

July 22, 2019

EXEMPT

Susan Jesmer d/b/a Native Trading Associates Attention: Bryan M. Haynes, Esquire Troutman Sanders Building 1001 Haxall Point Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): MULTIPLE STNS, SEE APPENDIX A

Dear Mr. Haynes:

The Food and Drug Administration (FDA) completed review of your June 6, 2019 and June 7, 2019 Requests for Exemption from Substantial Equivalence (EX REQs), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your EX REQs, we find the new tobacco products specified in Appendix A are exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

To market each of the new tobacco products that are the subject of these EX REQs, the following must be met:

- 1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and
- 2. Ninety days have passed since FDA <u>receipt</u> of your Abbreviated Report.

See Appendix B for FDA's recommended format for the submission of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA "approved" the new tobacco products specified in Appendix A; therefore, you may not promote or in any way represent the modified tobacco products specified in Appendix A, or their labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. These orders are subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the new tobacco products specified in Appendix A, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{1,2} using eSubmitter³. Alternatively, submissions may be mailed to:

Food and Drug Administration Center for Tobacco Products Document Control Center (DCC) Building 71, Room G335 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁴; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Kristopher Van Amburg, Regulatory Health Project Manager, at 301-348-3032 or Kristopher Van Amburg@fda.hhs.gov.

Sincerely,

Digitally signed by Glen D. Jones -S Date: 2019.07.22 09:30:32 -04'00'

For Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures – Appendix A: List of New Tobacco Products Subject of This Letter

Appendix B: FDA's Recommended Format of the Submission of an Abbreviated Report

http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm

¹ For more information about CTP Portal, see:

² FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

³ For more information about eSubmitter, see: http://www.fda.gov/ForIndustry/FDAeSubmitter

⁴ See https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

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List of new tobacco products that FDA has found exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent

Common Attributes of EX REQs	
Product Manufacturer:	Susan Jesmer d/b/a Native Trading Associates
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
New Tobacco Product Specific Attributes	
Submission Tracking Number:	EX0000587
Date of Submission:	June 6, 2019
Date of Receipt:	June 6, 2019
Product Name: ⁵	Native Menthol King Soft (Green)
Package Type:	Soft Pack
Package Quantity:	20 Cigarettes
Characterizing Flavor:	Menthol
Length:	84 mm
Diameter:	7.9 mm
Ventilation:	4%
Modifications:	Addition/Deletion of tobacco additives:
	 Deletion of non-fire standards compliant (FSC)
	cigarette paper (b) (4)
)
	Addition of FSC cigarette paper (b) (4)
)
Original Tobacco Product Specific Attributes	
Product Name: ⁵	Native Menthol Lights King soft pack
Package Type:	Soft Pack
Package Quantity:	20 Cigarettes
Characterizing Flavor:	Menthol
Eligibility Status:	Grandfathered
Length:	84 mm
Diameter:	7.9 mm
Ventilation:	4%

⁵ Brand/sub-brand or other commercial name used in commercial distribution

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New Tobacco Product Specific Attributes

EX0000588 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol 100's hard pack (Green)

Package Type: Hard Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 100 mm Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol Lights 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

Length: 100 mm 7.9 mm Diameter: Ventilation: 4%

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New Tobacco Product Specific Attributes

EX0000589 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol King hard pack (Green)

Package Type: Hard Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 84 mm Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol Lights King hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

Length: 84 mm 7.9 mm Diameter: Ventilation: 4%

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New Tobacco Product Specific Attributes

EX0000590 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol 100's Soft (Green)

Package Type: Soft Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 100 mm Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol Lights 100's soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000591 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol King hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 84 mm Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol King hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

Length: 84 mm 7.9 mm Diameter: Ventilation: 4%

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New Tobacco Product Specific Attributes

EX0000592 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol King Soft

Package Type: Soft Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 84 mm Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol King soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

Length: 84 mm 7.9 mm Diameter: Ventilation: 4%

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000593

Date of Submission: June 6, 2019

Date of Receipt: June 6, 2019

Product Name:⁵ Native Menthol 100's Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 100 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000594 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native King Soft (Ultra)

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None Length: 84 mm Diameter: 7.9 mm Ventilation: 30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Ultra Lights King soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000595 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Menthol 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes Menthol **Characterizing Flavor:** Length: 100 mm Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Menthol 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes **Characterizing Flavor:** Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000596 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native King Soft (Blue)

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None 84 mm Length: Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Lights King soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000597
Date of Submission: June 6, 2019
Date of Receipt: June 6, 2019

Product Name:⁵ Native King hard pack (Ultra)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Ultra Lights King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

Length: 84 mm
Diameter: 7.9 mm
Ventilation: 30%

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New Tobacco Product Specific Attributes

EX0000598 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native 100's hard pack (Ultra)

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None 100 mm Length: Diameter: 7.9 mm Ventilation: 30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Ultra Lights 100's hard pack

Package Type: **Hard Pack** Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000599 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native 100's Soft (Ultra)

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None Length: 100 mm Diameter: 7.9 mm Ventilation: 30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Ultra Lights 100's soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000600 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native 100's hard pack (Blue)

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None Length: 100 mm Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Lights 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000601 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native King hard pack (Blue)

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None 84 mm Length: Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Lights King hard pack

Package Type: **Hard Pack** Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000602
Date of Submission: June 6, 2019
Date of Receipt: June 6, 2019

Product Name:⁵ Native Full Flavor King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
Ventilation:

None
84mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

• Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000603

Date of Submission: June 6, 2019

Date of Receipt: June 6, 2019

Product Name:⁵ Native Full Flavor 100's Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:NoneLength:100 mmDiameter:7.9 mmVentilation:4%

Additional Properties: PBS-1 46 CU FSC cigarette paper

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

• Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000604 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Full Flavor King Soft

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None Length: 84 mm Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Full Flavor King soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

EX0000605 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native 100's Soft (Blue)

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None Length: 100 mm Diameter: 7.9 mm Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Lights 100's soft pack

Package Type: Soft Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes Error! Bookmark not defined.

EX0000606 **Submission Tracking Number:** Date of Submission: June 6, 2019 Date of Receipt: June 6, 2019

Product Name:5 Native Full Flavor 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None 100 mm Length: Diameter: 7.9 mm 4% Ventilation:

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:5 Native Full Flavor 100's hard pack

Package Type: Hard Pack Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000609

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol King hard pack (Green)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 84 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol Lights King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000610
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol King Soft (Green)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 84 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

) (b) (4

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol Lights King soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000611

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol 100's Soft (Green)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 100 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol Lights 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000612
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name^{:5} Native Menthol 100's hard pack (Green)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 100 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol Lights 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000613

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 84 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000614

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol King Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 84 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol King soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000615
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol 100's Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 100 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000616

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Menthol 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol
Length: 100 mm
Diameter: 7.9 mm
Ventilation: 4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Menthol 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes
Characterizing Flavor: Menthol

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000617
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native King Soft (Blue)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Lights King soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000618

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native King Soft (Ultra)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

) (b) (4

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Ultra Lights King soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

Length: 84 mm
Diameter: 7.9 mm
Ventilation: 30%

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000619
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native 100's Soft (Ultra)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
Ventilation:
None
100 mm
7.9 mm
30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Ultra Lights 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

 Length:
 100 mm

 Diameter:
 7.9 mm

 Ventilation:
 30%

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New Tobacco Product Specific Attributes

Submission Tracking Number:EX0000620Date of Submission:June 7, 2019Date of Receipt:June 7, 2019

Product Name:⁵ Native King hard pack (Ultra)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Ultra Lights King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000621
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native 100's hard pack (Ultra)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
Ventilation:
None
100 mm
7.9 mm
30%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Ultra Lights 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

 Length:
 100 mm

 Diameter:
 7.9 mm

 Ventilation:
 30%

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX000062 2
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native 100's hard pack (Blue)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
7.9 mm
Ventilation:
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Lights 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000623

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native 100's Soft (Blue)

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
7.9 mm
Ventilation:
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Lights 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

 Length:
 100 mm

 Dia meter:
 7.9 mm

 Ventilation:
 4%

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New Tobacco Product Specific Attributes

Submission Tracking Number:EX0000624Date of Submission:June 7, 2019Date of Receipt:June 7, 2019

Product Name:⁵ Native Full Flavor King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number:EX0000625Date of Submission:June 7, 2019Date of Receipt:June 7, 2019

Product Name:⁵ Native King hard pack (Blue)

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Lights King hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000626

Date of Submission: June 7, 2019

Date of Receipt: June 7, 2019

Product Name:⁵ Native Full Flavor King Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:

Diameter:

Ventilation:

None
84 mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor King soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000627
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native Full Flavor 100's Soft

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
7.9 mm
Ventilation:
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor 100's soft pack

Package Type: Soft Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status: Grandfathered

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New Tobacco Product Specific Attributes

Submission Tracking Number: EX0000628
Date of Submission: June 7, 2019
Date of Receipt: June 7, 2019

Product Name:⁵ Native Full Flavor 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor:
Length:
Diameter:
Ventilation:
None
100 mm
7.9 mm
4%

Modifications: Addition/Deletion of tobacco additives:

Deletion of non-FSC cigarette paper (b) (4)

Addition of FSC cigarette paper (b) (4)

Original Tobacco Product Specific Attributes

Product Name:⁵ Native Full Flavor 100's hard pack

Package Type: Hard Pack
Package Quantity: 20 Cigarettes

Characterizing Flavor: None

Eligibility Status Grandfathered
Length: 100 mm

Diameter: 7.9 mm Ventilation: 4%

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Appendix B FDA's Recommended Format of the Submission of an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services Food and Drug Administration Center for Tobacco Products Document Control Center Building 71, Room G335 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe
Vice President
Mock-Up Tobacco Company