

**Technical Project Lead (TPL) Review:**

**SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300,  
SE0004303 – SE0004306, SE0004309, and SE0004310**

<b>SE0004287: Marlboro 25's Box</b>	
Package Type	Hard Pack
Package Quantity	25 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004290: Marlboro Blend No. 27 Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004291: Marlboro Blend No. 27 Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004292: Marlboro Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	12%
Characterizing Flavor	None
Additional Properties	(b) (4)

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

<b>SE0004295: Marlboro Gold Pack Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	24%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004296: Marlboro Gold Pack Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	24%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004297: Marlboro Menthol Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	18%
Characterizing Flavor	Menthol
Additional Properties	(b) (4)
<b>SE0004298: Marlboro Menthol Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	18%
Characterizing Flavor	Menthol
Additional Properties	(b) (4)

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

<b>SE0004299: Marlboro Menthol Gold Pack Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	34%
Characterizing Flavor	Menthol
Additional Properties	(b) (4)
<b>SE0004300: Marlboro Menthol Gold Pack Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89
Ventilation	34%
Characterizing Flavor	Menthol
Additional Properties	(b) (4)
<b>SE0004303: Marlboro Red Label Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	22%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004304: Marlboro Red Label Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	22%
Characterizing Flavor	None
Additional Properties	(b) (4)

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

<b>SE0004305: Marlboro Soft Pack</b>	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004306: Marlboro Eighty-Threes Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004309: Marlboro Special Blend (Red Pack) Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>SE0004310: Parliament (White Pack) Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	35%
Characterizing Flavor	None
Additional Properties	(b) (4)
<b>Common Attributes of SE Reports</b>	
Applicant	Philip Morris USA, Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2018.06.06 16:01:39 -04'00'

Matthew J. Walters, Ph.D., MPH  
CDR, US Public Health Service  
Deputy Director  
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: 2018.06.06 16:15:45 -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:

<b>SE0004287: Marlboro 25's Box</b>	
Product Name	Marlboro Box 25's
Package Type	Hard Pack
Package Quantity	25 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
<b>SE0004290: Marlboro Blend No. 27 Box</b>	
Product Name	Marlboro Blend No. 27 Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	None
<b>SE0004291: Marlboro Blend No. 27 Soft Pack</b>	
Product Name	Marlboro Blend No. 27 Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	14%
Characterizing Flavor	None
<b>SE0004292: Marlboro Box</b>	
Product Name	Marlboro Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	12%
Characterizing Flavor	None

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<b>SE0004295: Marlboro Gold Pack Box</b>	
Product Name	Marlboro Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	None
<b>SE0004296: Marlboro Gold Pack Soft Pack</b>	
Product Name	Marlboro Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	None
<b>SE0004297: Marlboro Menthol Box</b>	
Product Name	Marlboro Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	21%
Characterizing Flavor	Menthol
<b>SE0004298: Marlboro Menthol Soft Pack</b>	
Product Name	Marlboro Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	21%
Characterizing Flavor	Menthol



TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

<b>SE0004299: Marlboro Menthol Gold Pack Box</b>	
Product Name	Marlboro Lights Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
<b>SE0004300: Marlboro Menthol Gold Pack Soft Pack</b>	
Product Name	Marlboro Lights Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
<b>SE0004303: Marlboro Red Label Box</b>	
Product Name	Marlboro Medium Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
<b>SE0004304: Marlboro Red Label Soft Pack</b>	
Product Name	Marlboro Medium Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

<b>SE0004305: Marlboro Soft Pack</b>	
Product Name	Marlboro Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
<b>SE0004306: Marlboro Eighty-Threes Box</b>	
Product Name	Marlboro Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
<b>SE0004309: Marlboro Special Blend (Red Pack) Box</b>	
Product Name	Marlboro Medium Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
<b>SE0004310: Parliament (White Pack) Box</b>	
Product Name	Parliament Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	35%
Characterizing Flavor	None

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

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received the SE Reports on April 6, 2012, and subsequently issued Acknowledgement letters on April 26, 2012, for SE0004310, June 20, 2012, for SE0004287, and SE0004290 – SE0004292, June 28, 2012, for SE0004295 – SE0004300, and October 10, 2012, for SE0004303 – SE0004306, and SE0004309. FDA issued an Advice/Information (A/I) Request letter on May 3,

2012, for SE0004310. In response, FDA received an amendment (SE0004557) on May 30, 2012, containing other features when comparing the new and predicate tobacco products and the environmental assessment for SE0004310. On August 7, 2012, FDA received unsolicited amendments (SE0004799, SE0004802 – SE0004807, SE0004810 – SE0004813, SE0004816, SE0004819, SE0004822, and SE0004823) containing the environmental assessments for the original SE Reports. FDA issued a Notification letter on November 30, 2012, indicating scientific review was expected to begin on January 14, 2013. On January 18, and February 14, 2013, FDA received unsolicited amendments (SE0006391, SE0007203) for SE0004310. On April 17, 2013, FDA received an amendment (SE0008239) containing the environmental assessment for SE0004300 and amendment (SE0008240) containing the response to FDA's A/I Request letter dated April 10, 2013, for SE0004292. FDA issued an A/I Request letter on April 19, 2013. On May 9, May 31, and June 18, 2013, FDA received extension requests (SE0008460, SE0008805, and SE0009053) to allow time to develop appropriate response to the A/I letter, due to CTP by June 18, 2013. On May 15, and July 8, 2013, FDA issued extension request denial letters to deny the May 9, and May 31, 2013 requests, respectively. On July 16, 2013, FDA received an appeal (AP0000001) of the extension request denials. FDA did not respond to the June 18, 2013, extension request, because the appeal of the May extension request denials was received before FDA had responded to this extension request in June. FDA denied the appeal on July 8, 2013. On September 6, 2013, FDA received the applicant's response to the A/I letter (SE0009686, SE0009687, SE0009690, SE0009693, SE0009695 – SE0009699, SE0009701, SE0009703 – SE0009706, SE0009710, and SE0009711). On September 6, 2013, FDA received an unsolicited amendment (SE0009712) containing published reference files for the original reports for all SE Reports.

The applicant submitted amendments (SE0009766, SE0009768, SE0009769, SE0009771-SE0009773, and SE0009767) on September 11, 2013. On September 11, 2013, FDA received an unsolicited amendment (SE0009774) containing a request to withdraw (b) (4) for all SE Reports, as the new tobacco products containing (b) (4) were being reviewed under March 18, 2011, SE Reports. On September 13, 2013, FDA received the applicant's updated response to the A/I letter (SE0009794 and SE0009795) with supplemental information for SE0004309 and SE0004310. On September 20, 2013, FDA received an amendment containing the requested information (SE0009813, SE0009815, SE0009817, SE0009818, SE0009821 – SE0009823, SE0009826 – SE0009830, SE0009831, and SE0009833). FDA issued an Acknowledgment Correction letter on October 25, 2013, to correct FDA records to include a change to the applicant product identification for the original SE Reports. On November 6, 2013, FDA issued an A/I Extension Granted letter with a response due date of November 22, 2013. On September 3, 2015, FDA received an unsolicited amendment (SE0012355) containing corrections to the ingredient list included in the original SE Reports. FDA issued a Preliminary Finding (Pfind) letter on June 28, 2017. On July 5, 2017, FDA received the applicant's 92-day extension request (SE0014194) to conduct studies needed for HPHC data. On July 26, 2017, FDA issued an extension granted letter with a response due date of October 28, 2017. On October 4, 2017, FDA received the applicant's 16-day extension request (SE0014370) to the extension request issued on July 26, 2017, to obtain laboratory results for studies needed for HPHC data. On October 19, 2017, FDA issued an extension granted letter with a response due date of November 13, 2017. On November 13, 2017, FDA received the response to the PFind letter (SE0014401). FDA issued a PFind letter on February 9, 2018. On March 8, 2018, FDA received the response to the PFind letter (SE0014572). On May 23, 2018, FDA received an unsolicited amendment (SE0014732) which provided a correction to SE0014572. The amendment was

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received after the scientific review was completed. The TPL reviewed the amendment and found that the changes provided did not change the scientific discipline reviews and therefore did not affect this TPL Review.

Product Name	SE Report	Amendments
Marlboro 25's Box	SE0004287	SE0004819 SE0008460 SE0008805 SE0009053 SE0009687 SE0009712 SE0009774 SE0009813 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Blend No. 27 Box	SE0004290	SE0004822 SE0008460 SE0008805 SE0009053 SE0009686 SE0009712 SE0009774 SE0009818 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Blend No. 27 Soft Pack	SE0004291	SE0004823 SE0008460 SE0008805 SE0009053 SE0009690 SE0009712 SE0009774 SE0009817 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

Marlboro Box	SE0004292	SE0004799 SE0008240 SE0008460 SE0008805 SE0009053 SE0009693 SE0009712 SE0009774 SE0009815 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Gold Pack Box	SE0004295	SE0004802 SE0008460 SE0008805 SE0009053 SE0009695 SE0009712 SE0009766 SE0009774 SE0009821 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Gold Pack Soft Pack	SE0004296	SE0004803 SE0008460 SE0008805 SE0009053 SE0009697 SE0009712 SE0009769 SE0009774 SE0009822 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Menthol Box	SE0004297	SE0004804 SE0008460 SE0008805

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

		SE0009053 SE0009696 SE0009712 SE0009774 SE0009823 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Menthol Soft Pack	SE0004298	SE0004805 SE0008460 SE0008805 SE0009053 SE0009711 SE0009712 SE0009774 SE0009826 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Menthol Gold Pack Box	SE0004299	SE0004806 SE0008460 SE0008805 SE0009053 SE0009698 SE0009712 SE0009774 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Menthol Gold Pack Soft Pack	SE0004300	SE0008239 SE0008460 SE0008805 SE0009053 SE0009699 SE0009712 SE0009774 SE0012355 SE0014194 SE0014370

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

		SE0014401 SE0014572 SE0014732
Marlboro Red Label Box	SE0004303	SE0004810 SE0008460 SE0008805 SE0009053 SE0009701 SE0009712 SE0009768 SE0009774 SE0009829 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Red Label Soft Pack	SE0004304	SE0004811 SE0008460 SE0008805 SE0009053 SE0009703 SE0009712 SE0009767 SE0009774 SE0009827 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Soft Pack	SE0004305	SE0004812 SE0008460 SE0008805 SE0009053 SE0009712 SE0009705 SE0009774 SE0009830 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732

TPL Review for SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310

Marlboro Eighty-Threes Box	SE0004306	SE0004813 SE0008460 SE0008805 SE0009053 SE0009704 SE0009712 SE0009771 SE0009774 SE0009828 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Marlboro Special Blend (Red Pack) Box	SE0004309	SE0004816 SE0008460 SE0008805 SE0009053 SE0009710 SE0009712 SE0009772 SE0009774 SE0009794 SE0009833 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572 SE0014732
Parliament (White Pack) Box	SE0004310	SE0004557 SE0006391 SE0007203 SE0008460 SE0008805 SE0009053 SE0009706 SE0009712 SE0009773 SE0009774 SE0009795 SE0009831 SE0012355 SE0014194 SE0014370 SE0014401 SE0014572



**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 Jonathan Kwan on May 3, 2012, June 21, 2012, April 10, 2013.

The final 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 as of February 15, 2007). The OCE reviews<sup>1</sup> dated December 20, 2012, December 21, 2012, January 4, 2013, January 24, 2013, and February 5, 2013, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated May 15, 2018, 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 Kimberly Agnew-Heard on March 28, 2013, and August 19, 2014, and by Jikun Liu on January 24, 2018.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition compared to the predicate tobacco products but

<sup>1</sup> Addendum reviews were completed on June 6, 2013, June 7, 2013, June 10, 2013, June 12, 2013, and June 13, 2013, to clarify the product quantity, length and package type, and on March 9, 2018, and March 12, 2018, to clarify the characterizing flavor of the predicate tobacco products as “none”. The addendums do not change the conclusion of the initial grandfather determinations dated December 20, 2012, December 21, 2012, January 4, 2013, January 24, 2013, and February 5, 2013.

the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following issues related to product composition:

- SE0004287, SE0004292, SE0004295, SE0004296, SE0004303 – SE0004306, SE0004309, and SE0004310: 30% – 36% higher amounts of (b) (4)
- SE0004297 – SE0004300: 69% higher level of (b) (4) and 20% higher amount of (b) (4)
- All SE Reports: higher amounts of total (b) (4) and/or (b) (4) in the cigarette paper
- SE0004287, SE0004295 – SE0004298, SE0004303 – SE0004306, SE0004309, and SE0004310: increased yields of (b) (4) under ISO and CI regimens
- SE0004287, SE0004292, SE0004305 and SE0004306: increased CO yields (12% under ISO regimen, and 8% – 10% under CI regimen)

Due to changes in tobacco blends and ingredients, FDA needed select HPHCs to determine if changes in the tobacco blends and ingredients influence HPHC yields and determine whether these changes cause the new products to raise different questions of public health. The applicant no longer had the predicate products available for testing, as such, the applicant provided surrogate predicate products to bridge the surrogate product to the predicate product for HPHC testing. The surrogate predicate products have the same or similar characteristics in terms of tobacco blends, ingredients, and design features to those of the original predicate products and was determined to be an acceptable bridge to the predicate tobacco products. The evaluation of the HPHC data from the 2017 surrogate predicate products indicates that although some of the HPHCs are increased in the new products, the smoke yields of the new and predicate products are statistically 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 related to product composition.

#### 4.2. ENGINEERING

Engineering reviews were completed by Christian Coyle on March 25, 2013, by Komal Ahuja on August 6, 2014, and by James Cheng on January 23, 2018.

The final engineering review concludes that the new tobacco products have different characteristics related to product design 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 issues related to product design:

- Alternate cigarette paper supplier
- Change in tipping paper weight
- SE0004297 – SE0004300, SE0004305 - SE0004306, and SE0004310: Decrease (1 – 2%) in cigarette filler weight
- SE0004297 – SE0004298: Decrease (14%) in filter ventilation
- SE0004303, SE0004304, and SE0004309: Increase (10% – 15%) in filter ventilation

- SE0004299 – SE0004300: Increase in filter tow
- SE0004303 – SE0004304, SE0004309: Decrease in filter tow
- SE0004305 - SE0004306: Decrease (1%) in cigarette length

The design specifications for the new and predicate products are similar in value with only minor differences such as cigarette length and filter ventilation. For design parameters that differ, the applicant provided TNCO test results for the new and predicate products that demonstrate that the TNCO yield values of the new products are lower than or comparable to the yields of the corresponding predicate 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 related to product design.

### 4.3. TOXICOLOGY

Toxicology reviews were completed by Hans Rosenfeldt on April 8, 2013, by Xin Fu on December 5, 2016, and by Wanyoike Kangethe on January 19, 2018.

The final 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 related to product toxicology:

- Addition of or increases in cigarette paper ingredients: (b) (4)
- Addition of or increases in cigarette seam adhesive ingredients: (b) (4)
- Increase in (b) (4) offset by decrease in (b) (4)
- -2% to 35% difference in amounts of (b) (4)
- SE0004297–SE0004300: Increase in (b) (4)

The evaluation of these differences was based on HPHC data provided, which showed that smoke yields of HPHCs that have been associated with combustion/pyrolysis of: (b) (4)

(b) (4) were statistically equivalent between the new and corresponding predicate products. The most significant difference in the tobacco blend was an increase in (b) (4). However, increased levels of ingredients such as (b) (4) that were reported in the (b) (4) used in the new products where there were decreases in these ingredients in other components of the tobacco blend and this increase in (b) (4) does not cause the new products to raise different questions of public health. Furthermore, TNCO and TSNAs yields under ISO and CI smoking regimens for the new and corresponding predicate products were 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 related to toxicology.

#### 4.4. SOCIAL SCIENCE

Social science reviews were completed by David Portnoy on March 13, 2013, and June 27, 2014.

The final social science review concludes that the characteristics which may affect consumer perception and use are the same for the new and corresponding predicate tobacco products. The review also evaluated the health information summary for each SE Report. FDA has determined that statements provided for these SE Reports which are required in a health information summary pursuant to section 910(a)(4) of the FD&C Act do not constitute modified risk claims. The applicant's health information summary for each new tobacco product does not potentially violate section 911.

#### 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 6, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 6, 2018.

#### 6. CONCLUSION AND RECOMMENDATION

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

- SE0004287, SE0004292, SE0004295, SE0004296, SE0004303 – SE0004306, SE0004309, and SE0004310: 30% – 36% higher amounts of (b) (4)
- SE0004297 – SE0004300: 69% higher level of (b) (4) and 20% higher amount of (b) (4)
- All SE Reports: higher amounts of total (b) (4) and/or (b) (4) in the cigarette paper
- SE0004287, SE0004295 – SE0004298, SE0004303 – SE0004306, SE0004309, and SE0004310: increased yields of (b) (4) under ISO and CI regimens
- SE0004287, SE0004292, SE0004305 and SE0004306: increased CO yields (12% under ISO regimen, and 8% – 10% under CI regimen)
- Alternate cigarette paper supplier
- Change in tipping paper weight
- SE0004297 – SE0004300, SE0004305 - SE0004306, and SE0004310: Decrease (1 – 2%) in cigarette filler weight
- SE0004297 – SE0004298: Decrease (14%) in filter ventilation
- SE0004303, SE0004304, and SE0004309: Increase (10% – 15%) in filter ventilation
- SE0004299 – SE0004300: Increase in filter tow
- SE0004303 – SE0004304, SE0004309: Decrease in filter tow

- SE0004305 - SE0004306: Decrease (1%) in cigarette length
- Addition of or increases in cigarette paper ingredients: (b) (4)
- Addition of or increases in cigarette seam adhesive ingredients: (b) (4)
- Increase in (b) (4) offset by decrease in (b) (4)
- SE0004297–SE0004300: Increase in (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Although some of the HPHCs have higher yields between the new and corresponding surrogate predicate tobacco products, these differences are statistically equivalent and the increases do not cause the new products to raise different questions of public health. Furthermore, the differences in design parameters tobacco blends, and ingredients did not significantly influence the HPHC yields between the new and corresponding surrogate predicate 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 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States 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 SE0004287, SE0004290 – SE0004292, SE0004295 – SE0004300, SE0004303 – SE0004306, SE0004309, and SE0004310 as identified on the cover page of this review.