

Technical Project Lead (TPL) Review of Exemption Request

New Tobacco Product Subject of this Review	
Submission tracking number (STN)	EX0001175
Attributes	
Submission date	June 17, 2020
Receipt date	June 17, 2020
Applicant	Santa Fe Natural Tobacco Company, Inc.
Product manufacturer	Santa Fe Natural Tobacco Company, Inc.
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submission	
EX0001175	None
Supporting FDA Memoranda Relied Upon in this Review	
EX0001175	None
Recommendation	
Issue an Exempt (EX) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.12.18 10:22:13 -05'00'

Charles Feng, Ph.D.
Chemistry Branch II Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.12.18 11:08:52 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

The applicant submitted information for the new and original tobacco products listed in detail in Appendix A.

1.2. REGULATORY ACTIVITY

See appendix for tobacco products.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco product subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewer(s)	Review Date
regulatory	Sequoia Bacon	6/24/2020
chemistry	Abdurrafy Shareef	12/2/2020
environmental science	Thomas Creaven	10/7/2020

Table 2. Consult

Discipline	Reviewer(s)	Review Date
engineering	James Melchiors	12/1/2020

2. COMPLIANCE REVIEW

The original tobacco product in EX0001175 was determined 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. A report under section 905(j)(1)(A)(ii) (Abbreviated Report) was submitted, and at least 90 days have elapsed since receipt of the Abbreviated Report 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.

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original tobacco product compared to the new tobacco product are the result of:

- increasing the quantity of an existing additive (cork tipping paper)
- increasing the quantity of an existing additive (tipping paper adhesive in cork tipping paper)
- decreasing the quantity of an existing additive (filter tow)

Additionally, the additive changes result in a 1 mm increase in tipping paper length and a 0.1 mm decrease in filter circumference.

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) 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 product. 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 applicant proposes increases in the quantities of cork tipping paper and tipping paper adhesive as well as a decrease in the quantity of filter tow. These modifications result in a 1 mm increase in tipping paper length and a 0.1 mm decrease in filter circumference. The applicant states that the purpose of these changes is to improve manufacturing efficiency. An engineering consult concludes that the changes in tipping paper length (less than 2%) and filter circumference (less than 1%) do not raise any concerns from an engineering standpoint. The chemistry review concludes that changes to the quantities of cork tipping paper, tipping paper adhesive, and filter tow are minor modifications. Tipping paper and tipping paper adhesive are not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase or decrease in content between the new and original product are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on December 2, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 2, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 4) are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. 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 product to be marketed would be appropriate for the protection of the public health. The applicant proposes increases in the quantities of cork tipping paper and tipping paper adhesive as well as a decrease in the quantity of filter tow. These modifications result in a 1 mm increase in tipping paper length and a 0.1 mm decrease in filter circumference. The applicant states that the purpose of these changes is to improve manufacturing efficiency. The chemistry review concludes that changes to the quantities of cork tipping paper, tipping paper adhesive, and filter tow are minor modifications. Tipping paper and tipping paper adhesive are not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase or decrease in content between the new and original product are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. Furthermore, an engineering consult concludes that in this case, the changes in tipping paper length (less than 2%) and filter circumference (less than 1%) do not raise any concern from an engineering standpoint. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. Lastly, I find that an exemption for these modification is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new tobacco product 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 Exempt by FDA, a report under section 905(j)(1)(A)(ii) (An abbreviated Report) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Report.

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

An exempt order should be issued for the new tobacco product in EX0001175, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Attributes of EX REQ		
Submission date	June 17, 2020	
Receipt date	June 17, 2020	
Applicant	Santa Fe Natural Tobacco Company, Inc.	
Product manufacturer	Santa Fe Natural Tobacco Company, Inc.	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001175	EX0000491
Product name	Natural American Spirit Full-Bodied Taste Box ²	Natural American Spirit Full-Bodied Taste ²
Eligibility status	Not applicable	Previously found exempt
Marketing authorization date	Not applicable	May 22, 2019
Abbreviated report date	Not applicable	September 6, 2019
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	20%	20%
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decrease in the quantity of filter tow³ (b) (4) (b) (4) target: (b) (4) mg/cigarette) • Increase in the quantity of cork tipping paper⁴ (b) (4) ; (b) (4) ; target: (b) (4) mg/cigarette) • Increase in the quantity of tipping paper adhesive (b) (4) (b) (4) ; target: (b) (4) mg/cigarette 	

² Brand/sub-brand or other commercial name used in commercial distribution.

³ New tobacco product filter has a 0.1 mm decrease in circumference.

⁴ New tobacco product tipping paper has a 1 mm increase in tipping paper length.