

**Technical Project Lead (TPL) Review:**
SE0012332-SE0012353 and SE0012356

SE0012332: Basic Blue Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012333: Basic Blue Pack Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012334: Basic Gold Pack 100's Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012335: Basic Gold Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012336: Basic Gold Pack 100's Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2

SE0012337: Basic Gold Pack Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012338: Basic Menthol Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0012339: Basic Menthol Gold Pack Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0012340: Basic Menthol Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0012341: Basic Menthol Silver Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2

SE0012342: Cambridge Gold Pack 100s Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	23%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012343: Cambridge Gold Pack Kings Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012344: L&M Blue Pack 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012345: L&M Blue Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0012346: Marlboro 72s Gold Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.9 mm
Filter Ventilation	31%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2

SE0012347: L&M Bold Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	79 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0012348: Marlboro Gold Pack 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0012349: Marlboro Gold Pack 100s Soft Pack	
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0012350: Marlboro Silver Pack 100s Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	50%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0012351: Marlboro Silver Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	46%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3

SE0012352: Marlboro Special Blend (Gold Pack) 100's Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0012353: Basic Menthol Gold Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0012356: Dave's Blue Pack Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
Common Attributes of SE Reports	
Applicant	Altria Client Services on behalf of Philip Morris USA, Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.12.01 14:21:43 -05'00'

Matthew R. Holman, Ph.D.
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 David Ashley -S
Date: 2015.12.01 15:28:56 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0012332	Basic Blue Pack Box
Product Name	Basic Ultra Lights Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	None
SE0012333	Basic Blue Pack Soft Pack
Product Name	Basic Ultra Lights Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	None
SE0012334	Basic Gold Pack 100's Box
Product Name	Basic Light 100's Box
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	None
SE0012335	Basic Gold Pack Box
Product Name	Basic Lights Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	None

SE0012336	Basic Gold Pack 100's Soft Pack
Product Name	Basic Light 100's Box
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	None
SE0012337	Basic Gold Pack Soft Pack
Product Name	Basic Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	None
SE0012338	Basic Menthol Box
Product Name	Basic Menthol Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0012339	Basic Menthol Gold Pack Soft Pack
Product Name	Basic Menthol Lights Soft Pack
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	None

SE0012340	Basic Menthol Soft Pack
Product Name	Basic Menthol Box (2007)
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0012341	Basic Menthol Silver Pack Box
Product Name	Basic Menthol Ultra Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	Menthol
Additional Property	None
SE0012342	Cambridge Gold Pack 100s Soft Pack
Product Name	Cambridge Lights 100's Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	99mm
Diameter	7.9 mm
Filter Ventilation	23%
Characterizing Flavor	None
Additional Property	None
SE0012343	Cambridge Gold Pack Kings Soft Pack
Product Name	Cambridge Lights Kings Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	None

SE0012344	L&M Blue Pack 100s Box
Product Name	Basic Lights 100's Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	99mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	None
SE0012345	L&M Blue Pack Box
Product Name	Basic Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Marlboro Lights Seventy-Twos Box
Package Type	Box
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.9 mm
Filter Ventilation	31%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Basic Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

SE0012346	Marlboro 72s Gold Pack Box
Product Name	Marlboro Lights 100's Box
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Marlboro Lights 100's Box
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	28%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Marlboro Ultra Lights 100's Box
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	50%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Marlboro Ultra Lights Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	46%
Characterizing Flavor	None
Additional Property	None

SE0012346	Marlboro Special Blend (Gold Pack) 100's Box
Product Name	Marlboro Lights 100's Box
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	28%
Characterizing Flavor	None
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Basic Menthol Lights Soft Pack
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	None
SE0012346	Marlboro 72s Gold Pack Box
Product Name	Basic Lights Soft Pack
Package Type	Soft pack
Package Quantity	20 cigarettes
Length	84mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted 23 SE Reports on September 3, 2015. The new and predicate tobacco products in these SE Reports are similar to the new and predicate tobacco products, respectively, in 23 SE Reports¹ submitted by the applicant in August 2013. FDA issued SE orders for the twenty-three 2013 SE Reports on June 16, 2015. During a June 24, 2015, teleconference, the applicant informed FDA that it had discovered inaccurate information was provided to FDA regarding reconstituted tobacco sheet ingredients found in the new and predicate tobacco products in the

¹ In August 2013, after holding a series of teleconferences with the applicant, the applicant submitted the following SE Reports: SE0009409 - SE0009411, SE0009413 - SE0009415, SE0009417 - SE0009423, SE0009425, SE0009426, SE0009428 - SE0009431, SE0009432, SE0009434, SE0009473, and SE0009475, which will be referred hereafter as the "2013 SE Reports."

2013 SE Reports. This inaccurate information was due to miscalculations in ingredient quantities. The applicant then provided the revised ingredients and calculations for those 23 SE Reports on July 2, 2015 (TC0001329). After review of the submission, FDA determined that the corrected inaccuracies constitute a change in the new and predicate products characteristics, thus creating distinctly different predicate products and distinctly different new products from those submitted in the 2013 SE Reports. Due to this, new premarket submissions are required for these products with the corrected ingredient quantities. The applicant submitted new SE Reports that are the subject of this TPL review on September 3, 2015. As explained by the applicant during conversations with FDA after the July 2, 2013, submission, these 2015 SE Reports are identical to the 2013 SE Reports except that they contain (1) different reconstituted tobacco sheet ingredient quantities and (2) a statement certifying that the content of these SE Reports is identical to the corresponding 2013 SE Reports except for the inaccurate ingredient information in 2013 SE Reports.

On October 23, 2015, FDA emailed the applicant with a list of amendments to the 2013 SE Reports that were not included in the corresponding 2015 SE Reports. In response, the applicant submitted amendments to the 2015 SE Reports on October 26, 2015, that contained all of the missing amendments from the 2013 SE Reports (SE0012522-SE0012545). Therefore, after receipt of the amendments on October 26, 2015, the contents of the 2013 and 2015 SE Reports were identical except for the inaccurate ingredient quantities in the 2013 SE Reports.

On October 28, 2015, FDA held a teleconference with the applicant to clarify the ingredient quantity information for the new and predicate tobacco products in the 2015 SE Reports. More specifically, the applicant explained that the material composition ingredient quantities in certain materials (tipping paper and adhesive, cigarette paper, and plug wrap) in the new and predicate tobacco products differed between the 2013 SE Reports and 2015 SE Reports. In response to the teleconference, the applicant submitted amendments on November 13, 2015 (SE0012603-SE0012625). The amendments clearly identified the differences in the material ingredients in the new and predicate tobacco products between the 2013 SE Reports and 2015 SE Reports, and explained the source of the differences:²

1. Supplier Update³: "We received updated information from the manufacturers of some materials. We have certification/verification that the material was not being made any differently, but rather the information was being reported to us differently. This update applied to both New Product and Predicate Product information. In all cases the materials reported in 2015 are identical to the materials reported in 2013."

² The explanations provided below are taken verbatim from the November 13, 2015, amendments.

³ This explanation as to the differences in material ingredients is applicable to all of the 2015 SE Reports.

2. Assumptions⁴: “As we continue to refine the assumptions we use to calculate and report data on materials, we have adjusted some of the assumptions we use for these calculations. Neither the material nor the material information we receive from the vendors has changed, only the assumptions we used to calculate what we reported based on that information were updated. This update applied to both New Product and Predicate Product information. In all cases the materials reported in 2015 are identical to the materials reported in 2013.”
3. Corrections: “As we reviewed the information being resubmitted we noticed we had erroneously reported materials in the 2013 Report, but this does not change what we intended to use in the New Product. These updates only applied to New Product information. None of these apply to Predicate Product Information. These fall into 3 categories:
 - a. For 2 New Products⁵ we neglected to include the (b) (4) (b) (4) in the table. The material being supplied by the vendor did not change.
 - b. For 2 New Products⁶ we inadvertently left one chemical off the list. The material being supplied by the vendor did not change.
 - c. For 5 New Products⁷ we listed the incorrect composition information in the table for the cigarette paper (the information provided was for a cigarette paper used on other products). At the time of submission of the 2013 Reports for the New Product that are the subject of the 2015 Reports, we intended to use the material reported in the 2015 Reports.”

FDA held a teleconference with the applicant on November 19, 2015. In response, the applicant submitted an amendment on November 20, 2015, confirming the following:

1. The design parameter information for the cigarette papers in the 2013 SE Reports are identical to those in the corresponding 2015 SE Reports.
2. The HPHC data submitted in the 2013 SE Reports was collected from the products containing the cigarette papers identified in the 2015 SE Reports.

⁴ This explanation as to the differences in material ingredients is applicable to SE0012332, SE0012333, SE0012334, SE0012336, SE0012338, SE0012340, SE0012341, SE0012342, SE0012343, SE0012344, SE0012347, SE0012348, SE0012349, and SE0012352.

⁵ This explanation as to the differences in material ingredients is applicable to SE0012332 and SE0012333.

⁶ This explanation as to the differences in material ingredients is applicable to SE0012353 and SE0012339.

⁷ This explanation as to the differences in material ingredients is applicable to SE0012348, SE0012350, SE0012351, SE0012352, and SE0012349.

3. The material quantities (expressed as mg/cigarette) in the April 22, 2014, amendments to the 2013 SE Reports (SE0010417 and SE0010418) were identical to those in the 2015 SE Reports.

The third clarification was needed in order for FDA to convert the material ingredient quantities from percentages (provided in the November 13, 2015, amendments) to quantities expressed as mg/cigarettes (in the December 1, 2015, chemistry review).

Product Name	2015 SE Report & Amendments ⁸	2013 SE Report
Basic Blue Pack Box	SE0012332 SE0012523 SE0012604 SE0012691	SE0009419
Basic Blue Pack Soft Pack	SE0012333 SE0012522 SE0012603 SE0012691	SE0009426
Basic Gold Pack 100s Box	SE0012334 SE0012524 SE0012606 SE0012691	SE0009418
Basic Gold Pack Box	SE0012335 SE0012526 SE0012605 SE0012691	SE0009410
Basic Gold Pack 100s Soft Pack	SE0012336 SE0012528 SE0012607 SE0012691	SE0009425
Basic Gold Soft Pack	SE0012337 SE0012527 SE0012609 SE0012691	SE0009422
Basic Menthol Box	SE0012338 SE0012525 SE0012608 SE0012691	SE0009415

⁸ Bolded STNs are SE Reports. Non-bolded STNs are amendments.

Product Name	2015 SE Report & Amendments ⁸	2013 SE Report
Basic Menthol Gold Pack Soft Pack	SE0012339 SE0012532 SE0012612 SE0012691	SE0009476
Basic Menthol Box Soft Pack	SE0012340 SE0012529 SE0012611 SE0012691	SE0009423
Basic Menthol Silver Pack	SE0012341 SE0012530 SE0012610 SE0012691	SE0009417
Cambridge Gold Pack 100s Soft Pack	SE0012342 SE0012533 SE0012613 SE0012691	SE0009421
Cambridge Gold Pack King Soft Pack	SE0012343 SE0012531 SE0012616 SE0012691	SE0009420
L&M Blue Pack 100s Box	SE0012344 SE0012544 SE0012617 SE0012691	SE0009411
L&M Blue Pack Box	SE0012345 SE0012535 SE0012615 SE0012691	SE0009413
Marlboro 72's Gold Pack Box	SE0012346 SE0012536 SE0012614 SE0012691	SE0009475
L&M Bold Box	SE0012347 SE0012534 SE0012619 SE0012691	SE0009414
Marlboro Gold Pack 100s Box	SE0012348 SE0012537 SE0012620 SE0012691	SE0009428

Product Name	2015 SE Report & Amendments ⁸	2013 SE Report
Marlboro Gold Pack 100s Soft Pack	SE0012349 SE0012539 SE0012621 SE0012691	SE0009434
Marlboro Silver Pack 100s Box	SE0012350 SE0012538 SE0012618 SE0012691	SE0009429
Marlboro Silver Pack Box	SE0012351 SE0012545 SE0012623 SE0012691	SE0009430
Marlboro Special Blend (Gold Pack) 100s Box	SE0012352 SE0012542 ⁹ SE0012543 SE0012624 SE0012691	SE0009432
Basic Menthol Gold Pack Box	SE0012353 SE0012540 SE0012625 SE0012691	SE0009473
Dave's Blue Pack Box	SE0012356 SE0012541 SE0012622 SE0012691	SE0009409

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for the applicant's 2013 SE Reports as well as the regulatory and chemistry reviews completed for SE0012332-SE0012353 and SE0012356. Staff within my division compared the contents of the 2013 SE Reports with the contents of SE0012332-SE0012353 and SE0012356. Division staff determined that SE0012332-SE0012353 and SE0012356 and the corresponding 2013 SE Reports are identical with the exception of a certification statement in SE0012332-SE0012353 and SE0012356 and minor differences in some ingredients in the reconstituted tobacco and in some material ingredients. In the certification statements, the senior vice president of Altria Client Services LLC certifies that SE0012332-SE0012353 and SE0012356 are identical to the corresponding 2013 SE Reports except for information about the reconstituted tobacco and material ingredients in the new and predicate tobacco products.

⁹ Amendments SE0012542 and SE0012543 are duplicate copies of one another.

Because of this certification statement and confirmation of its accuracy by division staff, the conclusions of the compliance and scientific reviews for the 2013 SE Reports are applicable to SE0012332-SE0012353 and SE0012356 except that a chemistry review was completed by Kimberly Agnew-Heard on December 1, 2015, to evaluate the reconstituted tobacco ingredients and material ingredients in SE0012332-SE0012353 and SE0012356. Therefore, this TPL review states the same information found in the June 15, 2015, TPL reviews for the 2013 SE Reports except that the chemistry review was completed by Kimberly Agnew-Heard on December 1, 2015, is also discussed in this TPL review. This TPL review also discusses the regulatory reviews, environmental assessment, and finding of no significant impact (FONSI) completed for SE0012332-SE0012353 and SE0012356.

2. REGULATORY REVIEW

Regulatory reviews were completed by Nathan Hurley on September 17, 2015.

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 completed in June 2012, September 2012, and October 2012 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.¹⁰

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 November 7, 2014, and November 30, 2015, conclude that the new tobacco products are in compliance with the FD&C Act.

¹⁰ In June 2013, OCE completed an addendum review to include package type and quantity as part of the identification of the predicate tobacco products.

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 Michael Koenig on October 23, 2012, and by Kimberly Agnew-Heard on December 10, 2012, December 11, 2013, January 2, 2014, November 24, 2014, and December 1, 2015.

The final chemistry reviews¹¹ conclude that the new tobacco products have different characteristics related to product composition compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The significant differences in composition are:

- Tobacco blend change
- Different cigarette paper
- (b)(4) in tipping paper

The quantity of tobacco decreased in the new tobacco products. In addition, the relative quantities of each type of tobacco changed, with the most significant change being an increase in the quantity of reconstituted tobacco. Because the absolute quantity of reconstituted tobacco is small, the relative quantity change was not significant. There are differences in the ingredient quantities added to the reconstituted tobacco, but the differences in ingredient quantities between the new and corresponding predicate tobacco products are small (i.e., do not exceed than 1 mg/cigarette). There were also differences in some other non-tobacco ingredients, but the differences were small.

The different cigarette paper did not cause significant increases in the yields of tar, nicotine, or carbon monoxide (TNCO) of the new products. TNCO yields

¹¹ The final chemistry reviews for the 2013 SE Reports and the final chemistry review for the 2015 SE Reports conclude that the new tobacco products have different characteristics related to product composition compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The 2015 final chemistry review focused on changes to the reconstituted tobacco and material ingredients that differed between the 2013 SE Reports and the 2015 SE Reports. For the reconstituted tobacco and material ingredients that decreased between the new and corresponding predicate tobacco products in the 2015 SE Reports, it was concluded that such decreases do not cause the new tobacco products to raise different questions of public health. For any other non-significant differences in product composition between the new and corresponding predicate products that are the subjects of the 2013 SE Reports and the 2015 SE Reports, it is appropriate to extrapolate from the 2013 final chemistry reviews. Therefore, the discussion in this section reflects those captured in the final chemistry reviews for the 2013 SE Reports. However, as indicated in the final chemistry review of the 2015 SE Reports, there was a (b)(4) in tipping paper in the new tobacco products than identified in the final chemistry reviews of the 2013 SE Reports. Therefore, discussion of (b)(4) in tipping paper is added in this TPL review.

decreased or increased slightly in the new tobacco products. The increased yields were not significantly different than the yields for the predicate tobacco products when variability in yield measurements were considered. In addition, TSNA quantities support a finding of substantial equivalence because the (b) (4) by at (b) (4) in comparison to the corresponding predicate products.

(b)(4) in the tipping paper of the new tobacco products by (b) (4) compared to the corresponding predicate tobacco products. (b) (4)

Therefore, users are not expected to inhale or ingested and (b)(4) (b)(4) from the tipping paper.

Taken together, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by James Melchiors on October 2, 2012, and December 16, 2013, Christian Coyle on December 11, 2012, and December 30, 2013, and by Komal Singh on November 24, 2014.

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 significant differences in product design are:

- Different cigarette paper
- (b)(4) decrease in puff count
- (b)(4) increase in cigarette paper band width
- (b)(4) decrease in plug wrap porosity¹²
- (b)(4) increase in pressure drop¹³
- (b)(4) increase in filter tow total denier¹³
- (b)(4) increase in filter density¹³

There were also differences in some other design parameters, but the differences were small. The decreased plug wrap porosity is compensated for by the increased tipping permeability. The increased filter tow total denier and filter density does not cause the new tobacco product to raise different questions of

¹² SE0012350 only

¹³ SE0012346 only

public health because these changes would either not affect or increase filter efficiency. For all of the SE Reports, tar yields decreased or increased slightly in the new tobacco products. The increased yields were not significantly different than the yields for the predicate tobacco products when variability in yield measurements were considered.

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

4.3. TOXICOLOGY

Toxicology reviews were completed by Hans Rosenfeldt on October 25, 2012, and December 11, 2012, and by Sheila Healy on March 19, 2014, and on May 8, 2015.

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 toxicology review identifies an increase in reconstituted tobacco, and the corresponding amount of ingredients, as a difference in characteristics between the new and corresponding predicate products for all of the SE Reports. All of the ingredients are present in the reconstituted tobacco at lower quantities than found in the corresponding predicate tobacco products or are only slightly higher in the reconstituted tobacco. Therefore, the increase in reconstituted tobacco does not cause the new tobacco products to raise different questions of public health. The review also identifies the following key differences in characteristics between the new and corresponding predicate tobacco products for all of the SE Reports except SE0012349:

(b) (4)

Because the estimated exposure levels of (b) (4) and (b) (4) (b) (4) in the new tobacco products are less than occupational exposure limits, the addition of (b) (4) does not cause the new tobacco products to raise different questions of public health. The totality of the data indicates that (b) (4) And, because the estimated exposure to individual (b) (4) products produced by the new tobacco products are less than occupational exposure limits, the addition of (b) (4) does not cause the new tobacco products to raise different questions of public health. Likewise, because the estimated exposure to (b) (4) in the new tobacco products is approximately (b) (4) than the exposure resulting from acceptable occupational exposure to (b) (4), the addition

(b) (4) does not cause the new tobacco products to raise different questions of public health. Therefore, the differences in characteristics related to product toxicology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.4. SOCIAL SCIENCE

Social science reviews for SE0012332-SE0012338, SE0012340-SE0012345, SE0012347-SE0012352, and SE0012356 were completed by Greta Tessman on December 17, 2013, and June 30, 2014.

The final social science review concludes that the new tobacco products have different characteristics related to social science 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 issues discussed in the review are:

- Change in cigarette paper between the new and corresponding predicate tobacco products
- Package quantity of 25 cigarettes for the new and predicate tobacco products¹⁴
- Health information summary

The review concludes that the change in cigarette paper does not cause the new tobacco products to raise different questions of public health from a social science perspective. The review considered the package quantity because there is a legal requirement to include a minimum of 20 cigarettes per package (section of the FD&C Act). However, because the package quantity is identical for the new and predicate tobacco products and the package quantity satisfies the legal requirements, the review concludes that this issue does not cause the new tobacco product to raise different questions of public health. A deficiency concerning the health information summary was included in the Preliminary Finding letter. In response to the Preliminary Finding letter, the applicant replaced the health information summary with a health information statement (i.e., the applicant will make a health information summary available upon request by any interested party). Therefore, the social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective.

There was an oversight and a social science review was not completed for SE0012339, SE0012346, and SE0012353. I conclude that these new tobacco

¹⁴ SE0009427 only

products have different characteristics related to social science 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 new and corresponding predicate tobacco products have different cigarette papers. Based on the June 30, 2014, social science review for SE0012332-SE0012338, SE0012340-SE0012345, SE0012347-SE0012352, and SE0012356, the change in cigarette paper does not cause the new tobacco products to raise different questions of public health. All of the new and predicate tobacco products contain 20 cigarettes. I did not identify any other differences in characteristics related to social science in these SE Reports. Although the Preliminary Finding letter for these SE Reports did not include a deficiency regarding the health information summary, the applicant replaced the health information summary with a health information statement in response to this letter based on the general information about health information summary included in the letter. Therefore, I conclude that these new tobacco products have different characteristics related to social science from the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 24, 2015. The FONSI was supported by an environmental assessment prepared by FDA on November 24, 2015.

6. CONCLUSION AND RECOMMENDATION

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

- Tobacco blend change (decrease in total quantity and significantly different relative quantities of each tobacco type)



- Different cigarette paper
- (b)(4) in tipping paper¹⁶
- Decrease in puff count (b)(4)
- Increase in cigarette paper band width (b)(4)
- Decreased plug wrap porosity (b)(4)¹⁷
- Increase in pressure drop (b)(4)¹⁸

¹⁵ All SE Reports *except* SE0012349.

¹⁶ All SE Reports *except* SE0012338, SE0012340, SE0012344, SE0012345, SE0012347.

¹⁷ SE0012350 only.

¹⁸ SE0012346 only.

- Increase in filter tow total denier (b)(4))¹⁸
- Increase in filter density (b)(4))¹⁸

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Toxicant levels from [REDACTED] are below occupational exposure limits. Therefore, addition of these ingredients does not cause the new tobacco products to raise different questions of public health. The TNCO yield and TSNA filler quantities were decreased or only slightly increased in the new tobacco products relative to the corresponding predicate tobacco products. Because HPHC yields do not increase significantly, these 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.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

All of 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 SE0012332-SE0012353 and SE0012356, as identified on the cover page of this review.