Technical Project Lead (TPL) Review:

SE0013536 and SE0013537

SE0013536: Wave Menthol King Size	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	(b) (4)
Characterizing Flavor	Menthol
Additional Property	Monogrammed tipping paper
SE0013537: Wave Full Flavor King Size	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	(b) (4)
Characterizing Flavor	None
Additional Property	Monogrammed tipping paper
Common Attributes of SE Reports	
Applicant	Japan Tobacco International USA, Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.08.25 12:00:20 -04'00'

For Todd Cecil, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

☐ Concur with TPL recommendation with additional comments (see separate memo)

☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2017.08.25 12:02:29 -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:

SE0013536: Wave Menthol King Size	
Product Name	Wave Menthol King Size
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	(b) (4)
Characterizing Flavor	Menthol
Additional Property	Monogrammed cigarette paper
SE0013537: Wave Full Flavor King Size	
Product Name	Wave Full Flavor King Size
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	(b) (4)
Characterizing Flavor	None
Additional Property	Monogrammed cigarette paper

The predicate tobacco products are Combusted Filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 20, 2016, Japan Tobacco International USA, Inc. (JTI) submitted two substantial equivalence (SE) reports for Wave Menthol King Size (SE0013536) and Wave Full Flavor King Size (SE0013537). The applicant submitted unsolicited amendment SE0013553 on August 2, 2016 to remove a submission tracking number (STN) reference that was included in error in the original submission. FDA issued Acknowledgement letters for the reports on August 3, 2016. FDA issued the applicant an Advice/Information Request (A/I) letter on October 20, 2016. In response, the applicant submitted amendment SE0013773 on December 14, 2016. On December 22, 2016, the applicant submitted solicited amendment SE0013797 to provide an English translation of a lab accreditation document. FDA issued a preliminary finding (PFind) letter on May 2, 2017. In response to the PFind Letter, the applicant submitted amendment SE0014124 on May 26, 2017.

Product Name	SE Report	Amendments
Wave Menthol King Size	SE0013536	SE0013553 SE0013773 SE0013797 SE0014124
Wave Full Flavor King Size	SE0013537	SE0013773 SE0013797 SE0014124

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 Iqra Javaid on August 3, 2016, Antonio Thornton on January 3, 2017, and Sarah Vichensont on June 8, 2017.

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

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review 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 review dated September 1, 2016, concludes 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 reviews 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 February 23, 2017, April 21, 2017, and July 27, 2017 conclude 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 Mimy Young on September 26, 2016 and February 15, 2017.

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 new tobacco products have the following key differences in product composition compared to the predicate tobacco products:

- Both SE Reports contain monogram ink ingredients in the cigarette paper of the predicate products whereas the monogram ink ingredients are present in the (b) (4) of the new products
- Both SE Reports lists that the new products contain differences in ingredients present in the (b) (4) (i.e., (b) (4)) relative to that in the corresponding predicate products

The review concludes that the reported tar, nicotine, and carbon monoxide levels obtained from the smoke yields of all the new tobacco products were (b) (4) than that found in the corresponding predicate tobacco products, which adequately demonstrates that 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. 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 Komal Ahuja on September 19, 2016 and by James Cheng on February 13, 2017. An engineering review addendum was completed by James Cheng on August 10, 2017 to correct target specification values in the February 13, 2017 engineering review.

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 new tobacco products have the following key differences in product design compared to the corresponding predicate tobacco products:

- The new products have an (b) (4) in filter efficiency (b) (4) compared to the corresponding predicate products

The review concludes that the slight (b) (4) in filter efficiency in the new products compared to the predicate products is not expected to have a significant effect on HPHC yields given that that the TNCO yields generated from the new tobacco products have (b) (4) . 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 Juan Crespo-Barreto on October 6, 2016 and February 14, 2017.

The final toxicology review concludes that the new tobacco products have slightly different characteristics related to the complex ingredients compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The changes in the complex ingredients were made to the (b) (4), which is not expected to be combusted or volatized, or otherwise released during normal cigarette consumption, so consumer exposure to added ingredients in the (b) (4) is not expected. Therefore, the changes in the complex ingredients do not raise different questions of public health from a toxicological perspective.

4.4. SOCIAL SCIENCE

Social science reviews were completed by Rhonda Moore on September 23, 2016.

The final social science review concludes that the new tobacco products have different characteristics related to consumer perception 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 tobacco products have a (b) (4) in total cigarette mass than the predicate tobacco products. However, given the small magnitude of change in portion size (b) (4), the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

The applicant submitted a health information summary. 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

Environmental reviews were completed by James Hobson on April 28, 2017. An environmental review addendum was completed by Gregory Gagliano on May 1, 2017 to correct the incorrect citation of some STNs in the May 1, 2017 environmental review.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 3, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 2, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- Differences in total cigarette mass
- Change in the placement of (b) (4)
- Differences in ingredients present in the (b) (4)
- Differences in filter efficiency (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. The difference in total cigarette mass of (b) (4) is of such small magnitude that it does not cause the new products to raise different questions of public health. The differences in the total cigarette mass between the new and predicate tobacco products are due to the change in (b) (4) ingredients made to accommodate the change in placement of the monogram ink (removal of ink from the combusted portion of the cigarette in the predicate product to the (b) (4) r in the new product). The change in the placement of the monogram ink from the portion of the cigarette that is combusted in the predicate tobacco product to the (b) (4) (uncombusted) in the new tobacco product reduces potential HPHCs caused by the combustion of the monogram ink. Therefore, the differences in monogram placement between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health. The changes to the ingredient in the (b) (4) may cause changes in tar and nicotine levels in the smoke of the new tobacco product when compared to the predicate tobacco product. However, both the measured tar and nicotine levels in the smoke of the new tobacco products were stated to be (b) (4) than from the predicate tobacco products despite a slight (b) (4) in the filter efficiency. Therefore, the differences in ingredients in the (b) (4) between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

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 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 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 SE0013536 and SE0013537, as identified on the cover page of this review.