



October 30, 2020

**EXEMPT**

Cheyenne International LLC  
Attention: Ralph Brown, Vice President, Governmental Affairs  
701 S Battleground Ave  
Grover, NC 28073

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

Dear Mr. Brown:

We completed review of your EX REQ<sup>1</sup>s and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.<sup>2</sup>

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.

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<sup>1</sup> Request for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

<sup>2</sup> See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal<sup>3,4</sup> using eSubmitter.<sup>5</sup> 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 date<sup>6</sup>; 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: 2020.10.30 16:51:14 -04'00'

Todd L. Cecil, Ph.D.  
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

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<sup>3</sup> For more information about CTP Portal, see

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

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

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

<sup>6</sup> <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

<b>Common Attributes</b>		
Submission date	August 31, 2020	
Receipt date	August 31, 2020	
Applicant	Cheyenne International LLC	
Product manufacturer	Cheyenne International LLC	
Product category	Cigar	
Product subcategory	Filtered, Sheet-Wrapped	
<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Original Tobacco Product</b>
STN	EX0001260	GF2009807
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Xotic Berry <sup>7</sup>	Cheyenne Little Cigars Xotic Berry Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	Berry	Berry
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) filter with plug wrap (b) (4) .; target: (b) (4)g/100 rods)</li> <li>• Addition of (b) filter with plug wrap (b) (4) .; target: (b) (4)g/100 rods)</li> </ul>	

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

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001261	GF2009805
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Full Flavor <sup>7</sup>	Cheyenne Little Cigars Full Flavor Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	None	None
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001262	GF2009804
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Peach <sup>7</sup>	Cheyenne Little Cigars Peach Flavor Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	Peach	Peach
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001263	GF2009809
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Vanilla <sup>7</sup>	Cheyenne Little Cigars Vanilla Flavor Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	Vanilla	Vanilla
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001264	GF2009803
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Menthol <sup>7</sup>	Cheyenne Little Cigars Menthol Flavor Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	Menthol	Menthol
Eligibility Status	Not Applicable	Grandfathered
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001265	GF2009808
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Wild Cherry <sup>7</sup>	Cheyenne Little Cigars Xotic Berry Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	Cherry	Cherry
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	0 %	0 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001266	GF2009806
Static Product ID	PD1	Not Applicable
Product Name	Cheyenne Cigars Classic <sup>7</sup>	Cheyenne Little Cigars Light Flavor Box 100's <sup>7</sup>
Package Type	Box	Box
Package Quantity	20 Cigars	20 Cigars
Characterizing Flavor	None	None
Eligibility Status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not Applicable	Not Applicable
Diameter	7.90 mm	7.90 mm
Product Length	99 mm	99 mm
Ventilation	35 %	35 %
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> <li>• Addition of (b) (4) filter with plug wrap (b) (4) target: (b) (4) g/100 rods)</li> </ul>	

**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