller than the corresponding predicate tobacco products. This product size reduction results in decreases in rod length, rod diameter, rod mass, and overall cigar mass (SE0015278 and SE0015286 only). There are also decreases in the weight of combusted components: filler mass (except SE0015284), binder, wrapper, seam adhesive, total tobacco and most individual tobacco types, except for an increase in [redacted] in SE0015284. However, the new tobacco product of SE0015284 has lower total tobacco and this minor [redacted] increase is not expected to measurably impact mainstream HPHC smoke yields. All new tobacco products feature changes in tobacco cut size except for SE0015286. There is an increase in tobacco rod moisture (SE0015277 and SE0015278 only), decrease in wrapper moisture, decrease in binder moisture, and ≤ 5% lower moisture content, and small changes in ingredients in the new tobacco products when compared to the corresponding predicate tobacco products. Taken together, all the changes described above are expected to lower HPHC quantities for all the new tobacco products. Two of the new tobacco products (SE015277 and SE0015279) replaced the [redacted] in the corresponding predicate tobacco product with the [redacted] in the wrapper. Given that the level of total pigment present in the new tobacco products is lower than that of the corresponding predicate tobacco product, the total pigment content in the new tobacco products does not cause the new tobacco products to raise different questions of public health when compared to the predicate tobacco product. There are sweetening ingredients added to two

new tobacco product tips that are absent in the corresponding predicate tobacco product tip; these cigar tips are not combusted when the new tobacco products are used as intended. There is a change from plastic tip to wood tip for the new tobacco product of SE0015277. However, cigar tips are not combusted during product use; thus, this cigar tip replacement does not raise different questions of public health when compared to the predicate tobacco product. Finally, the applicant tested and reported quantities of arsenic, cadmium, nicotine, NNK, and NNN in the tobacco rods of the new and corresponding predicate tobacco products, and all tobacco rod HPHC quantities are analytically equivalent between the new and corresponding predicate tobacco products. Therefore, the design changes, tobacco blend changes, and the ingredient changes do not cause the new tobacco products to raise different questions of public health when compared to the predicate tobacco products.

The applicant provided moisture (OV%), NNN and NNK contents of the new and corresponding predicate tobacco products. The moisture levels of the new tobacco products are insufficient to support fungal growth and comprehensive data to support bacterial growth at moisture contents of < 16% have not been substantiated. Therefore, based on the < 16% moisture content of the new tobacco products, equivalent NNN and NNK content of the new tobacco products compared to the corresponding predicate tobacco products, identical container-closure systems and lack of (b) (4) in the new tobacco products, the differences in humectant and preservative contents of the new tobacco products compared to the corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco products are 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 products do 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 these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0015277, SE0015278, SE0015279, SE0015284, and SE0015286 as identified on the cover page of this review.