

October 14, 2020

EXEMPT

Native Trading Associates LLC
Attention: Bryan M. Haynes, Esquire
Troutman Sanders LLP
1001 Haxall Point
Richmond, VA 23219

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Mr. Haynes:

We completed review of your EX REQs¹ and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.²

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

To market 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 receipt of your Abbreviated Report.**

See Appendix B for FDA’s recommended format for submitting of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ 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)

² See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{3,4} using eSubmitter.⁵ 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 FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁶; 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, please contact Kristopher Van Amburg, Regulatory Health Project Manager, at (301) 348 - 3032 or Kristopher.VanAmburg@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2020.10.14 08:20:11 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Original Tobacco Products Subject of This Letter
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

³ For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

⁴ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁵ For more information about eSubmitter, see <http://www.fda.gov/ForIndustry/FDAeSubmitter>

⁶ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

Appendix A
New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs		
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	EX0001188	SE0013386
Product name	Native Menthol King Hard Pack	Native Menthol King Hard Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [REDACTED]; [FSC (b) (4) CU] • Addition of FSC cigarette paper (b) (4) [REDACTED]; [FSC (b) (4)]) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001190	SE0013387
Product name	Native Menthol King Soft	Native Menthol King Soft Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 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	4.0%	4.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC (b) (4) CU] Addition of FSC cigarette paper (b) (4) [FSC (b) (4)] 	
STN	EX0001192	SE0014360
Product name	Native Menthol 100's Hard Pack (Green)	Native Menthol 100's Hard Pack (Green) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	Menthol	Menthol
Length	100 mm	100 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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC (b) (4) CU] Addition of FSC cigarette paper (b) (4) [FSC (b) (4)] 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001193	SE0014361
Product name	Native Menthol 100's Soft (Green)	Native Menthol 100's Soft Pack (Green) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	100 mm	100 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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [redacted]; [FSC (b) (4) CU] • Addition of FSC cigarette paper (b) (4) [redacted]; [FSC (b) (4)]) 	
STN	EX0001194	SE0013384
Product name	Native Menthol 100's Hard Pack	Native Menthol 100's Hard Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 2018
Abbreviated report date	Not applicable	Not applicable
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [redacted]; [FSC (b) (4) CU] • Addition of FSC cigarette paper (b) (4) [redacted]; [FSC (b) (4)]) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001195	SE0014362
Product name	Native Menthol King Hard Pack (Green)	Native Menthol King Hard Pack (Green) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [redacted]; [FSC^{(b) (4)} CU] • Addition of FSC cigarette paper (b) (4) [redacted]; [FSC^{(b) (4)}] 	
STN	EX0001196	SE0013385
Product name	Native Menthol 100's Soft	Native Menthol 100's Soft Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [redacted]; [FSC^{(b) (4)} CU] • Addition of FSC cigarette paper (b) (4) [redacted]; [FSC^{(b) (4)}] 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001197	SE0013374
Product name	Native Full Flavor King Hard Pack	Native Full Flavor King Hard Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU] • Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}] 	
STN	EX0001198	SE0014353
Product name	Native 100's Soft (Blue)	Native 100's soft pack (Blue) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	100 mm	100 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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU] • Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}] 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001199	SE0014357
Product name	Native 100's Soft (Ultra)	Native 100's Soft Pack (Ultra) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU]) Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}]) 	
STN	EX0001200	SE0013373
Product name	Native Full Flavor 100's Soft	Native Full Flavor 100's Soft Pack (2016)
Eligibility status	Not applicable	Previously Found SE
Market authorization date	Not applicable	May 3, 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU]) Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}]) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001203	SE0014358
Product name	Native King Hard Pack (Ultra)	Native King Hard Pack (Ultra) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	84 mm	84 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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU] Addition of FSC cigarette paper (b) (4) ; [FSC^{(b) (4)}] 	
STN	EX0001204	SE0014359
Product name	Native King Soft (Ultra)	Native King Soft Pack (Ultra) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	45.0%	45.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of Fire Standards Compliant (FSC) cigarette paper (b) (4) ; [FSC^{(b) (4)} CU] Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}] 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001206	SE0014354
Product name	Native King Hard Pack (Blue)	Native King Hard Pack (Blue) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	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 Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU] Addition of FSC cigarette paper (b) (4) ; [FSC^{(b) (4)}] 	
STN	EX0001207	SE0014352
Product name	Native 100's Hard Pack (Blue)	Native 100's Hard Pack (Blue) (2017)
Eligibility status	Not applicable	Previously Found SE
Market 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	26.0%	26.0%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of Fire Standards Compliant (FSC) cigarette paper (b) (4) [FSC^{(b) (4)} CU] Addition of FSC cigarette paper (b) (4) [FSC^{(b) (4)}] 	

Appendix B
FDA's Recommended Format for Submitting 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 **[ink or digital signature]**
Vice President
Mock-Up Tobacco Company