U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0001362-SE0001375, SE0001382, and SE0001409-SE0001421

SE0001362: Heron Red 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001363: Heron Red 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001364: Heron Red Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001365: Heron Gold 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None

SE0001366: Heron Gold 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001367: Heron Gold Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001368: Heron Gold Kings Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001369: Heron Menthol 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001370: Heron Menthol 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001371: Heron Menthol Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001372: Heron Menthol Kings Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001373: Heron Menthol Gold 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001374: Heron Menthol Gold 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001375: Heron Menthol Gold Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001382: Heron CRIMSON 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001409: Sands Red 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001410: Sands Red 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001411: Sands Red Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001412: Sands Red Kings Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None

SE0001413: Sands Gold 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001414: Sands Gold 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001415: Sands Gold Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001416: Sands Gold Kings Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001417: Sands Menthol 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001418: Sands Menthol 100s Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001419: Sands Menthol Kings Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001420: Sands Menthol Kings Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001421: Sands Menthol Blue 100s Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.86 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Seneca Manufacturing Company
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Not Substantially Equivalent (NSE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.10.18 11:28:04 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

☒ Concur with TPL recommendation and basis of recommendation

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

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

Digitally signed by Matthew R. Holman -S
Date: 2018.10.18 12:59:57 -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:

SE0001362: Heron Red 100s Box	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001363: Heron Red 100s Soft Pack	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001364: Heron Red Kings Box	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001365: Heron Gold 100s Box	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None

SE0001366: Heron Gold 100s Soft Pack	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001367: Heron Gold Kings Box	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001368: Heron Gold Kings Soft Pack	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001369: Heron Menthol 100s Box	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001370: Heron Menthol 100s Soft Pack	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001371: Heron Menthol Kings Box	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001372: Heron Menthol Kings Soft Pack	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001373: Heron Menthol Gold 100s Box	
Product Name	Heron Menthol Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001374: Heron Menthol Gold 100s Soft Pack	
Product Name	Heron Menthol Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001375: Heron Menthol Gold Kings Box	
Product Name	Heron Menthol Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001382: Heron CRIMSON 100s Box	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001409: Sands Red 100s Box	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None

SE0001410: Sands Red 100s Soft Pack	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001411: Sands Red Kings Box	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001412: Sands Red Kings Soft Pack	
Product Name	Heron Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001413: Sands Gold 100s Box	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None

SE0001414: Sands Gold 100s Soft Pack	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001415: Sands Gold Kings Box	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001416: Sands Gold Kings Soft Pack	
Product Name	Heron Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	None
SE0001417: Sands Menthol 100s Box	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

SE0001418: Sands Menthol 100s Soft Pack	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001419: Sands Menthol Kings Box	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001420: Sands Menthol Kings Soft Pack	
Product Name	Heron Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol
SE0001421: Sands Menthol Blue 100s Box	
Product Name	Heron Menthol Light 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	Not Provided
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 21, 2011, the applicant submitted 28 original SE Reports (SE0001362-SE0001375, SE0001382, and SE0001409-SE0001421). On August 2, 2011, FDA issued Acknowledgment letters for SE0001362-SE0001375 and SE0001382. On August 18, 2011, FDA issued

Acknowledgment letters for SE0001409-SE0001421. On September 29, 2011, FDA received an amendment correcting ingredients in the new products of all original SE Reports (SE0004159). On December 7, 2012, FDA issued Advice/Information Request (A/I) letters for SE0001362-SE0001375 and SE0001382. On December 31, 2012, FDA issued A/I letters for SE0001409-SE0001421. In response, on January 7, 2013, FDA received amendments for SE0001362-SE0001375 and SE0001382 (SE0005668-SE0005681 and SE0005688, respectively). Additionally, on January 28, 2013, FDA received amendments for SE0001409-SE0001421 (SE0006789-SE0006801). In response to a March 26, 2013 telecon, on June 14, 2013, FDA received an amendment with information relating to the date the products were first introduced or delivered for introduction into interstate commerce (SE0009051). On January 9, 2015, FDA issued a Notification letter to inform the applicant that substantive scientific review of the SE Reports would begin on February 25, 2015. On February 24, 2015, FDA received an amendment providing additional information for all SE Reports (SE0010933). On June 26, 2015, FDA issued an A/I letter for the SE Reports. In response, on August 25, 2015, FDA received an amendment for all SE Reports (SE0012308). On December 24, 2015, FDA issued a Preliminary Finding (PFind) letter. In response, on January 14, 2016, FDA received an amendment requesting a 90-day extension of time to respond to the December 24, 2015, PFind letter and a statement that the applicant would discontinue use of a computer modeling program to establish predicate comparisons and instead make and test "present day predicate products" (SE0012791).[1] On January 21, 2016, FDA granted the applicant's extension request, with all information identified as deficient in the PFind letter to be received by April 23, 2016. On April 25, 2016, FDA received a late amendment containing a partial response to our December 24, 2015 PFind letter for all SE Reports (SE0013334)[2,3], and a second late amendment containing certificates of analysis for SE0001362-SE0001368 and SE0001409-SE0001421 (SE0013335).[4] (b) (4) [redacted] . On June 20, 2016, FDA received an additional late amendment containing testing data and methodology for present day predicate products for SE0001362-SE0001367, SE0001369-SE0001371, SE0001373-SE0001375, SE0001382 , SE0001411, SE0001413, SE0001415, SE0001417, SE0001419, SE0001421 (SE0013434).[5] (b) (4) [redacted]

[1] A duplicate extension request letter was received by CTP Document Control Center (DCC) mailroom on January 15, 2016 and coded as amendment SE0012793. To ensure that TPL review reflects accurate and comprehensive information, amendment SE0012793 is captured in the regulatory activity section table.

[2] This amendment was received after the extension to the response due date of the PFind letter and thus was not reviewed by the discipline reviewers at that time (see memo dated June 2, 2016). Since FDA did not make a decision about the SE Reports for over two years after receiving the late amendment, the Technical Project Lead later determined that reviewing it would not delay the decision, and therefore accepted the amendment for review.

[3] (b) (4) [redacted]

[4] Amendment SE0013335 also included information for SE0001393, SE0001395, SE0001397, SE0001399, SE0001401 and SE0001403, which are not the subject of this TPL review. This amendment was received after the response due date of the PFind letter and thus was not reviewed by the discipline reviewers at that time. Since FDA did not make a decision about the SE Reports for over two years after receiving the late amendment, the Technical Project Lead later determined that reviewing it would not delay the decision, and therefore accepted the amendment for review.

[5] Amendment SE0013434 also included information for SE0001393, SE0001395, SE0001397, SE0001399, SE0001401 and SE0001403, which are not the subject of this TPL review. This amendment was received after the response due date of the PFind letter and thus was not reviewed by the discipline reviewers at that time. Since FDA did not make a decision about the SE Reports for over two years after receiving the late amendment, the Technical Project Lead later determined that reviewing it would not delay the decision, and therefore accepted the amendment for review.

(b) (4) [redacted] Since FDA did not make a determination about the SE Reports for over two years after receiving the late amedments (SE0013334, SE0013335, and SE0013434), the Technical Project Lead determined that reviewing them would not delay the decision, and therefore accepted the amendments for review.

Product Name	SE Report	Amendments
Heron Red 100s Box	SE0001362	SE0004159 SE0005668 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Heron Red 100s Soft Pack	SE0001363	SE0004159 SE0005669 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Heron Red Kings Box	SE0001364	SE0004159 SE0005670 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434

Product Name	SE Report	Amendments
Heron Gold 100s Box	SE0001365	SE0004159 SE0005671 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Heron Gold 100s Soft Pack	SE0001366	SE0004159 SE0005672 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Heron Gold Kings Box	SE0001367	SE0004159 SE0005673 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Heron Gold Kings Soft Pack	SE0001368	SE0004159 SE0005674 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556

Product Name	SE Report	Amendments
Heron Menthol 100s Box	SE0001369	SE0004159 SE0005675 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron Menthol 100s Soft Pack	SE0001370	SE0004159 SE0005676 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron Menthol Kings Box	SE0001371	SE0004159 SE0005677 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron Menthol Kings Soft Pack	SE0001372	SE0004159 SE0005678 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013371 SE0013556

Product Name	SE Report	Amendments
Heron Menthol Gold 100s Box	SE0001373	SE0004159 SE0005679 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron Menthol Gold 100s Soft Pack	SE0001374	SE0004159 SE0005680 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron Menthol Gold Kings Box	SE0001375	SE0004159 SE0005681 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434
Heron CRIMSON 100s Box	SE0001382	SE0004159 SE0005688 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013434

Product Name	SE Report	Amendments
Sands Red 100s Box	SE0001409	SE0004159 SE0006789 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Red 100s Soft Pack	SE0001410	SE0004159 SE0006790 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556
Sands Red Kings Box	SE0001411	SE0004159 SE0006791 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Red Kings Soft Pack	SE0001412	SE0004159 SE0006792 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556

Product Name	SE Report	Amendments
Sands Gold 100s Box	SE0001413	SE0004159 SE0006793 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Gold 100s Soft Pack	SE0001414	SE0004159 SE0006794 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556
Sands Gold Kings Box	SE0001415	SE0004159 SE0006795 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Gold Kings Soft Pack	SE0001416	SE0004159 SE0006796 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556

Product Name	SE Report	Amendments
Sands Menthol 100s Box	SE0001417	SE0004159 SE0006797 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Menthol 100s Soft Pack	SE0001418	SE0004159 SE0006798 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556
Sands Menthol Kings Box	SE0001419	SE0004159 SE0006799 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434
Sands Menthol Kings Soft Pack	SE0001420	SE0004159 SE0006800 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013371 SE0013556

Product Name	SE Report	Amendments
Sands Menthol Blue 100s Box	SE0001421	SE0004159 SE0006801 SE0009051 SE0010933 SE0012308 SE0012791 SE0012793 SE0013334 SE0013335 SE0013434

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 Rosanna Beltre on December 7, 2012 for SE0001362-SE0001375 and SE0001382, and on December 31, 2012 for SE0001409-SE0001421. All SE reports were found to be administratively incomplete.

The second round of regulatory reviews were completed by Joanna Randazzo on March 8, 2013 for SE0001382; March 15, 2013 for SE0001362-SE0001375; and July 19 , 2013 for SE0001409; and by Mary Jo Salerno on August 29, 2013 for SE0001410-SE0001421.

The final reviews conclude that SE Reports SE0001362-SE0001375 and SE0001382 are administratively complete. The final reviews conclude that SE Reports SE0001409-SE0001421 are not administratively complete because the following information is not included in the SE Reports:

1. Unique identification of the new and corresponding predicate products

This information was provided during the scientific review process for SE0001409-SE0001421. Therefore, these 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated March 23, 2015, 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.[6]

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 Fuqiang Liu on May 15, 2015, by Jeffrey Ammann on October 15, 2015, and by Melis Coraggio on October 1, 2018.

The final chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products and that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All of SE Reports indicate that you remanufactured the predicate products to the closest specifications possible to match the original grandfathered predicate products except for the use of (b) (4) low-ignition propensity (LIP) fire standard paper (FSC). However, all of your SE Reports indicate higher levels of (b) (4) (94-126%) tobacco for the new products compared to the corresponding predicate products. You explained that increases in (b) (4) tobacco increases nitrate levels, which suppresses the formation of PAHs and enhances the formation of TSNA. You later state that "PAHs are produced in higher yields from cigarettes made from (b) (4) than from (b) (4) tobacco." Products produced exclusively with (b) (4) tobacco content have been shown to yield higher levels of B[a]P in smoke compared to products made from (b) (4). Although the relative levels of PAHs may vary in mainstream smoke of different tobacco types, B[a]P is commonly used as a surrogate for total PAHs since it is the most extensively investigated PAH and its carcinogenicity is well documented. You claimed many PAHs are "anti-carcinogenic" and that using B[a]P as a surrogate for all PAHs presents "shortcomings"; however, you provided neither PAH nor TSNA smoke data for the new or corresponding predicate products. Without this information, we cannot determine if differences in tobacco blends cause the new products to raise different questions in public health.

2. All of your SE Reports addressed the increased (b) (4) quantities in the new product. You acknowledged that acetaldehyde is produced upon the pyrolysis of (b) (4) but you disagreed that benzene is produced upon pyrolysis. You stated that a recent FDA toxicology review of FSC paper concluded that new tobacco products containing FSC paper do not raise different questions of public health compared to predicate products that do not contain FSC paper. Conclusions of previous scientific reviews are based solely on data and scientific evidence provided for that specified SE

[6] Addendum reviews were completed on April 24, 2018, to clarify the characterizing flavor for the predicate tobacco products. The addendum reviews do not change the conclusion of the initial grandfather determination dated March 23, 2015.

Reports, and, therefore, are not appropriate for extrapolation for your current SE Reports. You provided neither acetaldehyde nor benzene smoke data for the new and corresponding predicate products. Without this information, we cannot determine if differences in (b) (4) cause the new products to raise different questions in public health.

3. All of your SE Reports addressed the increased (b) (4) quantities by explaining that there are two tobacco blends for the new products which have 0.1-1.5% (b) (4) added to the blends. You explained that the predicate products have relatively low levels of (b) (4) added to the top-flavors. You agreed that acrolein is produced upon the pyrolysis of (b) (4) but disagreed with the statement that formaldehyde is formed in any appreciable amount. You also cited references that report no formation of benzene from (b) (4) You stated that upon pyrolysis, (b) (4) is only a minor contributor to the formation of acrolein. You cited a study using radiolabeled (b) (4) and claimed most of the acrolein from (b) (4) is found in the side-stream smoke. However, you provided no acrolein, formaldehyde or benzene smoke data for the new and corresponding predicate products to support this statement. Without this information, we cannot determine if differences in (b) (4) levels cause the new products to raise different questions in public health.

4. SE0001382 and SE0001409 - SE0001421 contain some quantities of (b) (4) that requires further explanation. You provided ranges for the amount of (b) (4) present, however we need quantitative target values of (b) (4) in each product to fully evaluate your products. Without this information, we cannot determine if the differences in (b) (4) levels cause the new products to raise different questions of public health.

5. SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001417, SE0001419, SE0001421 have significantly higher values of tar (17-102%) and nicotine (28-153%) as compared to the corresponding predicate products. Moreover, the carbon monoxide levels (ISO) for the new products in SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001421 were determined to be higher by 17-89% than the corresponding predicate products. However, you provided no explanation or rationale to why these increases do not cause the new products to raise different questions of public health. Additionally, you did not provide TNCO data for the soft pack products of SE0001363, SE0001366, SE0001368, SE0001370, SE0001372, SE0001374, SE0001409, SE0001412, SE0001414, SE0001416, SE0001418, SE0001420. It is unclear if the soft pack tobacco products are identical to the hard pack tobacco products. Without this information, we cannot determine if the new products raise different questions of public health.

Therefore, the review concludes that the applicant did not demonstrate that 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 from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Beth Tirio on May 19, 2015 and October 20, 2015 and by James Melchiors on October 4, 2018.

The final engineering review concludes that the new tobacco products have different characteristics related to product design compared to the corresponding predicate tobacco products and that the SE Reports do not contain sufficient detail to determine that the differences with respect to product engineering do not cause the new tobacco products to raise different questions of public health. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All of your SE Reports have a discrepancy in the data provided that needs additional clarification. The product names used in the tables from your June 20, 2016 amendment to the SE Reports did not include the full product names, leaving off the packaging terms "soft pack" or "box". For SE0001368, SE0001372, SE0001410, SE0001412, SE0001414, SE0001416, SE0001418, and SE0001420, you stated that the new products were not tested. However, the test results from (b) (4) were cleared marked as the box versions of these products (SE0001367, SE0001371, SE0001409, SE0001411, SE0001413, SE0001415, SE0001417, and SE0001419). The test results are also clear for SE0001364, SE0001375, SE0001382, and SE0001421, because the application only included a box version for these new products. However, for SE0001362, SE0001363, SE0001365, SE0001366, SE0001369, SE0001370, SE0001373, and SE0001374, it unclear if the abbreviations used in the tables for the new products represent testing done on the soft pack version or the box version. The cigarettes used in soft pack and box products are often identical and it could be appropriate for a single set of tests to apply to both the soft pack and box versions of these new products. And while the information provided in the application does not indicate any differences between the cigarettes in soft pack and box versions of these products, the test results cannot be assumed to apply to both new products without verification that the soft pack and box versions actually contain identical cigarettes. Likewise, without the full name for these products, it cannot be assumed that the test results apply to one of the new products or to the other. Therefore, for SE0001362, SE0001363, SE0001365, SE0001366, SE0001369, SE0001370, SE0001373, and SE0001374, it will be necessary to provide clearly labelled puff count test results for each new product, as well as providing the puff count test results for the new products that were not tested (SE0001368, SE0001372, SE0001410, SE0001412, SE0001414, SE0001416, SE0001418, and SE0001420).

   If a difference exists in the puff counts between the new and corresponding predicate products, provide scientific evidence and a rationale for why the difference(s) does not cause the new product to raise different questions of public health.

2. All of your SE Reports include design parameter specifications, but do not include data confirming that specifications are met. You submitted tables in response to the December 2015 Preliminary Finding letter for data that do not appear to be test data. For example, Tables 2b, 2h, and 2j are identical to the specification tables provided for those design parameters (Tables 1a, 1b, and 1c respectively). Not only is each numerical

value identical between the corresponding tables, but the column headers of target, actual, upper, and lower are identical. Similarly, for Tables 2i and 2l, the target values provided for the new and predicate products are the same as the target specifications. Likewise, the upper values provided are the same as the upper range limit specifications and the lower values provided are the same as the lower range limit specifications. Test data is used to confirm that the new and predicate products conform to specifications. Cigarettes that are not produced to specifications could cause the new products to raise different questions of public health. Provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for the following design parameters for each new and predicate product:

a. Cigarette draw resistance (mm H_2O)
b. Filter denier per filament (dpf)
c. Filter total denier (g/9000m)
d. Filter pressure drop (mm H_2O)

Additionally, for the design parameters listed above that were tested according to national or international standards, identify the standards and state what deviations, if any, from the standards occurred.

Certificates of analysis (COAs) from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include: target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data, or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

3. SE00013365, SE00013366, SE00013367, SE00013368, SE00013373, SE00013374, SE00013375, SE00013413, SE00013414, SE00013415, SE00013416, and SE00013421 include values for the target specification for filter ventilation for the predicate products. However, you provide a value of NM (i.e., not measured) for the target specifications and for the test data for filter ventilation for the new product, but you do not provide scientific evidence and a rationale for why you do not specify or measure filter ventilation. Furthermore, you did not provide upper and lower range limits for the new and predicate products. A difference in filter ventilation may affect smoke constituent yields. For SE00013365, SE00013366, SE00013367, SE00013368, SE00013373, SE00013374, SE00013375, SE00013413, SE00013414, SE00013415, SE00013416, and SE00013421, provide target specifications and upper and lower range limits for filter ventilation for the new and predicate products or provide scientific evidence and a rationale for why the new and predicate products do not need to have filter ventilation specifications. If a difference exists in the target specifications or range limits between the new and corresponding predicate products, provide scientific evidence and a rationale for why the difference(s) does not cause the new product to raise different questions of public health.

   In addition, test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with

specifications and produced to specifications could cause the new products to raise different questions of public health. For SE00013365, SE00013366, SE00013367, SE00013368, SE00013373, SE00013374, SE00013375, SE00013413, SE00013414, SE00013415, SE00013416, and SE00013421, provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for filter ventilation for each new product.

4. All of your SE Reports provide target specifications and upper and lower range limits for cigarette paper band porosity for the new products but provide values of NM (i.e., not measured) for the test data for cigarette paper band porosity. You do not provide scientific evidence and a rationale for why you do not measure cigarette paper band porosity, and the COA from [redacted] for the cigarette paper used on the new product does not include information regarding the cigarette paper band porosity. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. Test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for the cigarette paper band porosity is needed for each new product.

   Certificates of analysis (COAs) from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include: target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data, or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

5. All of your SE Reports provide target specifications and upper and lower range limits for filter density for the new and predicate products but provide values of NM (i.e., not measured) for the test data for filter density. You do not provide scientific evidence and a rationale for why you do not measure filter density. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. Test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for the filter density is needed for each new product.

   Certificates of analysis (COAs) from the material supplier may satisfy this deficiency. If you choose to address this deficiency by providing COAs for any of the parameters listed above, the COAs must include: target specification; quantitative acceptance criteria; parameter units; test data average value; and either the standard deviation of the test data, or the minimum and maximum values of the test data. The COA must be a complete, unaltered COA from the material supplier.

6. All of you SE Reports provide information on the filter of the new and corresponding predicate tobacco products. Hoverer, some of your SE Reports include filter differences

that may cause the new product to raise different questions of public health as indicated below:

a. A 7%-40% decrease in filter pressure drop in SE0001362 – SE0001365, SE0001367 – SE0001375, SE0001382, SE0001411, SE0001412, and SE0001415 – SE0001421
b. A 33% decrease in filter length in SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420

Decreases in filter pressure drop and filter length may result in reduced filter efficiency, and in turn, an increase in tar and nicotine levels. You did not provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health. One example of scientific evidence is smoke constituent yields. Demonstrating that the decreases in filter pressure drop and filter length do not result in increased smoke constituent yields could satisfy this deficiency; however, every tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. As such, it will be necessary for you to provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health.

7. All of you SE Reports provide information on the tobacco rod density and tobacco oven volatiles of the new and corresponding predicate tobacco products. Hoverer, some of your SE Reports include design parameter differences that may cause the new product to raise different questions of public health as indicated below:

   a. 7% decrease in tobacco rod density (SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420)
   b. 13% decrease in tobacco oven volatiles (SE0001382 and SE0001409 – SE0001421)

   Design parameter differences can affect the performance and smoke constituent yields of the cigarettes. You did not provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health. One example of scientific evidence is smoke constituent yields. Demonstrating that the decreases in tobacco rod density and tobacco oven volatiles do not result in increased smoke constituent yields could satisfy this deficiency; however, every tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. As such, it will be necessary for you to provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health.

8. All of your SE Reports include test data for the tobacco oven volatiles for the predicate products. For each of the predicate products, the value that was provided for the

tobacco oven volatiles average was below the lower range limits that were provided. You need to explain why the test data value provided for tobacco oven volatiles for each of the predicate products was below the lower reject limit.

9. SE0001362, SE0001364, SE0001369, SE0001371, SE0001372, SE0001411, SE0001412, SE0001419, and SE0001420 include tobacco filler mass data for the new products where the upper value is higher than the upper range limit from the specifications. Additionally, for SE0001363, SE0001365, SE0001366, SE0001368, SE0001370, SE0001373, SE0001374, SE0001375, SE0001382, SE0001409, SE0001410, SE0001413, SE0001414, SE0001415, SE0001417, SE0001418, and SE0001421, you include tobacco filler mass data for the new products where the lower value is lower than the lower range limit from the specifications. You need to explain why the test data provided for tobacco filler mass for the new products included values that fall outside of the upper or lower range limits.

Therefore, the review concludes that the applicant did not demonstrate that 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 from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Gladys Erives on May 22, 2015 and by Carmine Leggett on December 21, 2015.[7]

The final toxicology review concludes that the new tobacco products have different characteristics related to product toxicity compared to the corresponding predicate tobacco products and that the SE Reports do not contain sufficient detail to determine that the differences with respect to product toxicology do not cause the new tobacco products to raise different questions of public health. The review identifies the deficiencies that are overlapping with the chemistry review above.

Therefore, the review concludes that the applicant did not demonstrate that 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 from a toxicology perspective.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(b), issuance of an order finding a tobacco product not substantially equivalent (NSE) under section 910(a) of the FD&C Act is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement (EIS). FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

[7] A 3rd toxicology review was not conducted as the 2nd toxicology review identified the same issues as the 2nd chemistry review and these issues were evaluated by chemistry in the 3rd chemistry review dated October 1, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Change in adhesives supplier; seam glue and tipping glue supplier changed from (b) (4) (b) (4) to (b) (4)
- Utilize cigarette paper with fire standard compliant bands
- Increase in (b) (4) tobacco (94-126%)
- Increase in nicotine (20-153%) and tar (17-102%) for SE0001362, SE0001364, SE0001365, SE0001367, SE0001369, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001417, SE0001419, and SE0001421
- Addition of (b) (4)
- A 33% decrease in filter length and a 7% decrease in tobacco rod density for SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420
- A 13% decrease in tobacco oven volatiles for SE0001382 and SE0001409 – SE0001421
- A filter pressure drop that decreases between 7% - 40% for SE0001362 - SE0001375, SE0001382, SE0001411, SE0001412, and SE0001415 - SE0001421
- A 25% increase in cigarette paper base paper porosity
- A 14% decrease in tobacco filler mass, a 15% decrease in cigarette length, and a 26% decrease in tipping length, and a 17% decrease in cigarette mass for SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420

The applicant has failed to demonstrate that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant did not provide information to uniquely identify all of the non-tobacco ingredients and tobacco blend, and similarly did not provide sufficient information on the product design features in order to fully characterize the new and corresponding predicate tobacco products. Furthermore, the applicant has failed to demonstrate that changes in ingredients and tobacco blends along with increases in HPHCs does not cause the new products to raise different questions of public health. Without sufficient information regarding the composition and design of the new and corresponding predicate tobacco products, FDA cannot perform an appropriate evaluation to determine whether there are differences between the new and corresponding predicate product, and if so, whether those differences do not cause the new products to raise different questions of public health. Although the applicant provides TNCO yields in mainstream smoke under ISO smoking regimens, the applicant has failed to provided scientific evidence why the increase in these yields does not cause the new product to raise different questions of public health. The applicant has failed to provide sufficient information to support a finding of substantial equivalence.

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

The chemistry, engineering and toxicology reviews conclude that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products and that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco

products to raise different questions of public health. I concur with these reviews and recommend that NSE order letters be issued.

Because the proposed action is issuing NSE orders, it is a class of action that is categorically excluded under 21 CFR 25.35(b). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determine that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

NSE orders letter should be issued for the new tobacco products in SE0001362 - SE0001375, SE0001382 and SE0001409 - SE0001421, as identified on the cover page of this review. The NSE order letters should cite the following deficiencies:

1. All of your SE Reports indicate that you remanufactured the predicate products to the closest specifications possible to match the original grandfathered predicate products except for the use of (b) (4) low-ignition propensity (LIP) fire standard complaint paper (FSC). However, all of your SE Reports indicate higher levels of (b) (4) tobacco (94-126%) for the new products compared to the corresponding predicate products. You needed to demonstrate that increases in (b) (4) tobacco do not cause the new products to raise different questions of public health and one way you may have demonstrated this is by providing PAH or TSNA smoke data for the new and corresponding predicate products.

2. All of your SE Reports show an increase in (b) (4) quantities in the new product. You acknowledge that acetaldehyde is produced upon the pyrolysis of (b) (4) but you disagreed that benzene is produced upon pyrolysis. You stated that a recent FDA toxicology review of FSC paper concluded that new tobacco products containing FSC paper do not raise different questions of public health compared to predicate products that do not contain FSC paper. However, conclusions of previous scientific reviews are based solely on data and scientific evidence provided for the specified SE Reports, and, therefore, are not appropriate for extrapolation for your current SE Reports. You may have provided evidence to account for this change in ingredient by providing acetaldehyde or benzene smoke data for the new and corresponding predicate products.

3. All of your SE Reports address the increased (b) (4) quantities by explaining that there are two tobacco blends for the new products which have 0.1-1.5% (b) (4) added to the blends. You explained that the predicate products have relatively low levels of (b) (4) added to the top-flavors. You agreed that acrolein is produced upon the pyrolysis of (b) (4) but disagreed with the statement that formaldehyde is formed in any appreciable amount. You also cited references that report no formation of benzene from (b) (4), however those references were not specific to the tobacco products currently under review. You stated that upon pyrolysis, (b) (4) is only a minor contributor to the formation of acrolein. However, you have not provided adequate evidence for the increase in (b) (4). One way this may have been addressed is by providing acrolein, formaldehyde or benzene from mainstream smoke for the new and corresponding predicate products to support these statements.

4. SE0001382 and SE0001409 - SE0001421 contain some quantities of (b) (4) that require further explanation. You provide ranges for the amount of (b) (4) present. However, in

order to evaluate the new and predicate tobacco products, you needed to provide the quantitative target values of (b) (4) to determine if the differences in (b) (4) levels cause the new products to raise different questions of public health.

5. SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001417, SE0001419, SE0001421 have significantly higher values of tar (17-102%) and nicotine (28-153%) as compared to the corresponding predicate products. Moreover, the carbon monoxide levels (ISO) for the new products in SE0001362, SE0001364, SE0001365, SE0001367, SE0001371, SE0001373, SE0001375, SE0001382, SE0001410, SE0001411, SE0001413, SE0001415, SE0001421 were determined to be higher by 17-89% than the corresponding predicate products. However, you failed to provide an explanation or rationale for why these increases do not cause the new products to raise different questions of public health.

6. All of your SE Reports have a discrepancy in the data provided that needs additional clarification. The product names used in the tables from your June 20, 2016 amendment to the SE Reports did not include the full product names, leaving off the packaging terms "soft pack" or "box". For SE0001368, SE0001372, SE0001410, SE0001412, SE0001414, SE0001416, SE0001418, and SE0001420, you stated that the new products were not tested. However, the test results from (b) (4) were clearly marked as the box versions of these products (SE0001367, SE0001371, SE0001409, SE0001411, SE0001413, SE0001415, SE0001417, and SE0001419). The test results were also clear for SE0001364, SE0001375, SE0001382, and SE0001421, because the SE Reports only included a box version for these new products. However, for SE0001362, SE0001363, SE0001365, SE0001366, SE0001369, SE0001370, SE0001373, and SE0001374, it unclear if the abbreviations in the tables for the new products represent testing done on the soft pack version or the box version. The cigarettes used in soft pack and box products are often identical and it could be appropriate for a single set of tests to apply to both the soft pack and box versions of these new products. While the information provided in the SE Reports does not indicate any differences between the cigarettes in soft pack and box versions of these products, the test results cannot be assumed to apply to both new products without verification that the soft pack and box versions actually contain identical cigarettes. Likewise, without the full name for these products, it cannot be assumed that the test results apply to one of the new products or to the other. Therefore, for SE0001363, SE0001366, SE0001368, SE0001370, SE0001372, SE0001374, SE0001409, SE0001412, SE0001414, SE0001416, SE0001418, SE0001420 you needed to provide clear labeling for these products and indicate if testing was conducted, including measurements for TNCO yields and puff count test results .

7. All of your SE Reports include design parameter specifications, but do not include data confirming that specifications are met. You submitted tables in response to the December 24, 2015 Preliminary Finding letter for data that do not appear to be test data. For example, Tables 2b, 2h, and 2j are identical to the specification tables provided for those design parameters (Tables 1a, 1b, and 1c respectively). Not only is each numerical value identical between the corresponding tables, but the column headers of target, actual, upper, and lower are identical. Similarly, for Tables 2i and 2l, the target values provided for the new and predicate products are the same as the target specifications. Likewise, the upper values provided are the same as the upper range limit specifications and the lower values provided are the same as the lower range limit specifications. Test data is used to confirm

that the new and predicate products conform to specifications. Cigarettes that are not produced to specifications could cause the new products to raise different questions of public health. You needed to provide the **test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results** for the following design parameters for each new and predicate product:

a. Cigarette draw resistance (mm H_2O)
b. Filter denier per filament (dpf)
c. Filter total denier (g/9000m)
d. Filter pressure drop (mm H_2O)

Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

8. SE00013365, SE00013366, SE00013367, SE00013368, SE00013373, SE00013374, SE00013375, SE00013413, SE00013414, SE00013415, SE00013416, and SE00013421 include values for the target specification for filter ventilation for the predicate products. However, you provide a value of NM (i.e., not measured) for the target specifications and for the test data for filter ventilation for the new product, but you do not provide scientific evidence and a rationale for why you do not specify or measure filter ventilation. Furthermore, you did not provide upper and lower range limits for the new and predicate products. A difference in filter ventilation may affect smoke constituent yields. You needed to provide target specifications and upper and lower range limits for filter ventilation for the new and predicate products or provide scientific evidence and a rationale for why the new and predicate products do not need to have filter ventilation specifications. Additionally, you needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for filter ventilation for each new product.

9. All of your SE Reports provide target specifications and upper and lower range limits for cigarette paper band porosity for the new products but provide values of NM (i.e., not measured) for the test data for cigarette paper band porosity. You do not provide scientific evidence and a rationale for why you do not measure cigarette paper band porosity, and the certificate of analysis (COA) from (b) (4) for the cigarette paper used on the new products do not include information regarding the cigarette paper band porosity. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. You needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for the cigarette paper band porosity for each new product.

   Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test

data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

10. All of your SE Reports provide target specifications and upper and lower range limits for filter density for the new and predicate products but provide values of NM (i.e., not measured) for the test data for filter density. You do not provide scientific evidence and a rationale for why you do not measure filter density. Test data is used to confirm that the cigarettes used in the new and predicate products conform to specifications. Cigarettes that are not designed with specifications and produced to specifications could cause the new products to raise different questions of public health. You needed to provide test data (i.e., measured values of design parameters), including test protocols, quantitative acceptance criteria, data sets, and a summary of the results for the filter density for each new product.

    Certificates of analysis (COAs) from the material supplier may have satisfied this concern by providing the target specification, quantitative acceptance criteria, parameter units, test data average value, and either the standard deviation of the test data, or the minimum and maximum values of the test data.

11. All of your SE Reports provide information on the filter of the new and corresponding predicate tobacco products. However, some of your SE Reports include filter differences that may cause the new product to raise different questions of public health as indicated below:

    a. A 7%-40% decrease in filter pressure drop in SE0001362 – SE0001365, SE0001367 – SE0001375, SE0001382, SE0001411, SE0001412, and SE0001415 – SE0001421
    b. A 33% decrease in filter length in SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420

    Decreases in filter pressure drop and filter length may result in reduced filter efficiency, and in turn, an increase in tar and nicotine levels. You did not provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health. Demonstrating that the decreases in filter pressure drop and filter length do not result in increased smoke constituent yields could satisfy this deficiency; however, every tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. Therefore, you needed to provide scientific evidence and a rationale as to why the decreases in filter pressure drop and the decreases in filter length do not cause the new products to raise different questions of public health.

12. All of your SE Reports provide information on the tobacco rod density and tobacco oven volatiles of the new and corresponding predicate tobacco products. However, some of your SE Reports include design parameter differences that may cause the new product to raise different questions of public health as indicated below:

a. 7% decrease in tobacco rod density (SE0001364, SE0001367, SE0001368, SE0001371, SE0001372, SE0001375, SE0001411, SE0001412, SE0001415, SE0001416, SE0001419, and SE0001420)
b. 13% decrease in tobacco oven volatiles (SE0001382 and SE0001409 – SE0001421)

Design parameter differences can affect the performance and smoke constituent yields of the cigarettes. You did not provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health. Demonstrating that the decreases in tobacco rod density and tobacco oven volatiles do not result in increased smoke constituent yields could satisfy this deficiency; however, all tar and nicotine value that you provided using the ISO smoking regimen showed an increase between the new and corresponding predicate products. Therefore, you needed to provide scientific evidence and a rationale as to why the decreases in tobacco rod density and tobacco oven volatiles do not cause the new products to raise different questions of public health.

13. All of your SE Reports include test data for the tobacco oven volatiles for the predicate products. For each of the predicate products, the value that was provided for the tobacco oven volatiles average was below the lower range limits that were provided. You needed to explain why the test data value provided for tobacco oven volatiles for each of the predicate products was below the lower reject limit.

14. SE0001362, SE0001364, SE0001369, SE0001371, SE0001372, SE0001411, SE0001412, SE0001419, and SE0001420 include tobacco filler mass data for the new products where the upper value is higher than the upper range limit from the specifications. Additionally, for SE0001363, SE0001365, SE0001366, SE0001368, SE0001370, SE0001373, SE0001374, SE0001375, SE0001382, SE0001409, SE0001410, SE0001413, SE0001414, SE0001415, SE0001417, SE0001418, and SE0001421, you include tobacco filler mass data for the new products where the lower value is lower than the lower range limit from the specifications. You needed to explain why the test data provided for tobacco filler mass for the new products included values that fall outside of the upper or lower range limits.