



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

May 12, 2022

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 Numbers (STNs): SE0016741, SE0017682, SE0017689 and SE0017790

Dear Ulli K. Becker:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are 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 products subject of this letter.

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).

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 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 complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Rodney Hammond, MPH, 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: 2022.05.12
08:02:26 -04'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A²
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Applicant	BBK Tobacco & Foods, LLP dba HBI International	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016741	Not Applicable
Product name	RAW ORANGIC HEMP 1 ¼	ELEMENTS 1 ¼ ³
Submission date	June 22, 2020	Not Applicable
Receipt date	June 22, 2020	Not Applicable
Product subcategory	Rolling Paper	Rolling Paper
Eligibility status	Not Applicable	Grandfathered
Package type	Booklet	Booklet
Package quantity	50 Papers	50 Papers
Characterizing flavor	None	None
Length	76 mm	76 mm
Width	44 mm	44 mm
Additional property	Off-white color "RAW" watermark	White color "HBI" watermark
STN	SE0017682	Not Applicable
Product name	RAW PRE-ROLLED CONE LEAN 20 RACK	TORPEDOES PRE ROLLED CONE PAPERS
Submission date	August 28, 2020	Not Applicable
Receipt date	August 28, 2020	Not Applicable
Product subcategory	Non-Filtered Cigarette Tube	Non-Filtered Cigarette Tube
Eligibility status	Not Applicable	Grandfathered
Package type	Cardboard Box	Plastic Container
Package quantity	20 Tubes	3 Tubes
Characterizing flavor	None	None
Length	109 mm	106 mm
Diameter	9 mm	20 mm
Additional property	Off-white color "RAW" watermark	White color "cones" watermark

² Brand/sub-brand or other commercial name used in commercial distribution.

³ The predicate product is described on the invoices as ELEMENTS ULTRA RICE PAPER 1 ¼ BOX25 MP.

STN	SE0017689	Not Applicable
Product name	RAW PRE-ROLLED CONE 98 SPECIAL 20 PACK	TORPEDOES PRE ROLLED CONE PAPERS
Submission date	August 28, 2020	Not Applicable
Receipt date	August 28, 2020	Not Applicable
Product subcategory	Non-Filtered Cigarette Tube	Non-Filtered Cigarette Tube
Eligibility status	Not Applicable	Grandfathered
Package type	Cardboard Box	Plastic Container
Package quantity	20 Tubes	3 Tubes
Characterizing flavor	None	None
Length	98 mm	106 mm
Diameter	11.5 mm	20 mm
Additional property	Off-white color "RAW" watermark	White color "cones" watermark
STN	SE0017790	Not Applicable
Product name	RAW SW DF (DOUBLE FEED)	ELEMENTS SW
Submission date	Septemeber 2, 2020	Not Applicable
Receipt date	Septemeber 2, 2020	Not Applicable
Product subcategory	Rolling Paper	Rolling Paper
Eligibility status	Not Applicable	Grandfathered
Package type	Booklet	Booklet
Package quantity	100 Papers	100 Papers
Characterizing flavor	None	None
Length	70 mm	70 mm
Width	37 mm	37 mm
Additional property	Off-white color "RAW" watermark	White color "HBI" watermark

Appendix B
Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.