

Technical Project Lead (TPL) Review: SE0015642, SE0015645 and SE0015647

SE0015642: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 millimeters (mm)
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015645: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015647: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 3
Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.03.26 08:05:08 -04'00'

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: 2020.03.26 08:11:04 -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:

SE0015642: Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015645: Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015647: Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	None
Characterizing Flavor	None
Additional Property	Tipping Paper 3

The predicate tobacco products are combusted, filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 8, 2020, FDA received three SE Reports (SE0015642, SE0015645 and SE0015647) from Altria Client Services, LLC (ALCS) on behalf of Philip Morris USA Inc. On January 16, 2020, FDA issued an Acceptance letter to the applicant.

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 Maria Suarez on January 15, 2020.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015642, SE0015645, and SE0015647 were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under:	SE Order Date
SE0015642	Chesterfield Box	SE0014892	January 15, 2019
SE0015645	Chesterfield Box	SE0014907	January 15, 2019
SE0015647	Chesterfield Box	SE0014815	September 27, 2018

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the new tobacco products are 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 February 27, 2020, 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 Lida Oum on February 21, 2020.

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:

- Addition of (b) (4) mg/cig)
- Removal ((b) (4) µg/cig of (b) (4)) or decrease (b) (4) µg/cig) of other ingredients in the monogram ink
- Addition of (b) (4) mg/cig (b) (4) in the tipping adhesive

The applicant provided certification statements for all SE Reports, certifying that the new and corresponding predicate tobacco products have identical characteristics except for minor differences in cigarette paper, monogram ink, and tipping adhesive. From a chemistry perspective, the only change in these components that may result in increases of harmful potentially harmful constituents (HPHCs) is the addition of (b) (4) mg/cig). This change may increase acetaldehyde, benzene, and benzo[a]pyrene. The applicant provided smoke yields for tar and 14 HPHCs, including nicotine, CO, acetaldehyde, benzene, and benzo[a]pyrene, for SE0015647 measured under International Organization of Standardization (ISO) and Health Canada Intense (CI) as surrogates for all three SE Reports. From a chemistry perspective, tar and HPHCs data for the new and predicate tobacco products in SE0015647 is acceptable as surrogates for all SE Reports. A comparison using the two one-sided test (TOST) indicates that all smoke yields are analytically equivalent.

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 Robert Meyer on February 20, 2020.

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:

The new tobacco products have the following differences compared to the corresponding predicate tobacco products:

- 5% increase in band width

It is determined that the cigarette paper is similar from an engineering perspective, with exception to a 5% increase in band width. The 5% increase may increase the tar, nicotine, and CO (TNCO) yields, so engineering defers this change to chemistry for their consideration. 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. TOXICOLOGY

A toxicology review was completed by Jueichuan Kang on February 21, 2020.

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:

- Increase in (b) (4) mg/cig absolute change)
- Decrease in (b) (4) mg/cig absolute change)
- Increase in (b) (4) mg/cig absolute change)
- Increase of (b) (4) mg/cig absolute change)
- Addition of (b) (4) mg/cig)
- Addition of (b) (4) mg/cig)
- Addition of (b) (4) mg/cig)

For all SE Reports, (b) (4) is added to the tipping adhesive in the new tobacco products, which does not impact the smoke chemistry. Furthermore, the smoker is not expected to have direct oral or dermal contact with any residual (b) (4) in the tipping adhesive as the glue is bound at the tipping paper seam which is covered by the tipping paper. However, there are changes in the cigarette paper in the burned portion of the new tobacco products, compared to their corresponding predicate tobacco products. These changes include increases in (b) (4), (b) (4), (b) (4), and additions of (b) (4) and (b) (4). Collectively, from a toxicology perspective, these changes could result in increases in smoke yields for CO, acetaldehyde, acrolein, formaldehyde, 1,3-butadiene, benzene, and benzo[a]pyrene. However, there are also decrease in (b) (4) and increase in (b) (4), which are expected to cause the cigarette paper to burn faster, thereby, results in lower puff counts, and decreased tar and HPHC yields. The applicant provided data for tar and the aforementioned HPHCs under ISO and CI regimens, and all smoke yields as reported are analytically equivalent between the new and corresponding predicate tobacco products by a TOST (two one-sided test) analysis.

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 Ronald Edwards on February 7, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 27, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 27, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Increase in (b) (4) mg/cig absolute change)
- Increase in (b) (4) mg/cig absolute change)
- Increase of (b) (4) mg/cig absolute change)
- Addition of (b) (4) mg/cig)
- Addition of (b) (4) mg/cig)
- Addition of (b) (4) mg/cig)
- Removal (b) (4) µg/cig of (b) (4)) or decrease (b) (4) µg/cig) of other ingredients in the monogram ink
- Decrease in (b) (4) mg/cig absolute change)
- 5% increase in band width

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For all SE Reports, addition of (b) (4) to the tipping adhesive and removal or decreases in monogram ink ingredients are not expected to impact smoke chemistry. Furthermore, the smoker is not expected to have direct oral or dermal contact with any residual (b) (4) in the tipping adhesive. However, the changes in the cigarette paper in the burned portion of the new tobacco products may impact smoke chemistry. These changes include increases in (b) (4) and additions of (b) (4). Collectively, these changes may result in increases in HPHC yields for CO, acetaldehyde, acrolein, formaldehyde, 1,3-butadiene, benzene, and benzo[a]pyrene. A 5% increase in band width could also increase TNCO yields. On the other hand, there are decrease in (b) (4) and increase in (b) (4), which are expected to cause the cigarette paper to burn faster, thereby, result in decreased tar and HPHC yields. The applicant provided data for tar and the aforementioned HPHCs under ISO and CI regimens, and all smoke yields as reported are analytically equivalent between the new and corresponding predicate tobacco products. 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 were previously determined to be substantially equivalent by FDA under SE0014892, SE0014907 and SE0014815.

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 products in SE0015642, SE0015645 and SE0015647 were previously determined to be substantially equivalent by FDA under SE0014892, SE0014907 and SE0014815, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Basic Full Flavor Box in SE0014892, Basic Full Flavor Box in SE0014907 and Basic Full Flavor Box in SE0014815) reveals that the new tobacco products have the following differences in characteristics from the Basic Full Flavor Box, the grandfathered tobacco product:

- Changes in cigarette paper
 - Increase in (b) (4) mg/cig absolute change)
 - Increase in (b) (4) mg/cig absolute change)
 - Increase of (b) (4) mg/cig absolute change)
 - Addition of (b) (4) mg/cig)
 - Addition of (b) (4) mg/cig)
 - Decrease in (b) (4) mg/cig absolute change)
 - 5% increase in band width
- Addition of (b) (4) mg/cig) in tipping glue
- Removal (b) (4) µg/cig of (b) (4) or decrease (b) (4) µg/cig) of other ingredients in the monogram ink
- Changes in base tipping paper, tipping ink, and tipping ink extender
 - Removal of (b) (4) from tipping ink (b) (4) mg/cig) and tipping ink extender (b) (4) mg/cig)
 - Addition of (b) (4) mg/cig) in the base tipping paper
 - Addition of (b) (4) mg/cig), (b) (4) mg/cig), and (b) (4) mg/cig) in the base tipping paper (SE001564)
 - Addition of (b) (4) mg/cig) and (b) (4) mg/cig) in the base tipping paper (SE0015647)

The differences in characteristics listed above, other than the differences in cigarette paper, tipping glue, and monogram ink, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014892, SE0014907 and SE0014815. Therefore, these differences do not cause the new tobacco products in SE0015642, SE0015645 and SE0015647 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in cigarette paper, tipping glue, and monogram ink between the new tobacco products in SE0015642, SE0015645 and SE0015647 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015642, SE0015645 and SE0015647 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

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 SE0015642, SE0015645, and SE0015647, as identified on the cover page of this review.