



**Technical Project Lead (TPL) Review:
Exemption Requests EX0000454 – EX0000462**

EX0000454: Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste

Length	84 mm
Diameter	7.9 mm
Ventilation	25%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none">• Deletion of filter center line adhesive (b)(4) [REDACTED]• [REDACTED]• Addition of filter center line adhesive (b)(4) [REDACTED]• Deletion of filter seam adhesive (b)(4) [REDACTED]• Addition of filter seam adhesive (b)(4) [REDACTED]

EX0000455: Natural American Spirit 100% US Grown Tobacco Mellow Taste

Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none">• Deletion of filter center line adhesive (b)(4) [REDACTED]• [REDACTED]• Addition of filter center line adhesive (b)(4) [REDACTED]• Deletion of filter seam adhesive (b)(4) [REDACTED]• Addition of filter seam adhesive (b)(4) [REDACTED]

EX0000456: Natural American Spirit Full-Bodied Taste

Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none">• Deletion of filter center line adhesive (b)(4) [REDACTED]• [REDACTED]• Addition of filter center line adhesive (b)(4) [REDACTED]• Deletion of filter seam adhesive (b)(4) [REDACTED]• Addition of filter seam adhesive (b)(4) [REDACTED]

EX0000457: Natural American Spirit Mellow Taste

Length	84 mm
Diameter	7.9 mm
Ventilation	35%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none">• Deletion of filter center line adhesive (b)(4) [REDACTED]• [REDACTED]• Addition of filter center line adhesive (b)(4) [REDACTED]

	<ul style="list-style-type: none"> • Deletion of filter seam adhesive (b)(4) • Addition of filter seam adhesive (b)(4)
EX0000458: Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	
Length	84 mm
Diameter	7.9 mm
Ventilation	32%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b)(4) • Addition of filter center line adhesive (b)(4) • Deletion of filter seam adhesive (b)(4) • Addition of filter seam adhesive (b)(4)
EX0000459: Natural American Spirit Made with Organic Tobacco Mellow Taste	
Length	84 mm
Diameter	7.9 mm
Ventilation	54%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b)(4) • Addition of filter center line adhesive (b)(4) • Deletion of filter seam adhesive (b)(4) • Addition of filter seam adhesive (b)(4)
EX0000460: Natural American Spirit Perique Blend Rich Robust Taste	
Length	84 mm
Diameter	7.9 mm
Ventilation	21%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b)(4) • Addition of filter center line adhesive (b)(4) • Deletion of filter seam adhesive (b)(4) • Addition of filter seam adhesive (b)(4)
EX0000461: Natural American Spirit Perique Blend Rich Taste	
Length	84 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b)(4) • Addition of filter center line adhesive (b)(4) • Deletion of filter seam adhesive (b)(4) • Addition of filter seam adhesive (b)(4)

EX0000462: Natural American Spirit Smooth Mellow Taste	
Length	84 mm
Diameter	7.9 mm
Ventilation	60%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> Deletion of filter center line adhesive (b)(4) Deletion of filter center line adhesive (b)(4) Addition of filter center line adhesive (b)(4) Deletion of filter seam adhesive (b)(4) Addition of filter seam adhesive (b)(4)
Common Attributes of Exemption Requests	
Applicant	Santa Fe Natural Tobacco Company, Inc.
Product Category	Cigarette
Product Sub-Category	Combusted, Filtered
Package Quantity	20 Cigarettes
Package Type	Box
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
 Date: 2019.04.05 11:49:06 -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 Glen D. Jones -S
 Date: 2019.04.05 13:05:11 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND	5
1.1. ORIGINAL TOBACCO PRODUCTS	5
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	7
1.3. SCOPE OF REVIEW.....	7
1.4. TOBACCO ADDITIVE MODIFICATION.....	7
2. REGULATORY REVIEW	7
3. COMPLIANCE REVIEW	7
4. SCIENTIFIC REVIEW	7
5. ENVIRONMENTAL DECISION.....	8
6. CONCLUSION AND RECOMMENDATION	8

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000454: Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	
Product Name	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	25%
Characterizing Flavor	None
EX0000455: Natural American Spirit 100% US Grown Tobacco Mellow Taste	
Product Name	Natural American Spirit 100% US Grown Tobacco Mellow Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	None
EX0000456: Natural American Spirit Full-Bodied Taste	
Product Name	Natural American Spirit Full-Bodied Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
EX0000457: Natural American Spirit Mellow Taste	
Product Name	Natural American Spirit Mellow Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	35%
Characterizing Flavor	None
EX0000458: Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	
Product Name	Natural American Spirit Made with Organic Tobacco Full-Bodied Taste
Package Quantity	20 Cigarettes

Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	32%
Characterizing Flavor	None
EX0000459: Natural American Spirit Made with Organic Tobacco Mellow Taste	
Product Name	Natural American Spirit Made with Organic Tobacco Mellow Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	54%
Characterizing Flavor	None
EX0000460: Natural American Spirit Perique Blend Rich Robust Taste	
Product Name	Natural American Spirit Perique Blend Rich Robust Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	21%
Characterizing Flavor	None
EX0000461: Natural American Spirit Perique Blend Rich Taste	
Product Name	Natural American Spirit Perique Blend Rich Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	45%
Characterizing Flavor	None
EX0000462: Natural American Spirit Smooth Mellow Taste	
Product Name	Natural American Spirit Smooth Mellow Taste
Package Quantity	20 Cigarettes
Package Type	Box
Length	84 mm
Diameter	7.9 mm
Ventilation	60%
Characterizing Flavor	None

The applicant manufactures the original tobacco products. The original tobacco products were found to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence by FDA under EX0000262 – EX0000270.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 15, 2019, FDA received nine Exemption Requests (EX0000454-EX0000462) from RAI Services Company on behalf of Santa Fe Natural Tobacco Company, Inc. On March 1, 2019, FDA issued an Acknowledgement letter to the applicant.

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:

- Deletion of filter center line adhesive (b)(4)
- Addition of filter center line adhesive (b)(4)
- Deletion of filter seam adhesive (b)(4)
- Addition of filter seam adhesive (b)(4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Nia White on March 1, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000454 – EX0000462 were determined by FDA, under EX0000262 – EX0000270, to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence, reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted on January 4, 2019, under AS0000061 -AS0000069, and at least 90 days have elapsed since FDA receipt of the Abbreviated Reports. Therefore, the original products are eligible for modification under the Exemption Request pathway.^{1,2}

4. SCIENTIFIC REVIEW

A scientific review was completed by Karina Zuck on April 4, 2019.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Filter center line adhesive and filter seam adhesive is used in the manufacturing of the original tobacco products and are additives because their intended use may reasonably be

¹ Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

² See memo to file on acceptance of Exemption Requests under 905(j)(3) of the FD&C Act dated April 4, 2019.

expected to result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modifications 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 center adhesive [b](4) and filter seam adhesive [b](4) followed by the addition of an alternative filter center line adhesive [b](4) and an alternative filter seam adhesive [b](4) due to a change in suppliers, is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. The filter center line adhesive and filter seam adhesive are not present in the tobacco column and are therefore not intended to be part of the combustion product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on March 27, 2019.

The final environmental review found that the applicant did not provide information on the current market volumes of the original products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of filter center line adhesive [b](4)
- Addition of filter center line adhesive [b](4)
- Deletion of filter seam adhesive [b](4)
- Addition of filter seam adhesive [b](4)

I concur with the conclusion of the scientific review that these modifications are minor modifications 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 center line adhesive [b](4) and filter seam adhesive [b](4) [b](4) and the addition of an alternative filter center line adhesive [b](4) and alternate filter seam adhesive [b](4) is an addition/deletion of tobacco additives. 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 determines that the deletion of filter center adhesive [b](4) and filter seam adhesive [b](4) followed by the addition of an alternative filter center line adhesive [b](4) and an alternative filter seam adhesive [b](4) due to a change in suppliers, is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating

source, or other features) of the products. Specifically, these modifications are made to the non-combusted component of the cigarettes; the alternative center line adhesive and alternate filter seam adhesive is not combusted, volatilized or otherwise released during normal cigarette consumption and so consumer exposure to chemical constituents from the alternative center line adhesive is not expected. Thus, these changes are considered minor modifications and meet the requirements set forth in section 905(j)(3)(A)(i) of the FD&C Act. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications 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 tobacco products are previously found Exempt by FDA under EX0000262 – EX0000270, reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted on January 4, 2019, under AS0000061 – AS0000069, and 90 days have elapsed since FDA receipt of the Abbreviated Reports.²

FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack information on the current market volumes of the original products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. In Table 1, provide the current market volumes of the original products. Mark any information you deem confidential, so it can be placed in a confidential appendix to the public EA document.

Table 1. Market Volume Information

STN	Original Product		Current-Year Market Volume of Original Product (Cigarettes)
	Name	STN of Previously Found SE	
EX0000454	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	EX0000265	
EX0000455	Natural American Spirit 100% US Grown Tobacco Mellow Taste	EX0000263	
EX0000456	Natural American Spirit Full-Bodied Taste	EX0000267	
EX0000457	Natural American Spirit Mellow Taste	EX0000266	
EX0000458	Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	EX0000262	

EX0000459	Natural American Spirit Made with Organic Tobacco Mellow Taste	EX0000264	
EX0000460	Natural American Spirit Perique Blend Rich Robust Taste	EX0000268	
EX0000461	Natural American Spirit Perique Blend Rich Taste	EX0000270	
EX0000462	Natural American Spirit Smooth Mellow Taste	EX0000269	

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000454 – EX0000462, as identified on the cover page of this review.