Technical Project Lead (TPL) Review: SE0015138 - SE0015143

SE0015138: Middleton's Cherry Blend	
Package Type	Box
Package Quantity	5 cigars
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Cherry
Additional Property	Plastic Tip
SE0015139: Middleton's Cherry Blend	
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Cherry
Additional Property	Plastic Tip
SE0015140: Black & Mild® Wine Wood Tip	
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Wood Tip
SE0015141: Black & Mild® Wine Wood Tip	
Package Type	Box
Package Quantity	5 cigars
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Wood Tip
SE0015142: Black & Mild® Wine	
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip

SE0015143: Black & Mild® Wine	
Package Type	Box
Package Quantity	5 cigars
Diameter	9.57 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip
Common Attributes of SE Reports	
Applicant	John Middleton Company
Report Type	Regular
Product Category	Cigar
Product Sub-Category	Sheet Wrapped Unfiltered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.06.14 13:28:09 -04'00'

Kenneth M. Taylor, 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: 2019.06.14 14:05:20 -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:

SE0015138: Middleton's Cherry Blend	
Product Name	Middleton's Cherry Blend
Package Type	Box
Package Quantity	5 cigars
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Cherry
Additional Property	Plastic Tip
SE0015139: Middleton's Cherry Blend	
Product Name	Middleton's Cherry Blend
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Cherry
Additional Property	Plastic Tip
SE0015140: Black & Mild® Wine Wood Tip	
Product Name	Black & Mild Wine
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip
SE0015141: Black & Mild® Wine Wood Tip	
Product Name	Black & Mild Wine
Package Type	Box
Package Quantity	5 cigars
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip

SE0015142: Black & Mild® Wine	
Product Name	Black & Mild Wine
Package Type	Cellophane
Package Quantity	1 cigar
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip
SE0015143: Black & Mild® Wine	
Product Name	Black & Mild Wine
Package Type	Box
Package Quantity	5 cigars
Diameter	9.62 mm
Length	126.9 mm
Characterizing Flavor	Wine
Additional Property	Plastic Tip

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 22, 2019, FDA received six SE Reports from Altria Client Services on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on March 29, 2019. No amendments were received.

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 March 29, 2019.
The reviews conclude that the SE Reports are administratively complete.

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 other than exclusively in test markets as of February 15, 2007). The OCE reviews dated April 30, 2019, conclude 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 review dated June 13, 2019 concludes 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 Youbang Liu on May 2, 2019.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry 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:

SE0015140, SE0015141, SE0015142, and SE0015143

- 5% increase of (b) (4)
- 0.3% increase of (b) (4)

The increase in (b) (4) in the new tobacco products can result in higher amounts of NNN and NNK. The applicant submitted HPHC testing data, including NNN and NNK, for all of the SE Reports. Two One-Sided T-Test evaluation[1] of the data determined that the quantities of NNN and NNK are analytically equivalent between the new and corresponding predicate tobacco products. Thus, the increases in (b) (4) do not cause concerns.

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 Michael Morschauser on May 3, 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:

[1] The Two One-Sided T-test is a statistical tool that calculates important analytical differences using the Horwitz-Thompson equation

SE0015138 & SE0015139

- 8% decrease in tobacco filler mass
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture

SE0015140-SE0015143

- 15% decrease in tobacco filler mass
- 10% decrease in tobacco filler density
- 9.3% decrease in tobacco rod moisture
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture

The decreases in tobacco filler mass, tobacco filler density, and wrapper/binder moisture are anticipated to reduce smoke TNCO. The engineering review defers evaluation of smoke TNCO and other HPHCs to the chemistry review. However, HPHC data was submitted only for tobacco filler.

Therefore, evaluation of smoke TNCO was not performed. However, since the new tobacco products have reduced tobacco filler mass and measured tobacco filler HPHC amounts are either less or analytically equivalent, evaluation of smoke TNCO is 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 an engineering perspective.

4.3. MICROBIOLOGY

A microbiology review was completed by Wen Lin on May 2, 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:

SE0015138 and SE0015139

- 8% decrease in tobacco filler mass
- 9% increase in moisture content
- 8% increase in NNN
- 16% decrease in NNK
- 7% decrease in (b) (4) content
- 13% decreases in the target contents of (b) (4) and (b) (4) in the tobacco filler
- Addition of (b) (4) (b) (4) g/cigar) as a preservative in the wrapper and binder
- 10% decrease in (b) (4) in the cigar seam adhesive
- Removal of (b) (4) (b) (4) g /cigar), a preservative in the wrapper and binder

- 1% decrease in tobacco rod diameter
- 12% decrease tobacco rod weight
- 6% decrease in total tobacco content

SE0015140, SE0015141, SE0015142 and SE0015143

- 5% increase of (b) (4)
- 0.3% increase of total (b) (4)
- 10% decrease in tobacco filler density
- 9% decrease in tobacco rod moisture
- 14% decrease in wrapper moisture
- 23% decrease in binder moisture
- 15% decrease in moisture content
- 2% decrease in NNN
- 7% decrease in NNK
- 22% decrease in (b) (4) content
- 55% and 5%, respective, decreases in (b) (4) the tobacco filler
- Removal of preservatives (b) (4) (b) (4) in the tobacco filler
- Addition of (b) (4) as a preservative in the wrapper and binder
- 10% decrease in (b) (4) in the cigar seam adhesive
- Removal of (b) (4)), a preservative in the wrapper and binder
- 1% increase in tobacco rod diameter
- 22% decrease in tobacco rod weight
- 6% decrease in total tobacco content

All new and corresponding predicate tobacco products differ in either humectant or preservative content, which 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 corresponding predicate tobacco products to address this concern. However, the applicant provided moisture (OV%), NNN, and NNK content of the finished new and corresponding predicate tobacco products. Based on the low moisture content of the new tobacco products (< 17%), which is not favorable for microbial growth, minor differences in NNN (< 8%) and NNK (< 16%) of the new tobacco products compared to the corresponding predicate tobacco products, identical container-closure systems and lack of (b) (4) tobacco in the new tobacco products, the differences in humectant and preservative content of the new tobacco products compared to the corresponding predicate products do not cause concerns.

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 Jueichuan Kang on May 3, 2019.

The toxicology review concludes that the new tobacco products have different characteristics related to product 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:

- Replacement of (b) (4) in the wrapper and the binder
- Addition of (b) (4) to replace (b) (4) in binder
- Slight increase in NNN in the (b) (4) cigar rod (SE0015138-SE0015139)
- Slight increase in ammonia in the (b) (4) cigar rod (SE0015140-SE0015143)

(b) (4) is the only ingredient that was added to the new products which resulted in a net increase. It represents less than 0.1% of the new products and is not anticipated to increase benzene yields in the new products when compared to the predicate products. (b) (4) was added to substitute for (b) (4) and is increased in the binder of the new products, but the net amount of (b) (4) from all components was decreased in the new products compared to the predicate products. The increases in NNN and ammonia in the new products are determined to be "analytically equivalent" by the chemistry review.

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

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 15, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 15, 2019.

6. CONCLUSION AND RECOMMENDATION

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

SE0015138 and SE0015139

- 9% increase in moisture content
- 8% increase in NNN
- 16% decrease in NNK
- 7% decrease (b) (4) content
- 13% decreases in the target contents of (b) (4) and (b) (4) in the tobacco filler
- Addition of (b) (4)) as a preservative in the wrapper and binder
- 10% decrease in (b) (4) in the cigar seam adhesive
- Removal of (b) (4) a preservative in the wrapper and binder
- 12% decrease tobacco rod weight
- 6% decrease in total tobacco content

SE0015140, SE0015141, SE0015142 AND SE0015143

- 15% decrease in moisture content
- 7% decrease in NNK
- 22% decrease in (b) (4) content
- 55% and 5%, respective, decreases in (b) (4) the tobacco filler
- Removal of preservatives (b) (4) and (b) (4) (b) (4) in the tobacco filler
- Addition of (b) (4) a preservative in the wrapper and binder
- 10% decrease in (b) (4) in the cigar seam adhesive
- Removal of (b) (4) a preservative in the wrapper and binder
- 22% decrease in tobacco rod weight
- 6% decrease in total tobacco content

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new tobacco products have decreases in tobacco filler mass, which will should have a favorable effect on HPHCs. The tobacco blend changes of increased (b) (4) and removal of the preservatives (b) (4) (b) (4) in the tobacco filler in the new products of SE0015140-SE0015143 could cause increases in NNK and NNN. However, HPHC data provided by the applicant was determined to be analytically equivalent between the new and corresponding predicate tobacco products, demonstrating that these changes do not cause concern. There are changes in humectants which could also affect microbial activity, however the microbiology review concluded that this was not a concern due to the analytical equivalence in NNK and NNN, low moisture content, and also that new tobacco products do not contain (b) (4) tobacco.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.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 15, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 15, 2019.

SE order letters should be issued for the new tobacco products in SE0015138-SE0015143, as identified on the cover page of this review.