Technical Project Lead (TPL) Review: SE0015206 and SE0015207

SE0015206: Black & Mild Jazz	
Package Type[1]	Cello
Package Quantity	1 Cigar
Characterizing Flavor[2]	None
Length	126.9 mm
Diameter	9.57 mm
Tip	Plastic tip
SE0015207: Black & Mild Jazz Wood Tip	
Package Type[1]	Cello
Package Quantity	1 Cigar
Characterizing Flavor[2]	None
Length	126.9 mm
Diameter	9.57 mm
Tip	Wood tip
Attributes of SE Reports	
Applicant	John Middleton Co.
Report Type	Regular
Product Category	Cigars
Product Sub-Category	Unfiltered, Sheet-Wrapped Cigar
Recommendation	
Issue a Substantially Equivalent (SE) orders.	

[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 "identifying flavor" to indicate whether it identifies the cigar product by use of a flavor identifier. For the new product, the applicant states that the identifying flavor is "none." Properties to uniquely identify the new tobacco product were provided by the applicant, and not confirmed by FDA. 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 Charles Feng -S
Date: 2019.11.14 08:52:37 -05'00'

Charles 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: 2019.11.14 09:15:57 -05'00'

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:

SE0015206: Black & Mild Jazz	
Product Name	Black & Mild Wine
Package Type[1]	Cello
Package Quantity	1 Cigar
Characterizing Flavor[3]	Wine
Length	126.9 mm
Diameter	9.62 mm
Tip	Plastic tip
SE0015207: Black & Mild Jazz Wood Tip	
Product Name	Black & Mild Wine
Package Type[1]	Cello
Package Quantity	1 Cigar
Characterizing Flavor[3]	Wine
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 April 24, 2019, FDA received two SE Reports from Altria Client Services LLC on behalf of John Middleton Co. FDA issued an Acknowledgement letter to the applicant on May 3, 2019. On July 18, 2019, FDA issued a Deficiency letter. On August 19, 2019, FDA received an amendment (SE0015405) from the applicant.

Product Name	SE Report	Amendments
Black & Mild Jazz	SE0015206	SE0015405
Black & Mild Jazz Wood Tip	SE0015207	

[3] The applicant uses the term "identifying flavor" to indicate whether it identifies the cigar product by use of a flavor identifier. For the predicate product, the applicant states that the identifying flavor is "wine." Properties to uniquely identify the predicate tobacco product were provided by the applicant, and not confirmed by FDA. In this case, FDA determined that no additional information regarding characterizing flavor was necessary to compare the new and predicate tobacco products.

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 May 3, 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 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 May 26, 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 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 October 23, 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

Chemistry reviews were completed by Scott Wasdo on July 12, 2019, and October 3, 2019.

The final 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:

- An increase in (b) (4) (7%) and decreases in (b) (4) (11%) and (b) (4) (16%)
- Decreases in humectants and flavorings including (b) (4) (b) (4) or 61%), (b) (4) or 21%), Specially (b) (4)

[redacted] or 57%), [redacted] or 30%), and [redacted] or 13%)
- Increases in [redacted] or 207 – 31000%)
- Addition of [redacted] and [redacted]

An increase in [redacted] may increase TSNAs. However, there was a decrease in [redacted], which may have the opposite effect. The applicant provided data confirming that the new and predicate products have analytically equivalent filler levels of NNN and NNK. Additionally, the testing data showed analytically equivalent levels of arsenic, cadmium, and nicotine in filler, which indicates that the tobacco blend differences do not raise concerns. With regard to the non-tobacco ingredient differences, the lower levels of humectants and certain flavorings in the new products were expected to produce lower quantities of their combustion products. The higher quantities of [redacted] account for ≤0.15% of tobacco rod weight and were deemed unlikely to measurably affect smoke chemistry.

Additionally, the flavor increases (i.e., [redacted] and additions [redacted] were deferred to toxicology for evaluation, and toxicology issued a deficiency asking for further information on the [redacted] used in the new tobacco products. The applicant provided smoke yields for 1,3-butadiene (a potential combustion product of [redacted] in the new and corresponding predicate tobacco products. Smoke yields of 1,3-butadiene in the new tobacco products were analytically equivalent to those of the corresponding predicate tobacco products. Therefore, the addition of [redacted] does not cause the new products to raise different questions of public health in regard to product chemistry.

For SE0015207, in addition to the differences identified by the chemistry reviewer, I noted a change in tip from polyethylene to wood. However, this change in cigar tip is not a concern because it is a non-combusted component.

Therefore, the differences do not cause the new products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Jimin Kim on June 11, 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:

- Decrease in tobacco filler mass (14.5%)
- Decrease in tobacco rod density (10.4%)
- Decrease in tobacco rod moisture (12%)

- Decrease in wrapper moisture (14.3%)
- Decrease in binder moisture (22.6%)
- Tobacco cut sizes of [redacted] in the new tobacco products, compared to tobacco cut sizes of [redacted] in the predicate tobacco products
- Increase in the percentage of [redacted] processed at [redacted] (23.5%) and [redacted] (52.4%)
- Increase in the percentage of [redacted] processed at [redacted] (13.8%)

A decrease in tobacco filler mass may reduce smoke TNCO yields because there is less tobacco burned. A decrease in tobacco rod density may modify burn properties and decrease TNCO yields. Decreases in tobacco rod, wrapper, and binder moisture may affect the temperature at which the coal burns, which in turn affects combustion and burn rate, and similarly result in a favorable decrease in smoke TNCO yields. However, there are multiple changes in the tobacco cut size. A change in tobacco cut size may affect the size of particulate matter and impact TNCO yields. The overall effect of tobacco cut size differences was inconclusive from an engineering perspective. Thus, the engineering review defers the evaluation of smoke TNCO yields to the chemistry review. However, HPHC data was submitted only for tobacco filler. Therefore, evaluation of smoke TNCO was not performed. The chemistry review considered that the changes in tobacco cut size are within a relatively narrow range in this case and therefore, are unlikely to have a measurable impact on tar or relevant HPHC (i.e., B[a]P) based on available information. Furthermore, since there are multiple changes that can potentially reduce TNCO yields and the fact that the tobacco filler HPHC data are analytically equivalent, the chemistry review concluded that smoke HPHC data is not needed.

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 Almaris Alonso Claudio on June 6, 2019.

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

- Filler: removal of [redacted] and [redacted] both preservatives; 33% decrease in (b) (4), 61% decrease in (b) (4), 1% decrease in [redacted], 21% decrease in [redacted], all humectants
- Wrapper: removal of [redacted] and addition of [redacted]; 9 % decrease in (b) (4)
- Binder: removal of [redacted] and addition of [redacted]; 33% increase in (b) (4)
- Seam adhesive: 10% decreases in [redacted] and [redacted]
- Finished product:

- 22% decrease in total moisture content (15.89% vs 20.28%, respectively)
- 30% decrease in total (b) (4) content
- 3% increase in NNN content and 0.3% decrease in NNK 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 (< 16%), ≤ 3% variations in NNK and NNN of the new tobacco products compared to the corresponding predicate tobacco products, identical container-closure systems and lack of fermented tobacco in the new tobacco products, the differences in humectant and preservative content do not raise concerns from a microbiological 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 microbiology perspective.

4.4. TOXICOLOGY

Toxicology reviews were completed by Mary Irwin on June 6, 2019, and October 1, 2019.

The final 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:

- Decreases in or removal of 54 ingredients including (b) (4) (b) (4) or 49.6%), (b) (4) (b) (4) | (b) (4) or 61%), (b) (4) or 21%), (b) (4) or 57%), (b) (4) (b) (4) or 30%), and (b) (4) or 13%)
- Increases in (b) (4) or 207 – 31000%)

The reductions or removals of ingredients include several respiratory toxicants (e.g., (b) (4) acetaldehyde) and ingredients associated with formation of a wide variety of HPHCs (e.g., (b) (4), (b) (4) |, (b) (4), (b) (4)). While the ingredients increased or newly added in the new tobacco products are associated with respiratory irritation and potential production of HPHCs, the order of magnitude in larger decreases in other ingredients likely offsets these relatively small increases. Moreover, as stated above (section 4.1), the higher quantities of (b) (4) account for ≤0.15% of tobacco rod weight and are unlikely to measurably affect smoke chemistry. In the original submission, there was a lack of detailed information about the complex ingredient (b) (4) used in

the new tobacco products. In the amendment, the applicant confirmed that this complex ingredient was not made to their specifications but provided uniquely identifying information requested. Furthermore, the applicant provided 1,3-butadiene in smoke data to support that the inclusion of [redacted] does not raise different questions of public health. There were no analytically non-equivalent changes in 1,3-butadiene in the new tobacco products as 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Rudaina Alrefai-Kirkpatrick on May 13, 2019, and September 26, 2019. An addendum review was completed by Rudaina Alrefai-Kirkpatrick on October 7, 2019.

The final environmental review found that the U.S. Environmental Protection Agency's online database indicated a 'noncompliance' or a 'violation' status involving RCRA for Philip Morris USA's manufacturing facility/complex in Richmond, VA where the manufacturing facility for the new products is located. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- An increase in [redacted] (7%) and decreases in [redacted] (11%) and [redacted] (16%) [redacted]
- Decreases in or removal of 54 ingredients including [redacted], or 49.6%), [redacted] or 57%), [redacted] or 61%), [redacted] or 21%), [redacted] or 30%), and [redacted] or 13%)
- Increases in [redacted] or 207 – 31000%)
- Addition of [redacted] and [redacted]
- Decrease in tobacco filler mass (14.5%)
- Decrease in tobacco rod density (10.4%)
- Decrease in tobacco rod moisture (12%)
- Decrease in wrapper moisture (14.3%)
- Decrease in binder moisture (22.6%)
- Multiple changes in tobacco cut size between [redacted]
- Replacement of a plastic tip with wood tip (SE0015207)

The new tobacco products have decreases in (b) (4) and overall tobacco mass which will reduce HPHC yields due to less tobacco available for combustion. Although there is an increase in (b) (4), the testing data in cigar tobacco filler shows analytically equivalent quantities of NNN, NNK, arsenic, cadmium, and nicotine, indicating that tobacco blend changes do not cause the new products to raise different questions of public health. Although there are increases or addition of seven ingredients, 54 other ingredients are decreased or removed from the new tobacco products. The much larger decreases in non-tobacco ingredients are expected to offset the effects of the relatively small increases of the seven ingredients, based on both the chemistry and toxicology reviews. The addition of (b) (4), a complex ingredient, may increase 1,3-butadiene, an HPHC considered to be a carcinogen, respiratory toxicant, and reproductive or developmental toxicant.[4] The applicant submitted uniquely identifying information for (b) (4) as well as smoke yields for 1,3-butadiene (a potential combustion product of (b) (4)) in both the new and corresponding predicate tobacco products, which were determined to be analytically equivalent by the chemistry review. In terms of design parameters, there are decreases in tobacco moisture contents and rod density, which are expected to reduce HPHC yields. Although there are some changes in tobacco cut size, however, in this case, the cut size differences are considered relatively narrow, and therefore, are unlikely to cause a measurable effect on smoke yields such as tar or B[a]P based on available information. Therefore, taken all together, 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 product meets statutory requirements because it was determined that it is a grandfathered product (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 found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing SE orders.

An Environmental Information Request letter should be issued requesting the following information:

> All your SE Reports contain information that your manufacturing facility is compliant with all applicable environmental regulations, including regulations under Resource Conservation and Recovery Act (RCRA). However, FDA became aware on October 1, 2019, that the U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) database indicates a noncompliance or a violation status of RCRA provisions. This violation citation is for Philip Morris USA's manufacturing facility complex in Richmond, VA where the manufacturing facility for the new products is located. Evidence that the manufacturing facility is compliant with relevant federal, state, and local environmental regulations provides information for assessing environmental impacts due to manufacturing the new products. The significance of environmental impacts (and thus the justification for a finding of no significant

[4] *Federal Register*, Vol. 77, No. 64, April 3, 2012, 20034 – 200037.

impact) is, in part, indicated by whether the actions may violate federal, state, or local law or requirements imposed for the protection of the environment (40 CFR 1508.27(b)(10)). Provide documentation from the Virginia Department for Environmental Quality (VADEQ) that the violation listed in the EPA's ECHO database has been resolved or that a solution satisfactory to VADEQ is in progress. If the current violation has not been resolved, discuss how any potential violations, including the RCRA violation described above, affects your compliance with the applicable environmental regulations.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an SE order letter should be issued for the new tobacco products in SE0015206 and SE0015207, as identified on the cover page of this review.