FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Request

New Product Subject of this Review[1]	
STN	EX0002160.PD1
Common Attributes	
Submission date	July 16, 2021
Receipt date	July 16, 2021
Applicant	Santa Fe Natural Tobacco Company, Inc.
Product manufacturer	Santa Fe Natural Tobacco Company, Inc.
Product category	Cigarette
Product subcategory	Combusted, Filtered
Cross-Referenced Submission	
EX0002160.PD1	None
Supporting FDA Memoranda Relied Upon in this Review	
EX0002160.PD1	Social science evaluation of design of cigarette tipping paper (May 11, 2017)
Recommendation	
Issue an Exempt (EX) order for the new tobacco product subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Matthew D. Hassink -S
Date: 2022.08.29 11:37:10 -04'00'

Matthew Hassink, Ph.D.
Team Supervisor
Division of Product Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S
Digitally signed by Todd L. Cecil -S
Date: 2022.09.09 12:47:36 -04'00'

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

[1] Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

The applicant submitted information for the new and original product listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for product.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new product that is the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1	
Discipline	**Reviewer**	**Review Date**
Regulatory	Crystal Caesar	8/4/2021
Chemistry	Vijay Gawandi	7/14/2022
Environmental Science	Christy Leppanen	6/1/2022

Table 2. Consultations

Discipline	Reviewer	Review Date
Engineering	Cao Chung	6/10/2022

2. COMPLIANCE REVIEW

The original product in EX0002160 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 product is eligible for modification under the Exemption Request pathway.[2]

[2] Any 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 product compared to the new product is the result of:

- deleting an additive (cigarette sideseam adhesive)
- adding an additive (alternate cigarette sideseam adhesive)
- deleting an additive (cork tipping paper)
- adding an additive (white tipping paper)[3]
- increasing the quantity of an existing additive (tipping paper adhesive)

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 product. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on June 3, 2022. The FONSI was supported by an environmental assessment prepared by FDA on June 3, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are a minor modification of a 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 product to be marketed would be appropriate for the protection of the public health. The applicant proposes to replace the tipping paper and cigarette sideseam adhesive and increase the quantity of tipping adhesive in the new product. 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, in conjunction with the engineering consult, concludes that changes to the tipping paper, tipping paper adhesive, and cigarette sideseam adhesive 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. The cigarette sideseam adhesive is combusted, however all the quantity differences are <0.1% of the total product weight. In addition, the cigarette sideseam adhesive in the original product is primarily composed of (b) (4)

[3] The addition of white tipping paper also resulted in a 0.1 millimeter (mm) decrease in circumference and a 1 mm increase in tipping paper length

(b) (4) while the new product adhesive is (b) (4) . (b) (4) [redacted] 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 this modification is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new product should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original product is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product is previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (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 product exempt and made a finding of no significant impact.

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

(b) (4) [redacted]

7. APPENDICES

Appendix A. New and original products

Common Attributes		
Submission date	July 16, 2021	
Receipt date	July 16, 2021	
Applicant	Santa Fe Natural Tobacco Company, Inc.	
Product manufacturer	Santa Fe Natural Tobacco Company, Inc.	
Product category	Cigarette	
Product subcategory	Combusted, Filtered	
Attributes	**New Product**	**Original Product**
STN	**EX0002160.PD1**	**EX0000457**
Product name	Natural American Spirit Original Blend Smooth Taste Box[5]	Natural American Spirit Mellow Taste
Eligibility status	Not Applicable (N/A)	Previously Found Exempt
Marketing authorization date	N/A	June 5, 2019
Abbreviated report date	N/A	September 6, 2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.9 mm	7.9 mm
Product Length	84 mm	84 mm
Ventilation	35%	35%
Nicotine Source[6]	Tobacco	Tobacco
Product modifications	Addition/Deletion of tobacco additives: • Deletion of cigarette sideseam adhesive ((b) (4)) • Addition of cigarette sideseam adhesive ((b) (4)) • Deletion of cork tipping paper (b) (4) mg/cigarette) • Addition of white tipping paper ((b) (4) /cigarette)[7] Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of tipping paper adhesive ((b) (4))	

[5] Brand/sub-brand or other commercial name used in commercial distribution.
[6] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification. https://www.congress.gov/bill/117th-congress/house-bill/2471
[7] The addition of white tipping paper also resulted in a 0.1 millimeter (mm) decrease in circumference and a 1 mm increase in tipping paper length.