



September 03, 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): EX0000629

Dear Dr. Becker:

The Food and Drug Administration (FDA) has completed review of your June 11, 2019, 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) for the following tobacco product:

Tobacco Product Manufacturer:	BBK Tobacco & Foods LLP dba HBI International
Tobacco Product Name:¹	RAW ORGANIC SINGLE WIDE CUT CORNERS
Tobacco Product Category:	Roll-Your-Own
Tobacco Product Sub-Category:	Roll-Your-Own
Package Type:	Rolling Paper
Package Quantity:	50 Sheets
Length:	70 mm
Width:	37 mm
Characterizing Flavor:	None
Eligibility Status of Original Tobacco Product:	Previously Found SE Under SE0015089
Modification:	Increasing/Decreasing the quantity of existing tobacco additives: Decreasing the quantity of (b) (4) and (b) (4) (b) (4)

Based on our review of your EX REQ, we find the new tobacco product specified above exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco product is substantially equivalent (see section 905(j)(3)(A) 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.

¹ Brand/sub-brand or other commercial name used in commercial distribution

See Appendix A for FDA's recommended format for the submission of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA "approved" the new tobacco product specified above; therefore, you may not promote or in any way represent the modified tobacco product specified above, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. This order is subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{2,3} using eSubmitter⁴. 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 the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁵; 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.

² For more information about CTP Portal, see:

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>

³ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁴ For more information about eSubmitter, see: <http://www.fda.gov/ForIndustry/FDAeSubmitter>

⁵ See <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

If you have any questions, you may contact Kaylene Charles, M.S., Regulatory Health Project Manager, at (301) 796-0731 or Kaylene.Charles@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.09.03 06:19:24 -04'00'

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

Enclosures: Appendix A: FDA's Recommended Format of the Submission of an Abbreviated Report

Appendix A
FDA's Recommended Format of the Submission of 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
Vice President
Mock-Up Tobacco Company