

**Technical Project Lead (TPL) Review:**

**SE0014960, SE0014961, SE0014962, SE0014963, SE0014964,  
SE0014965, SE0014966, SE0014967, and SE0014968**

<b>SE0014960: Nat's Yellow King<sup>1</sup></b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.80 mm
<b>Ventilation</b>	41%
<b>Characterizing Flavor</b>	None
<b>SE0014961: Classic</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014962: Originals Menthol</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	101 mm
<b>Diameter<sup>2</sup></b>	6.94 mm
<b>Ventilation</b>	35%
<b>Characterizing Flavor</b>	Menthol
<b>SE0014963: Originals Blue</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	101 mm
<b>Diameter<sup>2</sup></b>	6.94 mm
<b>Ventilation</b>	50%
<b>Characterizing Flavor</b>	None

<sup>1</sup> The applicant stated that the new tobacco product will also be identified as Select Yellow King.

<sup>2</sup> The applicant submitted the circumference which allowed for a calculation of diameter.

<b>SE0014964: Nat's King<sup>3</sup></b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.80 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014965: New York Cut Blue</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.86 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>SE0014966: New York Cut Original</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.86 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014967: Classic Menthol</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	Menthol
<b>SE0014968: Classic Blue</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	41%
<b>Characterizing Flavor</b>	None

<sup>3</sup> The applicant stated that the new tobacco product will also be identified as Select King.

<b>Common Attributes of SE Reports</b>	
<b>Applicant</b>	Sherman's 1400 Broadway, N.Y.C., LLC
<b>Report Type</b>	Regular
<b>Product Category</b>	Cigarettes
<b>Product Sub-Category</b>	Combusted, Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2019.02.04 14:57:50 -05'00'

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: 2019.02.05 09:09:31 -05'00'

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:

<b>SE0014960: Nat's Yellow King<sup>1</sup></b>	
<b>Product Name</b>	Naturals Lights King
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.80 mm
<b>Ventilation</b>	41%
<b>Characterizing Flavor</b>	None
<b>SE0014961: Classic</b>	
<b>Product Name</b>	Classic
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014962: Originals Menthol</b>	
<b>Product Name</b>	Naturals Mint
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	101 mm
<b>Diameter<sup>2</sup></b>	6.94 mm
<b>Ventilation</b>	35%
<b>Characterizing Flavor</b>	Menthol
<b>SE0014963: Originals Blue</b>	
<b>Product Name</b>	Naturals Lights
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	101 mm
<b>Diameter<sup>2</sup></b>	6.94 mm
<b>Ventilation</b>	50%
<b>Characterizing Flavor</b>	None

<b>SE0014964: Nat's King<sup>3</sup></b>	
<b>Product Name</b>	Naturals Originals King
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.80 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014965: New York Cut Blue</b>	
<b>Product Name</b>	New York Cut Light
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.86 mm
<b>Ventilation</b>	30%
<b>Characterizing Flavor</b>	None
<b>SE0014966: New York Cut Original</b>	
<b>Product Name</b>	New York Cut Original
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.86 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	None
<b>SE0014967: Classic Menthol</b>	
<b>Product Name</b>	Classic Mint
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	None
<b>Characterizing Flavor</b>	Menthol

<b>SE0014968: Classic Blue</b>	
<b>Product Name</b>	Classic Light
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	84 mm
<b>Diameter<sup>2</sup></b>	7.67 mm
<b>Ventilation</b>	41%
<b>Characterizing Flavor</b>	None

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

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 15, 2018, FDA received 9 SE Reports from Sherman's 1400 Broadway, N.Y.C., LLC. FDA issued Acknowledgement letters to the applicant on November 26, 2018.

On December 3, 2018, unsolicited amendments were received for SE0014965 and SE0014966.

Product Name	SE Report	Amendments
Nat's Yellow King / Select Yellow King	SE0014960	None
Classic	SE0014961	None
Originals Menthol	SE0014962	None
Originals Blue	SE0014963	None
Nat's King / Select King	SE0014964	None
New York Cut Blue	SE0014965	SE0014992
New York Cut Original	SE0014966	SE0014993
Classic Menthol	SE0014967	None
Classic Blue	SE0014968	None

## 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 Shireen Fotelargias on November 26, 2018.

The reviews conclude 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 December 15, 2018 (for SE0014961-SE0014964, SE0014967, SE0014968), December 17, 2018 (for SE0014965, SE0014966), and December 18, 2018 (for SE0014960), 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.

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated January 31, 2019 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. ENGINEERING**

An engineering review was completed by Drew Katherine on December 20, 2018.

The 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 difference:

- Decrease in the band permeability lower range limit from 6 CU to 0.1 CU.

Cigarette paper bands function to extinguish the cigarette and have low permeability. Because the lower limit for band permeability for the corresponding predicate products was already very low, lowering the band permeability lower limit from 6 CU to 0.1 CU in the new product is a change that is expected to have the same effect in terms of FSC properties as the corresponding predicate tobacco products.

Therefore, the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health from an engineering perspective.

### **5. ENVIRONMENTAL DECISION**

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 18, 2019. The FONSI was supported by an environmental assessment prepared by FDA on January 18, 2019.

## 6. CONCLUSION AND RECOMMENDATION

The following is the key difference in characteristics between the new and predicate tobacco products:

- Decrease in the band permeability lower range limit from 6 CU to 0.1 CU.

The applicant has demonstrated that this difference in characteristics does not cause the new tobacco products to raise different questions of public health. The corresponding predicate tobacco products have a lower limit band permeability that is very low. Lowering the band permeability lower limit from 6 CU to 0.1 CU in the new products is anticipated to have the same effect on the FSC properties as the corresponding predicate tobacco products. Therefore, the difference in characteristics between the new and corresponding predicate products does not cause the new tobacco products to raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act. In addition, the scientific review concludes 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 this review 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 SE0014960, SE0014961, SE0014962, SE0014963, SE0014964, SE0014965, SE0014966, SE0014967, and SE0014968, as identified on the cover page of this review.