



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

May 26, 2021

SUBSTANTIALLY EQUIVALENT

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): SE0015654

Dear Dr. Becker:

We completed our review of your SE Report¹ and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A and is in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco product subject of this letter.

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).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

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 Substantially Equivalent (SE) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Cynthia Colon, Regulatory Health Project Manager, at (301) 796-9094 or Cynthia.Colon@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.05.26 18:14:57 -04'00'

Todd Cecil, Ph.D.

Deputy Director

Office of Science

Center for Tobacco Products

Enclosures (if provided electronically, the Appendix is not included in physical mail):

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

Appendix B – Health Information Summary