Technical Project Lead (TPL) Review: SE0000004, SE0000005, SE0000006, SE0000007, SE0000008, SE0000009 and SE0000069

SE0000004: Winston Red Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter[1]	7.79 mm
Ventilation	17%
Characterizing Flavor	None
SE0000005: Winston White Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.79 mm
Ventilation	54%
Characterizing Flavor	None
SE0000006: Winston White 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79 mm
Ventilation	60%
Characterizing Flavor	None
SE0000007: Winston Red 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79mm
Ventilation	17%
Characterizing Flavor	None
SE0000008: Winston Gold Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None

SE0000009: Winston Gold 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98mm
Diameter	7.79 mm
Ventilation	28%
Characterizing Flavor	None
SE0000069: Salem 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	Menthol
Attributes of SE Reports	
Applicant	ITG Brands LLC
Report Type	Provisional
Product Category	Cigarettes
Product Sub-Category	Combusted, filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] The applicant submitted the circumference which allowed for a calculation of diameter.

Technical Project Lead (TPL):

Digitally signed by Todd L. Cecil -S
Date: 2019.10.17 13:28:57 -04'00'

Todd L. Cecil, Ph.D.
Associate 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: 2019.10.17 16:46:43 -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:

SE0000004: Winston Red Box	
Product Name	Winston Full Flavor Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None
SE0000005: Winston White Box	
Product Name	Winston Ultra Light Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.79 mm
Ventilation	54%
Characterizing Flavor	None
SE0000006: Winston White 100's Box	
Product Name	Winston Ultra Light 100s Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79 mm
Ventilation	60%
Characterizing Flavor	None
SE0000007: Winston Red 100's Box	
Product Name	Winston Full Flavor 100s Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	None

SE0000008: Winston Gold Box	
Product Name	Winston Light Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.79 mm
Ventilation	32%
Characterizing Flavor	None
SE0000009: Winston Gold 100's Box	
Product Name	Winston Light 100s Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79 mm
Ventilation	28%
Characterizing Flavor	None
SE0000069: Salem 100's Box	
Product Name	Salem Full Flavor Green Label 100s Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received seven SE Reports on September 1, 2010, November 5, 2010 and December 28, 2010, from R.J. Reynolds Tobacco Company (RJRT) and issued Acknowledgement letters on October 15, 2010, December 29, 2010, and February 15, 2011. FDA issued Advice/Information (A/I) 30-day Request letters on June 5, 2012, requesting full identification of the predicate tobacco product. On June 15, 2012, FDA received amendments (SE0004578, SE0004579, SE0004582, SE0004584, SE0004585, SE0004588, SE0004591) requesting a 90-day extension to respond to the A/I letters. On June 15, 2012, FDA received an amendment (SE0004573) confirming SE submissions by RJRT. On July 3, 2012, FDA granted the 90-day extension requests. On September 10, 2012, FDA received amendments (SE0004883-SE0004888 and SE0004896) responding to FDA's June 5, 2012, A/I Request letters. On May 10, 2013, FDA issued a Public Health Impact (PHI) A/I Request letter. On August 8, 2013, FDA received amendments (SE0009484, SE0009490, SE0009491, SE0009505, SE0009518, SE0009519,

SE0009539) from RAI Services Company (RAIS) in response to the May 10, 2013, PHI A/I Request letter. On May 29, 2015, FDA received unsolicited amendments (SE0011897-SE0011899) from RAIS, for SE0000006, SE0000007 and SE0000009, respectively, to amend the original SE Reports. On July 1, 2015, FDA received a General Correspondence (TC0001328) from RAIS informing FDA that the STNs subject of this review were transferred to ITG Brands LLC (ITGB), effective June 12, 2015. On June 24, 2016, FDA received an amendment (SE0013465) from ITGB to amend the original SE Reports. FDA issued an A/I Request letter on December 14, 2017, requesting responses from scientific deficiencies. On January 22, 2018, FDA received a request for a 60-day extension of time (SE0014480)[2] to respond to the December 14, 2017, A/I Request letter. FDA issued an Extension Granted letter on February 2, 2018, granting the 60-day extension request. On April 12, 2018, FDA received an amendment (SE0014624)[3] responding to FDA's December 14, 2017, A/I Request letter. FDA issued a Preliminary Finding (PFind) letter on June 29, 2018. On July 6, 2018, FDA received a request for a 30-day extension (SE0014807) to respond to the June 29, 2018, PFind letter. On July 10, 2018, FDA received a request for clarification (SE0014811) of the June 29, 2018, PFind letter. FDA issued a PFind Extension Request Granted letter on July 18, 2018, granting the 30-day extension request. On August 8, 2018, FDA received a subsequent request for a 30-day extension (SE0014848) to respond to the June 29, 2018, PFind letter. FDA issued a Corrected PFind letter on August 17, 2018, to clarify deficiencies in the June 29, 2018, PFind letter. On August 21, 2018, FDA received a request (SE0014856) to withdraw the August 8, 2018, 30-day extension request to respond to the June 29, 2018, PFind letter. On September 11, 2018, FDA received a 30-day extension request (SE0014872) to respond to the August 17, 2018, Corrected PFind letter. FDA issued an Extension Request letter on September 14, 2018, granting the 30-day extension to respond to the PFind letter. On October 10, 2018, FDA received an amendment (SE0014882) responding to FDA's August 17, 2018, PFind letter.

Product Name	SE Report	Amendments
Winston Red Box	SE0000004	SE0004573 SE0004582 SE0004883 SE0009484 SE0013465 SE0013568 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882

[2] On January 22, 2018, FDA received a request for additional time (SE0014479) to respond to the December 14, 2017, A/I Request letter; however, the submission was missing the last two pages and therefore, was resubmitted (SE0014480).
[3] On April 11, 2018, FDA received an amendment (SE0014615) responding to FDA's December 14, 2017, A/I Request letter; however, the submission was missing pagination and therefore, was resubmitted (SE0014624).

Winston White Box	SE0000005	SE0004573 SE0004585 SE0004884 SE0009505 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882
Winston White 100's Box	SE0000006	SE0004573 SE0004584 SE0004885 SE0009491 SE0011897 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882
Winston Red 100's Box	SE0000007	SE0004573 SE0004579 SE0004886 SE0009490 SE0011898 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882

Winston Gold Box	SE0000008	SE0004573 SE0004591 SE0004887 SE0009519 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882
Winston Gold 100's Box	SE0000009	SE0004573 SE0004578 SE0004888 SE0009518 SE0011899 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882
Salem 100's Box	SE0000069	SE0004573 SE0004588 SE0004896 SE0009539 SE0013465 SE0014479 SE0014480 SE0014615 SE0014624 SE0014807 SE0014811 SE0014848 SE0014856 SE0014872 SE0014882

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 on June 5, 2012, by Tamu Monroe (SE0000004-SE0000009) and Jennifer German (SE0000069), and by Marcella White on December 20, 2012.

The final reviews conclude that all 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 June 14, 2016, July 27, 2016, July 29, 2016, September 8, 2016 May 9, 2018, and May 14, 2018, 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.

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 Thomas Eads on November 17, 2016, Abdurrafay Shareef on May 31, 2018 and July 17, 2019, and Margaret Schmierer on November 28, 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, but the differences do not cause the new tobacco products to raise different questions of public health[4]. The review identified the following differences:

[4] The applicant provided data for a "remanufactured predicate tobacco product" for each SE Report. Because the "remanufactured predicate products" do not use identical materials to the predicate tobacco products, they are considered surrogate tobacco products. The predicate tobacco products and the corresponding surrogate tobacco products are stated to include different plug wraps. The plug wrap is not combusted and therefore differences in chemical components in the plug wrap will not affect the smoke chemistry from a chemistry perspective. Similarly, the design parameters of plug wraps known to change tobacco chemistry (e.g. porosity, length, etc.) do not differ enough between the predicate tobacco products and the corresponding surrogate predicate tobacco products to affect the constituents in the cigarette smoke. Therefore, the surrogate tobacco products were evaluated by the TPL and found to be suitable as surrogates for the predicate tobacco products for the purposed of comparing HPHC data.

- Increases in total tobacco amounts (13% to 14%) (SE0000004–SE0000009)
- Increases in (b) (4) tobacco amounts (37%[5]) (SE0000069)
- Increases in (b) (4) in cigarette paper and addition of (b) (4) to cigarette paper
  - SE0000004
    - Decrease in N-Nitrosonornicotine (NNN) (21% International Organization for Standardization (ISO), 20% Canadian Intense (CI)), nicotine-derived nitrosamine ketone (NNK) (21% ISO), and furfural (20% ISO)
    - Increase in styrene (23% CI)
  - SE0000005
    - Decrease in NNK (18% ISO)
    - Increase in *o*-cresol (24% ISO)
  - SE0000006
    - Decrease in NNN (27% ISO, 31%CI), NNK (28% ISO, 25% CI), benzo[a]pyrene (B[a]P) (40% ISO)
  - SE0000007
    - Decrease in furfural (19% ISO, 22% CI)
  - SE0000008
    - Decrease in NNK (25% ISO), (b) (4) (34% CI)
  - SE0000069
    - Decrease in NNN (20% CI), *m-, p*-cresol (19% CI), phenol (24% CI), (b) (4) (25% CI)

The applicant provided a side-by-side comparison of all non-tobacco ingredients, HPHC data, and sufficient information regarding testing methods and validation. Increase in (b) (4) in cigarette paper and addition of (b) (4) to cigarette paper may each lead to increases in carbonyls and polyaromatic hydrocarbons. The increase in total tobacco and (b) (4) tobacco may result in increases in tar, nicotine, and carbon monoxide (TNCOs) and harmful and potentially harmful constituents (HPHCs). To address these ingredient differences, the applicant provided TNCOs and HPHCs under ISO and CI smoking regimens. The TNCO differences resulting from increases in (b) (4) total tobacco, (b) (4) tobacco, and the addition of (b) (4), and HPHC differences determined not analytically equivalent[6] were deferred to toxicology for further review. 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 from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by James Cheng on November 17, 2016, and June 9, 2018.

[5] There was a 37% higher amount of (b) (4) tobacco observed for SE0000069, which was not included in the chemistry reviews, but was calculated by the TPL based on the information provided by the applicant.

[6] The differences in measured values were compared using a two one-sided t-test (TOST) that incorporates allowances for typical analytical variability in the methods used to make the measurement. To differentiate analyses using the TOST from strictly statistical approaches, the term “analytically important” or “analytically equivalent” is often used to indicate that measurements differ both statistically and analytically.

The final engineering review concludes that the new tobacco products have different characteristics related to product engineering 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 review identified the following differences:

- Tobacco filler mass (↓ 2% to ↑ 8%)
- Tobacco rod density (↑2% to ↑14%) (SE0000004-SE0000009)
- Cigarette paper base paper basis weight (↑ 8%)
- Cigarette paper band porosity (↓ 43%) (SE0000004-SE0000009)
- Cigarette paper band porosity (↑ 1150%) (SE0000069)
- Cigarette paper band width (↑17%)
- Cigarette paper band space (↓10%) (SE0000004-SE0000009)
- Cigarette paper band space (↓25%) (SE0000069)
- Cigarette mass (↓ 2% to ↑ 7%)
- Draw resistance (↓ 4% to ↓ 8%) (SE0000005, SE0000007-SE0000009)
- Filter pressure drop (↓ 5% to ↓ 6%) (SE0000007, SE0000009)
- Puff count (↑1% to ↑ 11.6%)
- Filter rod density (↓ 6%) (SE0000069)
- Denier per filter (↓ 16%) (SE0000069)

The applicant provided target specifications, range limits, and test data for design parameters. There are multiple design differences between each new and corresponding predicate tobacco product, some of which may lead to increases while others may lead to decreases in TNCO and HPHC yields. To address increases in TNCO and HPHC yields due to differences in design parameters, the applicant provided the measured TNCO and HPHC values which were deferred to chemistry.

Tobacco Filler Mass and Tobacco Rod Density: For all SE Reports, the tobacco filler mass increases in the new tobacco products (8%), with the exception of SE0000069 (which shows a decrease of 2%). SE0000004-SE0000009 show similar increases in the new tobacco products' tobacco rod density except for SE0000004 which has an increase of 14%. The overall cigarette mass shows increases and decreases in the new tobacco products proportionate to the differences in tobacco filler mass. An increase in tobacco filler weight may increase smoke constituents while reductions in tobacco filler weight reduces machine smoke yield of smoke constituents. To address changes in smoke constituents due to in design parameters, the applicant provided the measured TNCO and HPHC values which were deferred to chemistry.

Cigarette paper: For all SE Reports, there are differences in the cigarette paper base paper basis weight, base paper porosity, band porosity, band width and band space. An increase in Band porosity (SE0000069) may result in an increase in TNCOs, while a decrease in band porosity (SE0000004-SE0000009) may result in a decrease in TNCOs. The band width increases in the new tobacco products as compared to the corresponding predicate tobacco products while the band space is the same or lower than that of the corresponding predicate tobacco products. Both differences may affect the coal temperature which may lead to changes in the TNCOs and HPHCs. The differences in the cigarette paper base paper basis weight range from decreases of 3.6% to increases of 8%, while differences in base paper porosity range from decreases of 4% to 23% or are the same. A difference in basis weight may affect puff count

and smoke constituents while decreases in porosity may increase smoke constituents. To address decreases in smoke constituents due to differences in design parameters, the applicant provided the measured TNCO and HPHC values which were deferred to chemistry.

Draw Resistance: For SE0000007 - SE0000009, there are differences in draw resistance between ↓ 4% to ↓ 8%. Differences in draw resistance can affect the delivery of smoke constituents. However, the new tobacco products' target specifications are all within the corresponding predicate tobacco products' lower and upper range limits. Therefore, the differences do not cause the new products to raise different questions of public health from an engineering perspective.

Filter Pressure Drop: For SE0000007 and SE0000009, there are decreases in filter pressure drop. A decrease in filter pressure drop may result in reduced filter efficiency, and in turn, an increase in tar and nicotine levels. However, because the filter tow specifications for the new and corresponding predicate tobacco products' filters are the same, the differences in filter pressure drop do not cause the new tobacco products to raise different questions of public health.

Puff Count: For all SE Reports, the puff count increased from 1% to 11.6%. An increase in puff count has been shown to increase smoke constituents. To address increases in smoke constituents due to differences in design parameters, the applicant provided the measured TNCO and HPHC values which were deferred to chemistry.

Filter efficiency: The applicant did not provide a measurement of filter efficiency but did provide details of the filter construction (denier per filament, total denier, filter density, and filter pressure drop). An analysis of the denier per filament (thickness of a filament), total denier (thickness of polymer strands [combinations of filaments into a "rope" of filter material]), filter density (weight of filter per unit volume), and filter pressure drop (air flow effects) allow an alternative means to evaluate the effective efficiency of the filter. For SE0000004-SE0000009 there are no differences in the filter construction that are large enough to result in a change in the filter efficiency. For SE0000069, the total denier is effectively the same between the new tobacco product and the predicate tobacco product. The denier per filament (DPF) is lower in the new tobacco product than in the predicate tobacco product (16%). A decrease in DPF with no difference in total denier results in an increase in filter pressure drop which tends to increase filter efficiency. In addition, the new product shows a 5.9% decrease in filter density compared to the predicate tobacco product. A decrease in filter density will result in lower filter efficiency in the absence of other changes. However, in this case, the decrease in DPF in the new tobacco product compensates for the decrease in filter density, and thus the filter efficiency should be increased when taken together. Because increased filter efficiency may lead to lower particle-borne HPHC content,

the changes in DPF, filter pressure drop, and filter density do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

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 from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Pei-Hsuan Hung on September 1, 2017, June 22, 2018, August 15, 2018, March 20, 2019, and April 1, 2019.

For SE0000009, the final toxicology review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from a toxicology perspective. 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 toxicology.

For SE0000004, SE0000005, SE0000006, SE0000007, SE0000008 and SE0000069, 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 review identified the following differences:

SE0000004
- Decrease in NNN (21% ISO, 20% CI), NNK (21% ISO), and furfural (20% ISO)
- Increase in styrene (23% CI)

SE0000005
- Decrease in NNK (18% ISO)
- Increase in *o*-cresol (24% ISO)

SE0000006
- Decrease in NNN (27% ISO, 31%CI), NNK (28% ISO, 25% CI), B[a]P (40% ISO)

SE0000007
- Decrease in furfural (19% ISO, 22% CI)

SE0000008
- Decrease in NNK (25% ISO), (b) (4) [redacted] (34% CI)

SE0000069
- Decrease in NNN (20% CI), *m-, p*-cresol (19% CI), phenol (24% CI), (b) (4) [redacted] (25% CI)

For SE0000004, when considering measurements under the ISO smoking regimen, NNK, NNN, and furfural yields decreased. Under the CI smoking regimen, NNN was decreased and styrene was increased in the mainstream smoke of the new tobacco product when compared with the corresponding surrogate predicate tobacco product. Styrene has the potential to induce lung and lymphohematopoietic system cancers. NNN and NNK are classified as "*carcinogenic to*

humans." When all toxicological evidences are taken together, there is no clear evidence that the additional cancer risk associated with the increase in styrene would outweigh the cancer risk that is expected to be decreased by the reduction in the NNN content in the smoke of the new tobacco product when compared with the corresponding surrogate predicate tobacco product. Thus, the increased smoke yield of styrene alone under CI smoking regimen is not likely to cause the new tobacco product to raise different questions of public health from a toxicological perspective.

For SE0000005, when considering measurements under the ISO smoking regimen, NNK decreased by 18% while *o*-Cresol increased by 24% in the mainstream smoke of the new tobacco product when compared with those of the corresponding surrogate predicate tobacco product. The US Environmental Protection Agency (EPA) has classified the three cresol isomers (*o-, m-, p-*) as "*possible human carcinogens"* and NNK as "*carcinogenic to humans.*" When the toxicological evidence is taken together, there is no evidence to suggest that the additional cancer risk associated with the increased amount of *o*-cresol would outweigh the cancer risk that is expected to be decreased due to the decreased NNK for the new tobacco product compared with the corresponding surrogate predicate tobacco product, and hence the increase in *o*-cresol is not likely to cause the new tobacco product to raise different questions of public health from a toxicological perspective.

SE0000006, SE0000007, SE0000008, and SE0000069 are each reported to yield only decreases in the submitted HPHCs in the new tobacco products when compared to the corresponding surrogate predicate tobacco products. Decreases in HPHC yields of cigarette smoke may lead to decreases in the health risks and therefore the differences in the HPHC yields do not cause the new tobacco product 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 from a toxicology perspective.

4.4. SOCIAL SCIENCE

The social science review was completed by Katherine Margolis on November 28, 2018.

The social science review concludes that the new tobacco product has different characteristics from the corresponding predicate tobacco product for SE0000009, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. For SE0000004-SE0000008 and SE0000069, the social science reviewer concludes that there are no different characteristics from the corresponding predicate tobacco products from a social science perspective. The review identified the following differences:

- SE0000009 - 18% increase in product length

The Social science review stated that there was a difference in the length of the new and predicate tobacco products in SE0000009. I, as the TPL, disagree with this statement because the product length difference was found to be a typographical error in the social science review. Therefore, further considerations by the social science review are moot.

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 from a social science perspective.

The review also evaluated the health information summary for each SE Report. FDA has determined that the health information summary provided for these SE Reports would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco products into interstate commerce.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports (SE0000004-SE0000009 and SE0000069) is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

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

- Tobacco filler mass (↓ 2% to ↑ 8%)
- Tobacco rod density (↑2% to ↑14%) (SE0000004-SE0000009)
- Cigarette mass (↓ 2% to ↑ 7%)
- Increases in total tobacco amounts (13% to 14%) (SE0000004-SE0000009)
- Increases in (b) (4) tobacco amounts (37%) (SE0000069)
- Cigarette paper basis weight (↑ 8%)
- Cigarette paper band porosity (↓ 43%) (SE0000004-SE0000009)
- Cigarette paper band porosity (↑ 1150%) (SE0000069)
- Cigarette paper band width (↑17%)
- Cigarette paper band space (↓10%) (SE0000004-SE0000009)
- Cigarette paper band space (↓25%) (SE0000069)
- Puff count (↑1% to ↑ 11.6%)
- Filter pressure drop (↓ 5% to ↓ 6%) (SE0000007, SE0000009)
- Filter rod density (↓ 6%) (SE0000069)
- Denier per filter (↓ 16%) (SE0000069)
- Draw resistance (↓ 4% to ↓ 8%) (SE0000005, SE0000007-SE0000009)
- Increase in (b) (4) in cigarette paper and addition of (b) (4) to cigarette paper
- Several differences in HPHC yields, determined not analytically equivalent
  - SE0000004
    - Decrease in NNN (21% ISO, 20% CI), NNK (21% ISO), and furfural (20% ISO)
    - Increase in styrene (23% CI)
  - SE0000005
    - Decrease in NNK (18% ISO)
    - Increase in *o*-cresol (24% ISO)

- SE0000006
  - Decrease in NNN (27% ISO, 31%CI), NNK (28% ISO, 25% CI), B[a]P (40% ISO)
- SE0000007
  - Decrease in furfural (19% ISO, 22% CI)
- SE0000008
  - Decrease in NNK (25% ISO), (b) (4) [redacted] (34% CI)
- SE0000069
  - Decrease in NNN (20% CI), *m-, p*-cresol (19% CI), phenol (24% CI), (b) (4) [redacted] (25% CI)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health.

The changes to the tobacco product design, tobacco blend, and ingredients may result in differences in HPHC delivery of the new tobacco products when compared to the corresponding predicate tobacco products. A discussion of the specific changes to each of the products are discussed in discipline summaries in section 4 above. The applicant provided measured HPHC values of the new and corresponding surrogate predicate products. The applicant's data indicated that there were no increases in HPHCs or TNCOs in the new tobacco products in SE0000006-SE0000009 and SE0000069 when compared to the corresponding surrogate predicate tobacco products. Therefore, the changes in product design, tobacco blend, and ingredients do not cause these new tobacco products to raise different questions of public health.

However, the new tobacco product data also showed analytically important increases and decreases in HPHCs in SE0000004 and SE0000005. When all toxicological evidence is taken together, there is no clear evidence that the additional cancer risk associated with the increased HPHCs would outweigh the cancer risk that is expected to be decreased by the reduction of NNK (and NNN and furfural in SE0000004) in the smoke of the new tobacco products when compared with the corresponding surrogate predicate tobacco products. Therefore, the differences in product design, tobacco blend, and ingredients between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

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

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

SE order letters should be issued for the new tobacco products in SE0000004-SE0000009 and SE0000069, as identified on the cover page of this review.