

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001189, EX0001191, EX0001201, EX0001202, and EX0001205
Common Attributes	
Submission date	July 2, 2020
Receipt date	July 2, 2020
Applicant	Native Trading Associates LLC
Product manufacturer	Native Trading Associates LLC
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.11.25 07:24:02 -05'00'

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.11.25 12:49:45 -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 the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

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

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewer(s)	Review Date
regulatory	Cynthia Colon	7/14/2020
chemistry	Robert Gahl	11/3/2020
environmental science	Sang Ki Park	11/12/2020

2. COMPLIANCE REVIEW

The original tobacco products in EX0001189, EX0001191, EX0001201, EX0001202, and EX0001205 were 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 products are eligible for modification under the Exemption Request pathway.¹

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (fire standards compliant (FSC) cigarette paper) in all the EX Requests
- adding an additive (FSC cigarette paper) in all the EX Requests

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 products. The review concludes that the

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.

modifications are minor modifications of a tobacco 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 November 16, 2020. The FONSI was supported by an environmental assessment prepared by FDA on October 30, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that this modification (see Section 3) is a minor modification 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 products to be marketed would be appropriate for the protection of the public health.

The applicant intends to delete the original FSC cigarette paper and add an alternate FSC cigarette paper. There are minor differences in the levels of (b) (4)

in the FSC cigarette paper between the new and original tobacco products. However, these differences are not expected to have a significant impact on the product performance or HPHC yields. 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 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 tobacco products are 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 EX0001189, EX0001191, EX0001201, EX0001202, and EX0001205, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	July 2, 2020	
Receipt date	July 2, 2020	
Applicant	Native Trading Associates LLC	
Product manufacturer	Native Trading Associates LLC	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001189	SE0014363
Product name	Native Menthol King Soft (Green)	Native Menthol King soft pack (Green) (2017)
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	July 30, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	26.0%	26.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); (b) (4) • Addition of FSC cigarette paper (b) (4); (b) (4) 	
STN	EX0001191	SE0014356
Product name	Native 100's hard pack (Ultra)	Native 100's hard pack (Ultra) (2017)
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	July 30, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	100 mm	100 mm
Diameter	7.9 mm	7.9 mm
Ventilation	45.0%	45.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); (b) (4) • Addition of FSC cigarette paper (b) (4); (b) (4) 	
STN	EX0001201	SE0013372
Product name	Native Full Flavor 100's hard pack	Native Full Flavor 100's hard pack (2016)
Eligibility status	Not applicable	Previously found SE

Marketing authorization date	Not applicable	May 03, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	100 mm	100 mm
Diameter	7.9 mm	7.9 mm
Ventilation	4.0%	4.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); (b) (4) • Addition of FSC cigarette paper ((b) (4) (b) (4)) 	
STN	EX0001202	SE0013375
Product name	Native Full Flavor King Soft	Native Full Flavor King soft pack (2016)
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	May 03, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	4.0%	4.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4); (b) (4) • Addition of FSC cigarette paper ((b) (4) (b) (4)) 	

STN	EX0001205	SE0014355
Product name	Native King Soft (Blue)	Native King soft pack (Blue) (2017)
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	July 30, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Soft Pack	Soft Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	26.0%	26.0
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper ((b) (4)); (b) (4) • Addition of FSC cigarette paper ((b) (4) (b) (4) 	