FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000262

EX0000262: 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: • Addition of filter tow (b) (4) • Deletion of filter tow (b) (4)(b) (4)
Attributes of Exemption Request	
Applicant	Santa Fe Natural Tobacco Company, Inc.
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Box
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.10.22 15:44:09 -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: 2018.10.22 15:52:37 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000262: 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

The applicant manufactures the original tobacco product. It was previously found substantially equivalent by FDA under SE0006278.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Request EX0000262 on August 29, 2018. FDA issued an Acknowledgement letter on September 5, 2018. On September 20, 2018, FDA requested additional information for the Environmental Assessment (EA). On September 25, 2018, the applicant provided the information under EX0000271. On September 21, 2018, FDA requested additional information for product ventilation. On October 4, 2018 and on October 9, 2018, the applicant provided the information under EX0000275 and EX0000281, respectively.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Addition of filter tow (b) (4)
- Deletion of filter tow (b) (4)(b) (4)(b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Crystal Caesar on September 5, 2018. The review concludes that the Exemption Request is administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000262 was determined to be substantially equivalent by FDA under SE0006278. Therefore, the original product is eligible for modification under the Exemption Request pathway.[1]

4. SCIENTIFIC REVIEW

A scientific review was completed by Caroline Agarabi on October 11, 2018. The review states that the new tobacco product has been modified by adding and deleting a tobacco additive. Filter tow is used in the manufacturing of the original tobacco product, and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modification is a minor modification 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 tow and the addition of an alternative filter tow due to a supplier change is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. Although, filter tow can influence the ventilation of a product; the ventilation of the new and original tobacco products remained the same at 32%.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on October 3, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 22, 2018. The FONSI was supported by an environmental assessment prepared by FDA on October 22, 2018.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Addition of filter tow (b) (4)
- Deletion of filter tow (b) (4)(b) (4)

I concur with the conclusion of the scientific review that this modification is a minor modification 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 tow and addition of an alternative filter tow is an addition/deletion of a tobacco additive. In addition, it is my

[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.

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 protection of the public health. The review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change 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 product. The filter tow can influence the ventilation of a product, however, the ventilation of the new and original tobacco product remains the same at 32%. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, 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 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 product was previously found substantially equivalent by FDA under SE0006278.

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

An Exempt order letter should be issued for the new tobacco product in EX0000262 as identified on the cover page of this review.