

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000587 – EX0000606 , EX0000609 –
EX0000628**

EX0000587: Native Menthol King Soft (Green)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000588: Native Menthol 100's Hard Pack (Green)	
Package Type	Hard Pack
Length	20 Cigarettes
Diameter	100 mm
Ventilation	7.9 mm
Characterizing Flavor	4%
Additional Property	Menthol
Package Type	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000589: Native Menthol King Hard Pack (Green)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)

¹ FSC: Fire Standards Compliant

EX0000590: Native Menthol 100's Soft (Green)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000591: Native Menthol King Hard Pack	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000592: Native Menthol King Soft	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000593: Native Menthol 100's Soft	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)

EX0000594: Native King Soft (Ultra)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000595: Native Menthol 100's Hard Pack	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000596: Native King Soft (Blue)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000597: Native King Hard Pack (Ultra)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)

EX0000598: Native 100's Hard Pack (Ultra)	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000599: Native 100's Soft (Ultra)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000600: Native 100's Hard Pack (Blue)	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)
EX0000601: Native King Hard Pack (Blue)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4)

EX0000602: Native Full Flavor King Hard Pack	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000603: Native Full Flavor 100's Soft	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000604: Native Full Flavor King Soft	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000605: Native 100's Soft (Blue)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]

EX0000606: Native Full Flavor 100's Hard Pack	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000609: Native Menthol King Hard Pack (Green)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000610: Native Menthol King Soft (Green)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000611: Native Menthol 100's Soft (Green)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]

EX0000612: Native Menthol 100's Hard Pack (Green)	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000613: Native Menthol King Hard Pack	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000614: Native Menthol King Soft	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]
EX0000615: Native Menthol 100's Soft	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED] • Addition of FSC cigarette paper (b) (4) [REDACTED]

EX0000616: Native Menthol 100's Hard Pack	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000617: Native King Soft (Blue)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000618: Native King Soft (Ultra)	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000619: Native 100's Soft (Ultra)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])

EX0000620: Native King hard pack (Ultra)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000621: Native 100's Hard Pack (Ultra)	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000622: Native 100's Hard Pack (Blue)	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000623: Native 100's Soft (Blue)	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])

EX0000624: Native Full Flavor King Hard Pack	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000625: Native King Hard Pack (Blue)	
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000626: Native Full Flavor King Soft	
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])
EX0000627: Native Full Flavor 100's Soft	
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])

EX0000628: Native Full Flavor 100's Hard Pack	
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of non-FSC cigarette paper (b) (4) Addition of FSC cigarette paper (b) (4)
Common Attributes of Exemption Requests	
Applicant	Susan Jesmer d/b/a Native Trading Associates
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Package Quantity	20 Cigarettes
Recommendation	
Issue an Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Todd L. Cecil -S
 Date: 2019.07.19 09:14:54 -04'00'

For 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: 2019.07.19 09:55:18 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000587: Native Menthol King Soft (Green)	
Product Name	Native Menthol Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000588: Native Menthol 100's Hard Pack (Green)	
Product Name	Native Menthol Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000589: Native Menthol King Hard Pack (Green)	
Product Name	Native Menthol Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000590: Native Menthol 100's Soft (Green)	
Product Name	Native Menthol Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol

EX0000591: Native Menthol King Hard Pack	
Product Name	Native Menthol King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000592: Native Menthol King Soft	
Product Name	Native Menthol King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000593: Native Menthol 100's Soft	
Product Name	Native Menthol 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000594: Native King Soft (Ultra)	
Product Name	Native Ultra Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000595: Native Menthol 100's Hard Pack	
Product Name	Native Menthol 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol

EX0000596: Native King Soft (Blue)	
Product Name	Native Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000597: Native King Hard Pack (Ultra)	
Product Name	Native Ultra Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000598: Native 100's Hard Pack (Ultra)	
Product Name	Native Ultra Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000599: Native 100's Soft (Ultra)	
Product Name	Native Ultra Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000600: Native 100's Hard Pack (Blue)	
Product Name	Native Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

EX0000601: Native King Hard Pack (Blue)	
Product Name	Native Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000602: Native Full Flavor King Hard Pack	
Product Name	Native Full Flavor King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000603: Native Full Flavor 100's Soft	
Product Name	Native Full Flavor 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000604: Native Full Flavor King Soft	
Product Name	Native Full Flavor King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000605: Native 100's Soft (Blue)	
Product Name	Native Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

EX0000606: Native Full Flavor 100's Hard Pack	
Product Name	Native Full Flavor 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000609: Native Menthol King Hard Pack (Green)	
Product Name	Native Menthol Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000610: Native Menthol King Soft (Green)	
Product Name	Native Menthol Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000611: Native Menthol 100's Soft (Green)	
Product Name	Native Menthol Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000612: Native Menthol 100's Hard Pack (Green)	
Product Name	Native Menthol Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol

EX0000613: Native Menthol King Hard Pack	
Product Name	Native Menthol King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000614: Native Menthol King Soft	
Product Name	Native Menthol King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000615: Native Menthol 100's Soft	
Product Name	Native Menthol 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000616: Native Menthol 100's Hard Pack	
Product Name	Native Menthol 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	Menthol
EX0000617: Native King Soft (Blue)	
Product Name	Native Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

EX0000618: Native King Soft (Ultra)	
Product Name	Native Ultra Lights King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000619: Native 100's Soft (Ultra)	
Product Name	Native Ultra Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000620: Native King Hard Pack (Ultra)	
Product Name	Native Ultra Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000621: Native 100's Hard Pack (Ultra)	
Product Name	Native Ultra Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	30%
Characterizing Flavor	None
EX0000622: Native 100's Hard Pack (Blue)	
Product Name	Native Lights 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

EX0000623: Native 100's Soft (Blue)	
Product Name	Native Lights 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000624: Native Full Flavor King Hard Pack	
Product Name	Native Full Flavor King hard pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000625: Native King Hard Pack (Blue)	
Product Name	Native Lights King Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000626: Native Full Flavor King Soft	
Product Name	Native Full Flavor King Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None
EX0000627: Native Full Flavor 100's Soft	
Product Name	Native Full Flavor 100's Soft Pack
Package Quantity	20 Cigarettes
Package Type	Soft Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4%
Characterizing Flavor	None

EX0000628: Native Full Flavor 100's Hard Pack	
Product Name	Native Full Flavor 100's Hard Pack
Package Quantity	20 Cigarettes
Package Type	Hard Pack
Length	100 mm
Diameter	7.9 mm
Ventilation	4.0%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 6, 2019, FDA received Exemption Requests (EX0000587-EX0000606); and on June 7, 2019 (EX0000609 – EX0000628) from Susan Jesmer d/b/a Native Trading Associates on June 14, 2019, FDA issued Acknowledgement letters to the applicant. On June 19, 2019, FDA requested clarifying information for EX0000587, EX0000591, EX0000592, EX0000596, EX0000610, EX0000613, and EX0000628. On June 24, 2019, FDA received an amendment (EX0000640) containing the requested information. On July 1, 2019, FDA issued a correction letter to notify the applicant that we revised our records to reflect a change to the submission tracking numbers for EX0000587-EX0000593.

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 products:

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper

2. REGULATORY REVIEW

Regulatory reviews were completed by Kristopher Van Amburg and Emily Busta on June 14, 2019. The reviews conclude that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated July 2, 2019 for EX0000587-EX0000606, EX0000609-EX0000613 and July 3, 2019 for EX000614-EX000628, concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Jikun Liu on July 15, 2019].

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Cigarette paper is used in the manufacturing of the original tobacco products 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 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 review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new tobacco products is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased HPHC yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 14, 2017, toxicology memo.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Thomas Creaven on July 3, 2019 for EX0000587-EX0000606 and Ronald Edwards on June 28, 2019 for EX0000609-EX0000628.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 3, 2019 for EX0000609-EX0000628 and July 5, 2019 for EX0000587-EX0000606. The FONSI was supported by environmental assessments prepared by FDA on July 3, 2019 for EX0000609-EX0000628 and July 5, 2019 for EX0000587-EX0000606.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper

² 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.

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 deletion of non-FSC cigarette paper and the addition of FSC cigarette paper is an addition/deletion of a tobacco additive. 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. At this time, based on the information available and CTP’s scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the tobacco product (e.g., no changes to blend, filter, design parameters such as ventilation, etc.), the benefit of using FSC cigarette paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC cigarette paper. 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 products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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

Exempt order letters should be issued for the new tobacco products in EX0000587 – EX0000606 and EX0000609 – EX0000628 as identified on the cover page of this review.