

December 18, 2019

**EXEMPT**

BBK Tobacco & Foods LLP dba HBI International  
Attention: Ulli K. Becker, Ph.D.  
Senior Chemist, Regulatory Specialist  
3401 West Papago Street  
Phoenix, AZ 85009

**FDA Submission Tracking Number (STN):** EX0000832, see Appendix A

Dear Dr. Becker:

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

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.

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<sup>1</sup> 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)

<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 Kaylene Charles, M.S., Regulatory Health Project Manager, at (301) 796-0731 or [Kaylene.Charles@fda.hhs.gov](mailto:Kaylene.Charles@fda.hhs.gov).

Sincerely,

Digitally signed by Matthew R. Holman -S  
Date: 2019.12.18 06:20:52 -05'00'

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

Enclosures:

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

Attributes of EX REQ		
<b>Date of Submission:</b>	November 5, 2019	
<b>Date of Receipt:</b>	November 5, 2019	
<b>Product Manufacturer:</b>	BBK Tobacco & Foods LLP dba HBI International	
<b>Product Category:</b>	Roll-Your-Own Tobacco Products	
<b>Product Sub-Category:</b>	Other	
	New Tobacco Product	Original Tobacco Product
	EX0000832: Raw Auto Box 79 mm <sup>7</sup>	N/A: Zen Automatic Roll Box 79 mm <sup>7</sup>
<b>Package Type:</b>	Box	Box
<b>Package Quantity:</b>	1 per Box	1 per Box
<b>Characterizing Flavor:</b>	None	None
<b>Eligibility Status:</b>	N/A	Grandfathered
<b>Modifications:</b>		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> <li>• Addition of black spray paint and red/beige ink on the container closure system</li> </ul>		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> <li>• Decreasing the quantity of (b) (4) on the container closure system</li> <li>• Increasing the quantity of (b) (4) in the (b) (4)</li> </ul>		

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

**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