



**Technical Project Lead (TPL) Review: SE0009409-
SE0009411; SE0009413-SE0009415; SE0009417-
SE0009423; SE0009425-SE0009426; SE0009428-
SE0009430; SE0009432; SE0009434**

SE0009409: Dave's Blue Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009410: Basic Gold Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009411: L&M Blue Pack 100's Box	
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009413: L&M Blue Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2

SE0009414: L&M Bold Box	
Package Type	Box
Package Size	20 cigarettes
Length	79 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0009415: 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	Cigarette Paper 2
SE0009417: Basic Menthol Silver Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Tobacco Cut Size	30 cuts/in
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0009418: Basic Gold Pack 100's Box	
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009419: Basic Blue Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2

SE0009420: Cambridge Gold Pack Kings Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009421: Cambridge Gold Pack 100's Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	23%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009422: Basic Gold Pack Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009423: Basic Menthol Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0009425: Basic Gold Pack 100's Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2

SE0009426: Basic Blue Pack Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009428: Marlboro Gold Pack 100's Box	
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0009429: Marlboro Silver Pack 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	Cigarette Paper 3
SE0009430: Marlboro Silver Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	46%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
SE0009432: Marlboro Special Blend (Gold Pack) 100's Box	
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26%
Characterizing Flavor	None
Additional Property	Cigarette Paper 3

SE0009434: Marlboro Gold Pack 100's Soft Pack	
Package Type	Soft pack
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26 %
Characterizing Flavor	None
Additional Property	Cigarette Paper 3
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	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.06.15 18:36:19 -04'00'

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: 2015.06.15 20:42:06 -04'00'

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:

SE0009409: Dave's Blue Pack Box	
Product Name	Basic Lights Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	18 %
Characterizing Flavor	None
Additional Property	None
SE0009410: Basic Gold 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
SE0009411: L&M Blue Pack 100's Box	
Product Name	Basic Lights 100's Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	20 %
Characterizing Flavor	None
Additional Property	None
SE0009413: 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

SE0009414: L&M Bold 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
SE0009415: 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
SE0009417: Basic Menthol Silver Pack Box	
Product Name	Basic Menthol Ultra Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83
Diameter	7.9
Filter Ventilation	43 %
Characterizing Flavor	Menthol
Additional Property	None
SE0009418: Basic Gold Pack 100's Box	
Product Name	Basic Lights 100's Box
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20 %
Characterizing Flavor	None
Additional Property	None

SE0009419: Basic Blue Pack Box	
Product Name	Basic Ultra Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43 %
Characterizing Flavor	None
Additional Property	None
SE0009420: 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 %
Tobacco Cut Size	30 cuts/in
Characterizing Flavor	None
Additional Property	None
SE0009421: Cambridge Gold Pack 100's Soft Pack	
Product Name	Cambridge Lights 100's Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	23 %
Characterizing Flavor	None
Additional Property	None
SE0009422: 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

SE0009423: 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
SE0009425: Basic Gold Pack 100's Soft Pack	
Product Name	Basic Lights 100's Box
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	20 %
Characterizing Flavor	None
Additional Property	None
SE0009426: Basic Blue Pack Soft Pack	
Product Name	Basic Ultra Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	43 %
Characterizing Flavor	None
Additional Property	None
SE0009428: Marlboro Gold Pack 100's Box	
Product Name	Marlboro Lights 100's Box
Package Type	Box
Package Size	20 cigarettes
Length	98 mm
Diameter	7.9 mm
Filter Ventilation	26 %
Characterizing Flavor	None
Additional Property	None

SE0009429: Marlboro Silver Pack 100's 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
SE0009430: Marlboro Silver Pack Box	
Product Name	Marlboro Ultra Lights Box
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	46 %
Characterizing Flavor	None
Additional Property	None
SE0009432: Marlboro Special Blend (Gold Pack) 100's 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
SE0009434: Marlboro Gold Pack 100's Soft Pack	
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

The predicate tobacco products are combusted, filtered cigarettes manufactured by Philip Morris USA, Inc.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 5, 2011, the applicant submitted 20 original SE Reports (SE0003654 – SE0003656, SE0003658 – SE0003660, SE0003662 – SE0003668,

SE0003670 – SE0003671, SE0003705, SE0003707 – SE0003708, SE0003710, and SE0004210). On April 23, 2012, FDA sent the applicant Advice/Information (A/I) request letters for these SE Reports. In response, the applicant submitted amendments to the original SE Reports. The applicant also submitted unsolicited amendments. Following our review of the original and amended SE Reports, FDA sent A/I letters to the applicant on November 2, 2012. On November 15, 2012, the applicant submitted a request for an extension to respond to the A/I letter, which FDA granted on November 28, 2012. The applicant responded to the A/I letter by amending their SE Reports. Teleconferences with the applicant were held on August 12 and 14, 2013 and on September 6, 2013 during which FDA informed the applicant that the multiple cigarette papers (Cigarette Paper 1 and Cigarette Paper 2 or Cigarette Paper 3) used in the new products constituted different new products such that each SE Report contained 2 new products. Because a change in cigarette paper makes up a distinct tobacco product, in August 2013, FDA created additional STNs from the original SE Reports to capture the change in paper as distinct products and submissions. For the new products containing Cigarette Paper 2 and Cigarette Paper 3, the following new STNs were assigned: SE0009409-SE0009411; SE0009413-SE0009415; SE0009417-SE0009423; SE0009425-SE0009426; SE0009428-SE0009430; SE0009432, and SE0009434.

[REDACTED]

Also, in October 2013, FDA sent the applicant Acknowledgement letters for the new products containing Cigarette Paper 2 and Cigarette Paper 3. The SE Reports and amendments in the Table below reflect those for the new products containing Cigarette Paper 2 and Cigarette Paper 3. Following our review of the amended SE Reports, FDA sent a Preliminary Finding letter to the applicant on March 25, 2014. The applicant responded to the Preliminary Finding letter by amending their SE Reports. FDA held a teleconference with the applicant on October 24, 2014, to clarify several engineering deficiencies. In response, the applicant submitted an additional amendment (SE0010723). FDA held a teleconference with the applicant on November 18, 2014, to discuss a number of questions the response to which is needed to complete the environmental assessment of the products under review. The applicant submitted an amendment (SE0010750) containing information related to the environmental assessment.

TPL Review for SE0009409-SE0009411; SE0009413–SE0009415; SE0009417–
 SE0009423; SE0009425-SE0009426; SE0009428–SE0009430; SE0009432; SE0009434

Product Name	SE Report	Amendments
Dave's Blue Pack Box	SE0009409	SE0004532 SE0005211 SE0007146 SE0008330 SE0008345 SE0009666 SE0009775 SE0009843 SE0010014 SE0010417 SE0010723 SE0010750
Basic Gold Pack Box	SE0009410	SE0004534 SE0005211 SE0007146 SE0008330 SE0008331 SE0009654 SE0009775 SE0009844 SE0010014 SE0010417 SE0010723
L&M Blue Pack 100's Box	SE0009411	SE0004535 SE0005211 SE0006082 SE0007146 SE0008330 SE0008346 SE0009663 SE0009775 SE0009845 SE0010014 SE0010417 SE0010723 SE0010750

TPL Review for SE0009409-SE0009411; SE0009413–SE0009415; SE0009417–
 SE0009423; SE0009425-SE0009426; SE0009428–SE0009430; SE0009432; SE0009434

Product Name	SE Report	Amendments
L&M Blue Pack Box	SE0009413	SE0004533 SE0005211 SE0007146 SE0008330 SE0008347 SE0009664 SE0009775 SE0009846 SE0010014 SE0010417 SE0010723 SE0010750
L&M Bold Box	SE0009414	SE0004536 SE0005211 SE0007146 SE0008330 SE0008348 SE0009665 SE0009775 SE0009850 SE0010014 SE0010417 SE0010723 SE0010750
Basic Menthol Box	SE0009415	SE0004537 SE0005211 SE0007146 SE0008330 SE0008342 SE0009656 SE0009775 SE0009848 SE0010014 SE0010417 SE0010723 SE0010750

Product Name	SE Report	Amendments
Basic Menthol Silver Pack Box	SE0009417	SE0004539 SE0005211 SE0007146 SE0008330 SE0008371 SE0009658 SE0009775 SE0009847 SE0010014 SE0010417 SE0010723 SE0010750
Basic Gold Pack 100's Box	SE0009418	SE0004540 SE0005211 SE0006083 SE0007146 SE0008330 SE0008328 SE0009653 SE0009775 SE0009851 SE0010014 SE0010417 SE0010723 SE0010750
Basic Blue Pack Box	SE0009419	SE0004541 SE0005211 SE0007146 SE0008330 SE0008325 SE0009650 SE0009775 SE0009853 SE0010014 SE0010417 SE0010723 SE0010750

TPL Review for SE0009409-SE0009411; SE0009413–SE0009415; SE0009417–
 SE0009423; SE0009425-SE0009426; SE0009428–SE0009430; SE0009432; SE0009434

Product Name	SE Report	Amendments
Cambridge Gold Pack Kings Soft Pack	SE0009420	SE0004542 SE0005211 SE0007146 SE0008330 SE0008344 SE0009659 SE0009775 SE0009854 SE0010014 SE0010417 SE0010723 SE0010750
Cambridge Gold Pack 100's Soft Pack	SE0009421	SE0004543 SE0005211 SE0006036 SE0007146 SE0008330 SE0008333 SE0009660 SE0009775 SE0009986 SE0010014 SE0010417 SE0010723 SE0010750
Basic Gold Pack Soft Pack	SE0009422	SE0004544 SE0005211 SE0007146 SE0008330 SE0008339 SE0009651 SE0009775 SE0009852 SE0010014 SE0010417 SE0010723 SE0010750

TPL Review for SE0009409-SE0009411; SE0009413–SE0009415; SE0009417–
 SE0009423; SE0009425-SE0009426; SE0009428–SE0009430; SE0009432; SE0009434

Product Name	SE Report	Amendments
Basic Menthol Soft Pack	SE0009423	SE0004545 SE0005211 SE0007146 SE0008330 SE0008343 SE0009662 SE0009775 SE0009855 SE0010014 SE0010417 SE0010723 SE0010750
Basic Gold Pack 100's Soft Pack	SE0009425	SE0004547 SE0005211 SE0006037 SE0007146 SE0008330 SE0008329 SE0009652 SE0009775 SE0009859 SE0010014 SE0010417 SE0010723 SE0010750
Basic Blue Pack Soft Pack	SE0009426	SE0004548 SE0005211 SE0007146 SE0008327 SE0008330 SE0009775 SE0009858 SE0010014 SE0010417 SE0010723 SE0010750

Product Name	SE Report	Amendments
Marlboro Gold Pack 100's Box	SE0009428	SE0004930 SE0005211 SE0006034 SE0007146 SE0008330 SE0008341 SE0009071 SE0009675 SE0009775 SE0009863 SE0010014 SE0010417 SE0010723 SE0010750
Marlboro Silver Pack 100's Box	SE0009429	SE0004932 SE0005211 SE0006035 SE0007146 SE0008330 SE0008350 SE0009072 SE0009673 SE0009775 SE0009862 SE0010014 SE0010417 SE0010723 SE0010750
Marlboro Silver Pack Box	SE0009430	SE0004933 SE0005211 SE0007146 SE0008330 SE0008370 SE0009073 SE0009667 SE0009775 SE0009861 SE0010014 SE0010417 SE0010723 SE0010750

Product Name	SE Report	Amendments
Marlboro Special Blend (Gold Pack) 100's Box	SE0009432	SE0004935 SE0005211 SE0006032 SE0007146 SE0008330 SE0008338 SE0009075 SE0009676 SE0009775 SE0009864 SE0010014 SE0010417 SE0010723 SE0010750
Marlboro Gold Pack 100's Soft Pack	SE0009434	SE0004931 SE0005211 SE0006033 SE0007146 SE0008330 SE0008336 SE0009077 SE0009672 SE0009775 SE0009865 SE0010014 SE0010417 SE0010723 SE0010750

1.3. SCOPE OF REVIEW

This memo captures all administrative, compliance, and scientific reviews completed for these SE Reports.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Jonathan Kwan on March 23, 2012, and June 21, 2012, for SE0009409-SE0009411; SE0009413–SE0009415; SE0009417–SE0009423; and SE0009425-SE0009426. Administrative completeness reviews were completed by Nathan Hurley on June 5, 2013, and July 5, 2013, for SE0009428–SE0009430; SE0009432, and SE0009434.

The final completeness reviews¹ 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 products² are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated June 2012 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.³

The Office of Compliance and Enforcement (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 November 7, 2014, concludes that the new tobacco products are in compliance with the FD&C Act. The OCE review dated May 18, 2015, is an addendum to the November 7, 2014, review and concludes that the new tobacco products are still in compliance with section 919 of the FD&C Act (user fees).

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 11, 2013, and November 24, 2014.

The final chemistry review concludes 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

¹ The completeness reviews were completed for the original SE Reports (i.e., original STNs) with two cigarette papers for each tobacco product. When the new SE Reports (i.e., new STNs) were created with a single cigarette paper (Cigarette Paper 2 or Cigarette Paper 3) for each tobacco product, the administrative reviews for the original SE Reports were applied to the new SE Reports.

² It should be noted that, in its April 2014 amendment (SE0010417), the applicant provides information for “additional predicate products” alongside the information for the new and predicate products identified in the SE Reports prior to conducting scientific review. As explained in the OS memorandum dated January 20, 2015, the additional predicate products were not considered during FDA’s review of the SE Reports because scientific review had already begun.

³ In June 2013, OCE completed an addendum review to include package type and quantity as part of the identification of the predicate tobacco products.

raise different questions of public health. The significant differences in composition are:

(b) (4)

The (b) (4) in the new tobacco products. In addition, the (b) (4) changed, with the most significant change being a (b) (4). Because the (b) (4) (b) (4) the (b) (4) (b) (4) change was not significant. There were also differences in some other (b) (4) but the differences were small.

The different (b) (4) did not cause (b) (4) of the new products. For 14 of the SE Reports, (b) (4) in the new tobacco products relative to the corresponding predicate tobacco products. (b) (4) were noted in 6 of the new products but none of these were (b) (4) and, when (b) (4) values were considered, did not appear to differ significantly.

Therefore, 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, and by Komal Ahuja 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:

(b) (4)

(b) (4). For 14 of the SE Reports, (b) (4); for 6 of the SE Reports, (b) (4) were noted in the new tobacco products. The (b) (4) were not significantly different than the (b) (4) for

the predicate tobacco products when [REDACTED] (b) (4) 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, 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 [REDACTED] (b) (4), and the corresponding [REDACTED] (b) (4), as a difference in characteristics between the new and corresponding predicate products for all of the SE Reports. (b) (4)

[REDACTED]. Therefore, the [REDACTED] (b) (4) 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 SE0009434:

[REDACTED] (b) (4)

Because the estimated exposure levels of benzene and phthalate from (b) (4) (b) (4) in the new tobacco products are less than occupational exposure limits, the addition of [REDACTED] (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) has low toxicity via the inhalation route. And, because the estimated exposure to individual (b) (4) products produced by the new tobacco products are less than occupational exposure limits, the [REDACTED] (b) (4) does not cause the new tobacco products to raise different questions of public health. Likewise, because the estimated exposure to [REDACTED] (b) (4) in the new tobacco products is approximately [REDACTED] (b) (4) than the exposure resulting from acceptable occupational exposure to [REDACTED] (b) (4), the (b) (4) of [REDACTED] (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 were completed by Greta Tessman on December 17, 2013, and June 30, 2014.

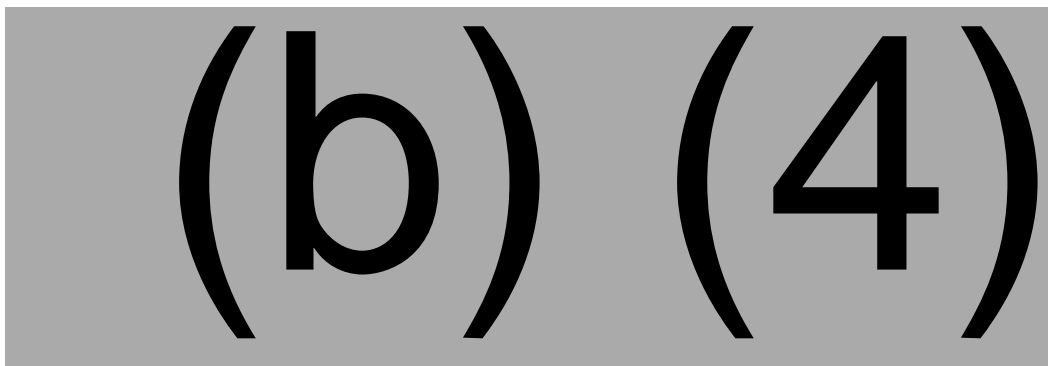
The social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The review also evaluated the adequacy of the health information summary. 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 differences in characteristics related to social science between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 2, 2015. The FONSI was supported by an environmental assessment prepared by FDA on June 2, 2015.

6. CONCLUSION AND RECOMMENDATION

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



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 (b) (4) are below occupational exposure limits. Therefore, (b) (4) does not

cause the new tobacco products to raise different questions of public health. For 14 of the SE Reports, (b) (4) in the new tobacco product relative to the corresponding predicate tobacco product. In 6 SE Reports, there were (b) (4) emitted by the new tobacco product relative to the corresponding predicate tobacco product. However, the (b) (4) were not significant and do not reflect a meaningful change (b) (4). Because (b) (4) by insignificant amounts in the new products, 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.

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 SE0009409-SE0009411; SE0009413-SE0009415; SE0009417-SE0009423; SE0009425-SE0009426; SE0009428-SE0009430; SE0009432; and SE0009434, as identified on the cover page of this review.