

**Technical Project Lead (TPL) Review:  
Exemption Request EX0000263 – EX0000270**

<b>EX0000263: Natural American Spirit 100% US Grown Tobacco Mellow Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)</li> <li>• Deletion of filter tow (b) (4)(b) (4)</li> </ul>
<b>EX0000264: Natural American Spirit Made with Organic Tobacco Mellow Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	54%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)</li> <li>• Deletion of filter tow (b) (4)(b) (4)(b) (4)</li> </ul>
<b>EX0000265: Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	25%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)(b) (4)</li> <li>• Deletion of filter tow (b) (4)</li> </ul>
<b>EX0000266: Natural American Spirit Mellow Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	35%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)</li> <li>• Deletion of filter tow (b) (4)(b) (4)</li> </ul>
<b>EX0000267: Natural American Spirit Full-Bodied Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	20%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)(b) (4)</li> <li>• Deletion of filter tow (b) (4)</li> </ul>

<b>EX0000268: Natural American Spirit Perique Blend Rich Robust Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	21%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)(b) (4)</li> <li>• Deletion of filter tow (b) (4)</li> </ul>
<b>EX0000269: Natural American Spirit Smooth Mellow Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	60%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)</li> <li>• Deletion of filter tow (b) (4)(b) (4)(b) (4)</li> </ul>
<b>EX0000270: Natural American Spirit Perique Blend Rich Taste</b>	
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	45%
<b>Characterizing Flavor</b>	None
<b>Product Modifications</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of filter tow (b) (4)</li> <li>• Deletion of filter tow (b) (4)(b) (4)</li> </ul>
<b>Attributes of Exemption Requests</b>	
<b>Applicant</b>	Santa Fe Natural Tobacco Company, Inc.
<b>Product Category</b>	Cigarette
<b>Product Sub-Category</b>	Combusted Filtered
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Recommendation</b>	
Issue Exempt order letters.	

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2018.11.06 11:13:16 -05'00'

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: 2018.11.06 11:25:11 -05'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science

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## 1. BACKGROUND

### 1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

**Table 1. Original Tobacco Products**

<b>EX0000263: Natural American Spirit 100% US Grown Tobacco Mellow Taste</b>	
<b>Product Name</b>	Natural American Spirit 100% US Grown Tobacco Mellow Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	None
<b>EX0000264: Natural American Spirit Made with Organic Tobacco Mellow Taste</b>	
<b>Product Name</b>	Natural American Spirit Made with Organic Tobacco Mellow Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	54%
<b>Characterizing Flavor</b>	None
<b>EX0000265: Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste</b>	
<b>Product Name</b>	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	25%
<b>Characterizing Flavor</b>	None
<b>EX0000266: Natural American Spirit Mellow Taste</b>	
<b>Product Name</b>	Natural American Spirit Mellow Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	35%
<b>Characterizing Flavor</b>	None

<b>EX0000267: Natural American Spirit Full-Bodied Taste</b>	
<b>Product Name</b>	Natural American Spirit Full-Bodied Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	20%
<b>Characterizing Flavor</b>	None
<b>EX0000268: Natural American Spirit Perique Blend Rich Robust Taste</b>	
<b>Product Name</b>	Natural American Spirit Perique Blend Rich Robust Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	21%
<b>Characterizing Flavor</b>	None
<b>EX0000269: Natural American Spirit Smooth Mellow Taste</b>	
<b>Product Name</b>	Natural American Spirit Smooth Mellow Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	60%
<b>Characterizing Flavor</b>	None
<b>EX0000270: Natural American Spirit Perique Blend Rich Taste</b>	
<b>Product Name</b>	Natural American Spirit Perique Blend Rich Taste
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Length</b>	84 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	45%
<b>Characterizing Flavor</b>	None

The applicant manufactures the original tobacco products. The original tobacco products were previously found substantially equivalent by FDA under SE0000118, SE0006279, SE0000117, SE0006280, SE0006276, SE0006288, SE0006289, and SE0000116 for EX0000263 – EX0000270, respectively.

**1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

The applicant submitted the Exemption Requests EX0000263 – EX0000270 on September 7, 2018. FDA issued Acknowledgement letters for these Exemption Requests on September 14, 2018. On October 2, 2018, FDA requested additional information related to product ventilation and the environmental assessment. On October 9, 2018, the applicant provided the information under EX0000280.

**1.3. SCOPE OF REVIEW**

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

**1.4. TOBACCO ADDITIVE MODIFICATION**

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

EX0000263, EX0000264, EX0000266, EX0000269, and EX0000270:

- Addition of filter tow (b) (4)
- Deletion of filter tow (b) (4)(b) (4)

EX0000265, EX0000267, and EX0000268:

- Addition of filter tow (b) (4)(b) (4)(b) (4)
- Deletion of filter tow (b) (4)

**2. REGULATORY REVIEW**

A regulatory review was completed by Brandon Rose on September 14, 2018. The review concludes that these Exemption Requests are administratively complete.

**3. COMPLIANCE REVIEW**

The original tobacco products in EX0000263-EX0000270 were previously determined to be substantially equivalent by FDA as shown in the table below.

EX Request	Original Tobacco Product	Original Tobacco Product Found SE Under:	Date
EX0000263	Natural American Spirit 100% US Grown Tobacco Mellow Taste	SE0000118	
EX0000264	Natural American Spirit Made with Organic Tobacco Mellow Taste	SE0006279	

EX0000265	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	SE0000117	June 6, 2018
EX0000266	Natural American Spirit Mellow Taste	SE0006280	
EX0000267	Natural American Spirit Full-Bodied Taste	SE0006276	
EX0000268	Natural American Spirit Perique Blend Rich Robust Taste	SE0006288	
EX0000269	Natural American Spirit Smooth Mellow Taste	SE0006289	
EX0000270	Natural American Spirit Perique Blend Rich Taste	SE0000116	

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Megan Mekoli on October 24, 2018. The review states that the new tobacco products have been modified by adding and deleting a tobacco additive. Filter tow is used in the manufacturing of the original tobacco products and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review determines that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. Although, filter tow can influence the ventilation of a product; the ventilation of the new and corresponding original tobacco products remained the same.

#### 5. ENVIRONMENTAL DECISION

An environmental review was completed by Susan Addo Ntim on October 11, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 6, 2018. The FONSI was supported by an environmental assessment prepared by FDA on November 6, 2018.

#### 6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

EX0000263, EX0000264, EX0000266, EX0000269, and EX0000270:

- Addition of filter tow (b) (4)
- Deletion of filter tow (b) (4)(b) (4)

EX0000265, EX0000267, and EX0000268:



- Addition of filter tow (b) (4)(b) (4)(b) (4)
- Deletion of filter tow (b) (4)

I concur with the conclusion of the scientific review that this modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines ‘additive’ as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . .” I concur with the scientific review that the deletion of filter tow and addition of an alternative filter tow is an addition/deletion of a tobacco additive. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health. The review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. The filter tow can influence the ventilation of a product, however, the ventilation of the new and corresponding original tobacco products remained the same. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP’s scientific understanding, that an exemption for this modification is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products were previously found substantially equivalent by FDA under SE0000118, SE0006279, SE0000117, SE0006280, SE0006276, SE0006288, SE0006289, and SE0000116.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

Exempt order letters should be issued for the new tobacco products in EX0000263 – EX0000270 as identified on the cover page of this review.