U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

August 2, 2022

EXEMPT

BBK Tobacco & Foods dba HBI International
Attention: Ulli Becker, PhD, Senior Chemist/ Regulatory Specialist
3401 West Papago Street
Phoenix, AZ 85009

FDA Submission Tracking Numbers (STNs): EX0001834.PD1 and EX0001835.PD1

Dear Ulli Becker:

We completed review of your EX REQs[1] 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 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 date[6]; 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 Rodney Hammond, CHES, Regulatory Health Project Manager, at (301) 796-4667 or Rodney.Hammond@fda.hhs.gov.

Sincerely,

Todd L. Cecil -S

Digitally signed by Todd L. Cecil -S
Date: 2022.08.02 07:53:16 -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[7]

New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes		
Submission date	April 2, 2021	
Receipt date	April 2, 2021	
Applicant	BBK Tobacco & Foods dba HBI International	
Product manufacturer	BBK Tobacco & Foods dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Rolling Paper	
Attributes	**New Product**	**Original Product**
STN	**EX0001834.PD1**	**SE0015544**
Product name	RAW BLACK ORGANIC HEMP 1¼	RAWBLACK 1¼
Eligibility status	Not Applicable (N/A)	Previously found SE
Marketing authorization date	N/A	7/23/2020
Package type	Booklet	Booklet
Package quantity	50 Papers	50 Papers
Characterizing flavor	None	None
Length	76 millimeters (mm)	76 mm
Width	44 mm	44 mm
Additional property	Off-white, "RAW" watermark	Off-white, "RAW" watermark
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decrease in the quantity of (b) (4)	
Attributes	**New Product**	**Original Product**
STN	**EX0001835.PD1**	**SE0015423**
Product name	RAW BLACK ORGANIC HEMP King Size Slim	RAWBLACK KING SIZE SLIM
Eligibility status	N/A	Previously found SE
Marketing authorization date	N/A	2/3/2020
Package type	Booklet	Booklet
Package quantity	32 Papers	32 Papers
Characterizing flavor	None	None
Length	108 mm	108 mm
Width	44 mm	44 mm
Additional property	Off-white, "RAW" watermark	Off-white, "RAW" watermark
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: • Decrease in the quantity of (b) (4)	

[7] 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