

Technical Project Lead (TPL) Review:

SE0014352 - SE0014363

SE0014352: Native 100's Hard Pack (Blue) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	None
SE0014353: Native 100's Soft (Blue) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	None
SE0014354: Native King Hard Pack (Blue) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	None
SE0014355: Native King Soft (Blue) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	None
SE0014356: Native 100's Hard Pack (Ultra) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None

SE0014357: Native 100's Soft (Ultra) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None
SE0014358: Native King Hard Pack (Ultra) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None
SE0014359: Native King Soft (Ultra) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None
SE0014360: Native Menthol 100's Hard Pack (Green) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	Menthol
SE0014361: Native Menthol 100's Soft (Green) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	Menthol

SE0014362: Native Menthol King Hard Pack (Green) (2017)	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	Menthol
SE0014363: Native Menthol King Soft (Green) (2017)	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	26%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Susan Jesmer dba NTA
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2018.07.27 12:17:59 -04'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

- ☒ Concur with TPL recommendation and basis of recommendation
- ☐ Concur with TPL recommendation with additional comments (see separate memo)
- ☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2018.07.27 14:31:49 -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:

SE0014352: Native 100's Hard Pack (Blue) (2017)	
Product Name	Native Full Flavor 100's Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014353: Native 100's Soft (Blue) (2017)	
Product Name	Native Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014354: Native King Hard Pack (Blue) (2017)	
Product Name	Native Full Flavor King Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014355: Native King Soft (Blue) (2017)	
Product Name	Native Full Flavor King Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

SE0014356: Native 100's Hard Pack (Ultra) (2017)	
Product Name	Native Full Flavor 100's Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014357: Native 100's Soft (Ultra) (2017)	
Product Name	Native Full Flavor 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014358: Native King Hard Pack (Ultra) (2017)	
Product Name	Native Full Flavor King Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
SE0014359: Native King Soft (Ultra) (2017)	
Product Name	Native Full Flavor King Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

SE0014360: Native Menthol 100's Hard Pack (Green) (2017)	
Product Name	Native Menthol 100's Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
SE0014361: Native Menthol 100's Soft (Green) (2017)	
Product Name	Native Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
SE0014362: Native Menthol King Hard Pack (Green) (2017)	
Product Name	Native Menthol King Hard Pack
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
SE0014363: Native Menthol King Soft (Green) (2017)	
Product Name	Native Menthol King Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 26, 2017, FDA received twelve SE Reports from Susan Jesmer d/b/a Native Trading Associates (NTA). FDA issued Acknowledgement letters to the applicant on October 2, 2017.

FDA issued an Advice/Information Request (A/I) letter on December 22, 2017. On January 18, 2018, FDA received the applicant's response to the December 22, 2017, A/I letter (SE0014470). On January 19, 2018, FDA conducted a teleconference to clarify the correlation of responses to the applicable SE Reports and inform the sponsor of a discrepancy between a submission tracking number and tobacco product name in the amendment received January 18, 2018. On January 22, 2018, FDA received the applicant's amended responses to the December 22, 2017, A/I letter (SE0014481). FDA issued a Preliminary Finding (PFind) letter on April 18, 2018. On May 15, 2018, FDA received the response to the PFind letter (SE0014722). On May 29, 2018, FDA conducted a teleconference to clarify the response to question 2 in the amendment received January 18, 2018, and to determine if the applicant plans to replace their currently marketed products with the products subject of these SE Reports if SE orders are issued. On May 31, 2018, FDA received the response to the May 29, 2018, teleconference (SE0014743).

Product Name	SE Report	Amendments
Native 100's Hard Pack (Blue) (2017)	SE0014352	SE0014470 SE0014481 SE0014722 SE0014743
Native 100's Soft (Blue) (2017)	SE0014353	
Native King Hard Pack (Blue) (2017)	SE0014354	
Native King Soft (Blue) (2017)	SE0014355	
Native 100's Hard Pack (Ultra) (2017)	SE0014356	
Native 100's Soft (Ultra) (2017)	SE0014357	
Native King Hard Pack (Ultra) (2017)	SE0014358	
Native King Soft (Ultra) (2017)	SE0014359	
Native Menthol 100's Hard Pack (Green) (2017)	SE0014360	
Native Menthol 100's Soft (Green) (2017)	SE0014361	
Native Menthol King Hard Pack (Green) (2017)	SE0014362	
Native Menthol King Soft (Green) (2017)	SE0014363	

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

A regulatory review was completed by Maryanne Dingman on October 2, 2017.

The review concludes that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco 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 November 2, 2017 (for all SE Reports) 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.¹

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated July 27, 2018, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Youbang Liu, on November 30, 2017, and February 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. The review identified the following differences:

- Change from non-FSC² to FSC cigarette paper
- Different plug wrap with increases of (b) (4) /cigarette pulp (b) (4)
- Different tipping paper with addition of (b) (4) /cigarette (b) (4)

The change to FSC paper results in some ingredient differences. Specifically, pulp (b) (4) is 5-6% less in the new products compared to the corresponding predicate products. The lower amount of pulp (b) (4) in the new products unlikely causes the new products to raise different questions of public health. In addition, oxidized starch is present in all new products at (b) (4) mg/cig, but is not present in the corresponding predicate products. The applicant provided testing data for benzo[a]pyrene, acetaldehyde, benzene, tar, and carbon monoxide under both ISO and CI smoking regimens, which showed reductions for these HPHCs in the new products. This HPHC data demonstrates that the change from non-FSC cigarette paper in the predicate products to FSC cigarette paper in the new products and the accompanying ingredient differences do not cause the new products to raise different questions of public health.

¹ Addendum reviews were completed on March 30, 2018 (SE0014352-SE0014353, SE0014355-SE0014357, SE0014359-SE0014363), and April 3, 2018, (SE0014354 and SE0014358), to clarify that the characterizing flavor of the predicate tobacco product is "None" or "Menthol." The addendum review does not change the conclusion of the initial grandfather determination dated November 2, 2017.

² Fire Standards Compliant

For plug wrap, the absolute increase of the pulp (b) (4) in the new products is from 1.3 to 1.6 mg/cig compared to the corresponding predicate products. In the tipping paper, (b) (4) is present in the new products at (b) (4) /cig but is not present in the corresponding predicate products. The plug wrap and tipping paper are not intended to be combusted. Thus, the differences of the pulp (b) (4) and (b) (4) should not affect smoke chemistry.

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 Karen Coyne, on November 28, 2017, and March 01, 2018, and by Michael Morschauser on June 29, 2018.

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:

All SE Reports

- Change from non-FSC to FSC cigarette paper
- 12% increase in cigarette paper basis weight
- 232% increase in cigarette paper base paper porosity
- 14-45% decrease in cigarette draw resistance
- 550-1,025% increase in ventilation

SE0014352 and SE0014353

- 7% decrease in puff count
- 14% increase in burn rate

SE0014356-SE0014359

- 6-10% increases in puff count

SE0014358 and SE0014359

- 12% decrease in burn rate

The engineering review explains that most of the design differences that may increase smoke constituent yields are offset by a corresponding design difference that decrease the smoke constituent yields. As covered in the chemistry review, benzo[a]pyrene, acetaldehyde, benzene, tar, nicotine, and carbon monoxide (TNCO) values for the new tobacco products are lower or within analytical variability compared to the corresponding predicate tobacco products.

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

A toxicology review was completed by La’Nissa Brown-Baker on November 29, 2017.

The toxicology review concludes that the new tobacco products have different characteristics related to 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:

- Change from non-FSC to FSC cigarette paper
- Change in tipping paper
- Change in plug wrap

For all SE Reports, the change to FSC paper and related ingredient differences are not a concern from a toxicology perspective. TNCO, benzene, benzo[a]pyrene, acetaldehyde, and formaldehyde yields were either less than or within analytical variability for the new products compared to the corresponding predicate tobacco products. Additionally, the use of different tipping paper and plug wrap in the new products is not a concern because these components are not combusted and therefore, are not expected to affect smoke chemistry.

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.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 26, 2018. The FONSI was supported by an environmental assessment prepared by FDA on July 26, 2018. The environmental assessment indicates that all amendments (e.g. SE0014470, SE0014481, SE0014722, and SE0014743) were reviewed.

6. CONCLUSION AND RECOMMENDATION

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

- Change from non-FSC to FSC cigarette paper

- 12% increase in cigarette paper basis weight
- 232% increase in cigarette paper base paper porosity
- Different plug wrap with increases of (b) (4) cigarette pulp (b) (4)
- Different tipping paper with addition of (b) (4) /cigarette (b) (4) 14-45% decreases in cigarette draw resistance
- 550-1,025% increases in ventilation
- 7% decrease in puff count (SE0014352 and SE0014353)
- 14% increase in burn rate (SE0014352 and SE0014353)
- 6-10% increases in puff count (SE0014356-SE0014359)
- 12% decrease in burn rate (SE0014358 and SE0014359)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant provided tar, nicotine, carbon monoxide, benzene, benzo[a]pyrene, acetaldehyde, and formaldehyde yields for both ISO and Canadian Intense smoking regimens. The values were either less than or within analytical variability for the new products compared to the corresponding predicate tobacco products. Additionally, the use of different tipping paper and plug wrap in the new products are not a concern because these components are not combusted and therefore are not expected to affect smoke chemistry. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that 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 new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0014352 - SE0014363 as identified on the cover page of this review.