Technical Project Lead (TPL) Review: SE0009473, SE0009475, SE0009476

SE0009473: Basic Menthol Gold Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	Cigarette Paper 2
SE0009475: Marlboro 72's Gold Pack Box	
Package Type	Box
Package Size	20 cigarettes
Length	72 mm
Diameter	7.9 mm
Filter Ventilation	31%
Characterizing Flavor	None
Additional Property	Cigarette Paper 2
SE0009476: Basic Menthol Gold Pack Soft Pack	
Package Type	Soft Pack
Package Size	20 cigarettes
Length	83 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
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: 2015.06.15 18:39:10 -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 20:42:47 -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:

SE0009473: Basic Menthol Gold Pack Box	
Product Name	Basic Menthol Lights Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
Additional Property	None
SE0009475: Marlboro 72's Gold Pack Box	
Product Name	Marlboro Lights Seventy-Twos Box
Package Type	Box
Package Size	20 cigarettes
Length	72 mm
Diameter	7.9 mm
Filter Ventilation	31%
Characterizing Flavor	None
Additional Property	None
SE0009476: Basic Menthol Gold Pack Soft Pack	
Product Name	Basic Menthol Lights Soft Pack
Package Type	Soft pack
Package Size	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	14%
Characterizing Flavor	Menthol
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 November 3, 2011, the applicant submitted 3 original SE Reports (SE0003964, SE0003966, and SE0004124). On January 26, 2012, February 15, 2012, and September 27, 2012, FDA sent the applicant an Advice/Information (A/I) request letter for each of the three reports, respectively. In response, the applicant submitted amendments to the original SE Reports (see Table below). The applicant also submitted unsolicited amendments. Following review of the original and amended SE Reports, FDA sent A/I letters to

the applicant on February 11, 2013. On March 4, 2013, the applicant submitted a request for an extension to respond to the A/I letter, which FDA granted on March 28, 2013. The applicant responded to the A/I letters by amending their SE Reports. Teleconferences with the applicant were held on August 12 and 14, 2013, and September 6, 2013, during which FDA informed the applicant that the multiple cigarette papers (Cigarette Paper 1 and Cigarette Paper 2) 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, the following new STNs were assigned: SE0009473, SE0009475, and SE0009476. (b) (4) Also, in October 2013, FDA sent the applicant acknowledgement letters for the new products containing Cigarette Paper 2. The SE Reports and amendments in the Table below reflect those for the new products containing Cigarette Paper 2. 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 design parameter information. 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 also submitted an amendment (SE0010750) containing information related to the environmental assessment. FDA held a teleconference with the applicant on May 13, 2015, to discuss the deficiency in the health information summary. On May 13, 2015, the applicant submitted an amendment (SE0011762) containing a health information statement.

Product Name	SE Report	Amendments
Basic Menthol Gold Pack Box	SE0009473	SE0004282 SE0004284 SE0007885 SE0009283 SE0009284 SE0009657 SE0009867 SE0010014 SE0010418 SE0010723 SE0010750 SE0011762

Product Name	SE Report	Amendments
Marlboro 72's Gold Pack Box	SE0009475	SE0004312 SE0004383 SE0007885 SE0009283 SE0009287 SE0009869 SE0010014 SE0010418 SE0010723 SE0010750 SE0011762
Basic Menthol Gold Pack Soft Pack	SE0009476	SE0004925 SE0004973 SE0007884 SE0009283 SE0009285 SE0009655 SE0009870 SE0010014 SE0010418 SE0010723 SE0010750 SE0011762

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 for SE0009473 were completed by Nathan Hurley on January 26, 2012, and Jonathan Kwan on June 21, 2012. Administrative completeness reviews for SE0009475 were completed by Nathan Hurley on February 15, 2012, and February 7, 2013. Administrative completeness reviews for SE0009476 were completed by Jonathan Kwan on September 27, 2012, and Nathan Hurley on February 7, 2013.

The final completeness reviews[1] conclude that the SE Reports are administratively complete.

[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) for each tobacco product, the administrative reviews for the original SE Reports were applied to the new SE Reports.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products[2] are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated September 2012 (SE0009473) and October 2012 (SE0009475 and SE0009476) 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 Kimberly Agnew-Heard on December 10, 2012, January 2, 2014, 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 raise different questions of public health. The significant differences in composition are:

(b) (4)

The (b) (4) in all three new tobacco products in spite of identical cigarette dimensions in the new and corresponding predicate tobacco

[2] It should be noted that, in its April 2014 amendment (SE0010418), the applicant provides information for "(b)(4) " 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 (b)(4) 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.

products. And, the (b) (4) changed significantly in all three new tobacco products. Because the (b) (4) is small, the relative (b) (4) change was not significant. There were also differences (b) (4), but the differences were small. (b) (4) were evaluated to determine the effect of these tobacco and cigarette paper differences. The (b) (4) in the new tobacco products (b) (4) in comparison to the corresponding predicate products. For all three SE Reports, (b) (4) slightly in the new tobacco products. The (b) (4) were not significantly different than the (b) (4) for the predicate tobacco products when (b) (4) were considered.

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 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 are different with respect to product design than 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)

There were also differences in some other design parameters, but the differences were small. The (b) (4) in SE0009475 does not cause the new tobacco product to raise different questions of public health because these changes would either not affect (b) (4) For all three SE Reports, (b) (4) in the new tobacco products. The (b) (4) were not significantly different than the (b) (4) for the predicate tobacco products when (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 December 11, 2012, by Sheila Healy on March 19, 2014, and 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 (b) (4), and the corresponding (b) (4), as a difference in characteristics between the new and corresponding predicate products for all of the SE Reports. (b) (4) Therefore, the (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:

(b) (4)

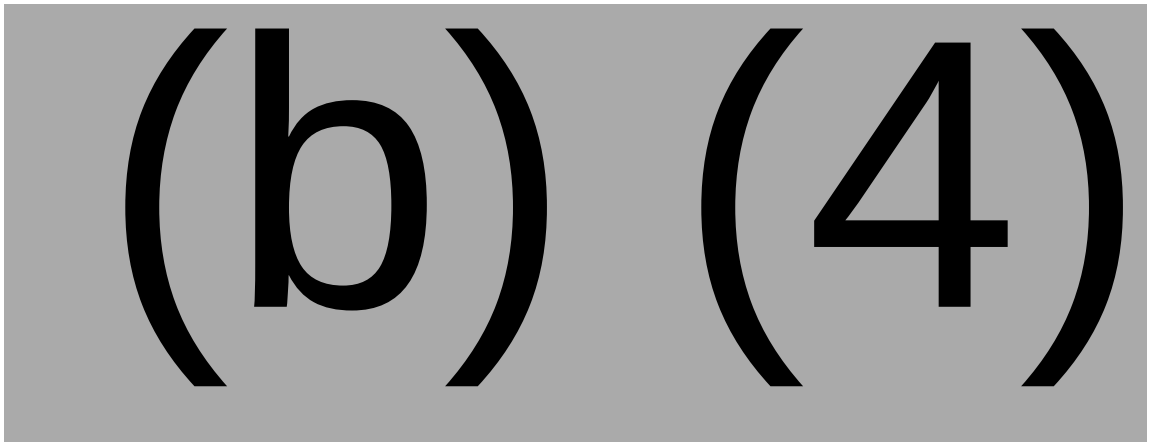
Because the estimated exposure levels of benzene and phthalate from (b) (4) in the new tobacco products are less than occupational exposure limits, the (b) (4) does not cause the new tobacco products to raise different questions of public health. The totality of the data indicates that (b) (4) has low 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 (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 (b) (4) of (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.

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. The (b) (4) in the new tobacco products relative to the corresponding predicate tobacco products. Because HPHC yields do not increase significantly, 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.

A health information summary was included in each SE Report. A social science review was not complete to evaluate the health information summary. However, the health information summary is identical to those included in other SE Reports submitted by the applicant: SE0009408-SE0009434. A social science review completed on December 17, 2013, for SE0009408-SE0009434 concluded that the health information summary is not adequate to satisfy section 910(a)(4) of the FD&C Act. Therefore, the health summary in the SE Reports that are subject of this TPL review is not adequate to satisfy section 910(a)(4) of the FD&C Act. On May 13, 2015, the Office of Science (OS) contacted the applicant to convey this conclusion. In response, the applicant submitted a statement that it will provide an will provide upon request, by any person, an adequate summary of health

information related to the new tobacco product in each SE Report. This statement is sufficient to satisfy 910(a)(4) of the FD&C Act.

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 SE0009473, SE0009475, and SE0009476 as identified on the cover page of this review.