

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000490 – EX0000498**

| EX0000490: Natural American Spirit 100% US Grown Tobacco Mellow Taste | |
|---|--|
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 40% |
| 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) |
| EX0000491: Natural American Spirit Full-Bodied Taste | |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 20% |
| 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) |
| EX0000492: Natural American Spirit Mellow Taste | |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 35% |
| 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) |

| EX0000493: 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) |
| EX0000494: 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) |
| EX0000495: Natural American Spirit Smooth Mellow Taste | |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 60% |
| 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) |
| EX0000496: 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) |

| EX0000497: 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) |
| EX0000498: Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste | |
| Length | 84 mm |
| Diameter | 7.9 mm |
| Ventilation | 25% |
| 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) |
| 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: 2019.04.17 09:10:14 -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 Matthew R. Holman -S
Date: 2019.04.17 09:31:16 -04'00'

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

| EX0000490: 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 |
| EX0000491: 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 |
| EX0000492: 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 |
| EX0000493: 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 |

| EX0000494: 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 |
| EX0000495: 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 |
| EX0000496: 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 | 2 1% |
| Characterizing Flavor | None |
| EX0000497: 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 |
| EX0000498: 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 |

The applicant manufactures the original tobacco products. The original tobacco products were previously found substantially equivalent by FDA under SE0000116 – SE0000118, SE0006276, SE0006278 – SE0006280, SE0006288, and SE0006289.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 15, 2019, FDA received Exemption Requests (EX0000490-EX0000498) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On March 22, 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 Sarah Vichensont on March 22, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0000490 – EX0000498 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 |
|------------|--|--|--------------|
| EX0000490 | Natural American Spirit 100% US Grown Tobacco Mellow Taste | SE0000118 | June 6, 2018 |
| EX0000491 | Natural American Spirit Full-Bodied Taste | SE0006276 | |
| EX0000492 | Natural American Spirit Mellow Taste | SE0006280 | |

| | | | |
|-----------|---|-----------|--|
| EX0000493 | Natural American Spirit Made with Organic Tobacco Mellow Taste | SE0006279 | |
| EX0000494 | Natural American Spirit Made with Organic Tobacco Full-Bodied Taste | SE0006278 | |
| EX0000495 | Natural American Spirit Smooth Mellow Taste | SE0006289 | |
| EX0000496 | Natural American Spirit Perique Blend Rich Robust Taste | SE0006288 | |
| EX0000497 | Natural American Spirit Perique Blend Rich Taste | SE0000116 | |
| EX0000498 | Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste | SE0000117 | |

4. SCIENTIFIC REVIEW

A scientific review was completed by Karina Zuck on April 17, 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 are used in the manufacturing of the original tobacco products and are additives because their intended use may reasonably be 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.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on April 16, 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) and the addition of an alternative filter center line adhesive (b)(4) and alternate filter seam adhesive (b)(4) are additions/deletions 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 cigarette; the alternative center line adhesive and alternate filter seam adhesive are not combusted, volatilized or otherwise released during normal cigarette consumption and so consumer exposure to chemical constituents from the alternative center line adhesive and alternate filter seam 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 products were previously found substantially equivalent by FDA under SE0000116 – SE0000118, SE0006276, SE0006278 – SE0006280, SE0006288, and SE0006289.

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 market volumes of the original products. Identify any information you deem confidential so that 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 (# of Cigarettes) |
| | Name | STN | |
| EX0000490 | Natural American Spirit 100% US Grown Tobacco Mellow Taste | SE0000118 | |
| EX0000491 | Natural American Spirit Full-Bodied Taste | SE0006276 | |
| EX0000492 | Natural American Spirit Mellow Taste | SE0006280 | |
| EX0000493 | Natural American Spirit Made with Organic Tobacco Mellow Taste | SE0006279 | |
| EX0000494 | Natural American Spirit Made with Organic Tobacco Full-Bodied Taste | SE0006278 | |
| EX0000495 | Natural American Spirit Smooth Mellow Taste | SE0006289 | |
| EX0000496 | Natural American Spirit Perique Blend Rich Robust Taste | SE0006288 | |
| EX0000497 | Natural American Spirit Perique Blend Rich Taste | SE0000116 | |
| EX0000498 | Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste | SE0000117 | |

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 EX0000490 – EX0000498, as identified on the cover page of this review.