

December 18, 2020

EXEMPT

Santa Fe Natural Tobacco Company, Inc.
Attention: Michael W. Ogden Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

FDA Submission Tracking Number (STN): EX0001175, see Appendix A

Dear Dr. Ogden:

We completed review of your EX REQ¹ and determined that the new tobacco product listed in Appendix A is exempt from the requirements of Substantial Equivalence.²

Our finding does not mean we “approved” the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product 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 product that is the subject of this EX REQ, 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 product 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 product specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Request for Exemption from Substantial Equivalence (EX REQ) 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 Barbara Banchemo, Regulatory Health Project Manager, at (301) 796-1937 or Barbara.Banchemo@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2020.12.18 11:56:47 -05'00'

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

Enclosures:

Appendix A – New and Original Tobacco Product 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 A⁷
New and Original Tobacco Product Subject of This Letter

Attributes of EX REQ		
Submission date	June 17, 2020	
Receipt date	June 17, 2020	
Applicant	Santa Fe Natural Tobacco Company, Inc.	
Product manufacturer	Santa Fe Natural Tobacco Company, Inc.	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001175	EX0000491
Product name	Natural American Spirit Full-Bodied Taste Box ⁷	Natural American Spirit Full-Bodied Taste Box ⁷
Eligibility status	Not applicable	Previously found exempt
Marketing authorization date	Not applicable	May 22, 2019
Abbreviated report date	Not applicable	September 6, 2019
Package type	Box	Box
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	84 mm	84 mm
Diameter	7.9 mm	7.9 mm
Ventilation	20%	20%
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decrease in the quantity of filter tow⁸ (b) (4) (b) (4) target: (b) (4) mg/cigarette) • Increase in the quantity of cork tipping paper⁹ (b) (4) (b) (4) ; target: (b) (4) mg/cigarette) • Increase in the quantity of tipping paper adhesive (b) (4) (b) (4) ; target: (b) (4) mg/cigarette 	

⁷ Brand/sub-brand or other commercial name used in commercial distribution.

⁸ New product filter has a 0.1 mm decrease in circumference.

⁹ New product tipping paper has a 1 mm increase in tipping paper length.

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