

Technical Project Lead (TPL) Review of Exemption Requests: EX0000826 – EX0000827

Common Attributes of EX Requests		
Applicant	Santa Fe Natural Tobacco Company, Inc.	
Product Category	Cigarette	
Product Subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission Tracking Number	EX0000826	SE0006275
Product Name	Natural American Spirit Balanced Taste Box	Natural American Spirit Balanced Taste
Eligibility Status	N/A	Previously found SE
Marketing Order Date	N/A	October 24, 2018
Abbreviated Report Date	N/A	N/A
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	34%	34%
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cigarette paper seam adhesive (b) (4) [REDACTED] Target: (b) (4) mg/cigarette] • Addition of cigarette paper seam adhesive (b) (4) [REDACTED] Target: (b) (4) mg/cigarette] 	

Tobacco Product	New	Original
Submission Tracking Number	EX0000827	SE0006275
Product Name	Natural American Spirit Smooth Taste Box	Natural American Spirit Balanced Taste
Eligibility Status	N/A	Previously found SE
Marketing Order Date	N/A	October 24, 2018
Abbreviated Report Date	N/A	N/A
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	34%	34%
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper ^{(b) (4)} [REDACTED] ((b) (4)); Target: ^{(b) (4)} [REDACTED] mg/cigarette] • Addition of white tipping paper ^{(b) (4)} [REDACTED] ((b) (4)); Target: ^{(b) (4)} [REDACTED] mg/cigarette] • Deletion of cigarette paper seam adhesive ^{(b) (4)} [REDACTED] Target: ^{(b) (4)} [REDACTED] mg/cigarette] • Addition of cigarette paper seam adhesive ^{(b) (4)} [REDACTED] Target: ^{(b) (4)} [REDACTED] mg/cigarette] 	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Todd L. Cecil -S

Digitally signed by Todd L. Cecil -
S
Date: 2020.04.17 15:30:45 -04'00'

Todd L. Cecil, Ph.D.
Associate 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: 2020.04.20 06:46:36 -04'00'

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 5
 1.3. SCOPE OF REVIEW 5
 1.4. TOBACCO ADDITIVE MODIFICATION 5

2. REGULATORY REVIEW5

3. COMPLIANCE REVIEW.....5

4. SCIENTIFIC REVIEW.....6

5. ENVIRONMENTAL DECISION6

6. CONCLUSION AND RECOMMENDATION6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are combusted, filtered cigarettes manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 30, 2019, FDA received two Exemption Requests (EX0000826 and EX0000827) from RAI Services Company on behalf of Santa Fe Natural Tobacco Company, Inc. FDA issued the applicant an Acceptance letter on October 31, 2019. FDA issued a Deficiency letter on December 30, 2019. In response, the applicant submitted an amendment (EX0000940) to the Exemption Requests, received by FDA on January 9, 2020.

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 product:

- deleting an additive (cigarette paper seam adhesive obtained from (b) (4)) in all the EX Requests
- adding an additive (cigarette paper seam adhesive obtained from (b) (4)) in all the EX Requests
- deleting an additive (white tipping paper obtained from (b) (4)) in EX0000827
- adding an additive (white tipping paper obtained from (b) (4)) in EX0000827

2. REGULATORY REVIEW

Regulatory reviews were completed by Jennifer Schmitz on October 31, 2019. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000826 and EX0000827 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA.

Therefore, the original tobacco product is eligible for modification under the Exemption Request pathway.¹

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.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by Selvin Edwards on December 23, 2019 and An Vu on April 16, 2020.

The reviews state that the new tobacco products have been modified by adding or deleting tobacco additives and increasing tobacco additives. Tipping paper (white)² and cigarette seam adhesive are used in the manufacturing of the original tobacco product and are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. The reviews conclude 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 concludes that the deletion of white tipping paper and the addition of an alternate white tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. Additionally, there were no changes in the perforation in the tipping paper between the new and original tobacco products. Finally, the addition of quantity of (b) (4) mg/cigarette), (b) (4) mg/cigarette), (b) (4) mg/cigarette) in the cigarette paper seam adhesive used in the tobacco products are small and are not likely to contribute substantially to the smoke chemistry and tobacco user exposure to mainstream smoke HPHCs when the new tobacco products are combusted. Despite of the fact that the cigarette paper seam adhesive is combusted, volatilized, and otherwise released during normal cigarette consumption, the applicant stated that the HPHCs found in mainstream smoke decreased compared to the original tobacco product. Therefore, this change is a minor modification of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on November 19, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 2, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 2, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- deleting an additive (cigarette paper seam adhesive obtained from (b) (4)) in all the EX Requests
- adding an additive (cigarette paper seam adhesive obtained from (b) (4)) in all the EX Requests
- deleting an additive (white tipping paper obtained from (b) (4)) in EX0000827

² EX0000827 only

- adding an additive (white tipping paper obtained from (b) (4)) in EX0000827

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 changes represent the deletion of tobacco additives (tipping paper², cigarette seam adhesive). 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. For EX0000827, the applicant proposes the deletion of white tipping paper and the addition of an alternate white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. There were no changes in the perforation of the tipping paper between the new and original tobacco products. For EX0000826 and EX0000827, the applicant proposes to delete the cigarette seam adhesive and add an alternate cigarette seam adhesive which 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 tobacco products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP’s scientific understanding, that an exemption for these modifications are 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 product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original tobacco product was previously found SE and in compliance with the FD&C Act by FDA.

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

An exempt order should be issued for the new tobacco products in EX0000826 and EX0000827, as identified on the cover page of this review.