



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

April 20, 2020

**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):** SE0015653, see Appendix A

Dear Dr. Becker:

We completed our review of your SE Report<sup>1</sup> 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.

---

<sup>1</sup> 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](mailto:Cynthia.Colon@fda.hhs.gov).

Sincerely,

Digitally signed by Matthew R. Holman -

Date: 2020.04.20 13:18:25 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

**Enclosures:**

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

Appendix B – Health Information Summary

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

Common Attributes of SE Report		
<b>Date of Submission:</b>	January 22, 2020	
<b>Date of Receipt:</b>	January 22, 2020	
<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>	Rolling Paper	
	New Tobacco Product	Predicate Tobacco Product
	SE0015653: RAW CLASSIC ROLLS SINGLE WIDE <sup>2,3</sup>	N/A: ELEMENTS ROLLS ULTRA THIN SW <sup>2</sup>
<b>Package Type:</b>	Cardboard Holder/Box <sup>4</sup>	Plastic Holder/Box <sup>4</sup>
<b>Package Quantity:</b>	1 Roll	1 Roll
<b>Characterizing Flavor:</b>	None	None
<b>Eligibility Status:</b>	N/A	Grandfathered
<b>Length:</b>	5000 mm	5000 mm
<b>Width:</b>	37 mm	37 mm
<b>Additional Property:</b>	Watermark Design: "RAW"	Watermark Design: "HBI"

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

<sup>3</sup> Applicant refers to the new tobacco product as "RAW CLASSIC ROLLS SINGLE WIDE" and "RAW CLASSIC SINGLE WIDE ROLLS" interchangeably throughout the application.

<sup>4</sup> Applicant refers to package type as both "booklet" and "holder/box" interchangeably throughout submission. Images in the submission show packaging to be a holder/box.

**Appendix B**  
Health Information Summary

Your SE Report did not provide a summary of any health information related to the new tobacco product, required by section 910(a)(4) of the FD&C Act; however, your SE Report 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 Report 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 product, or the following statement if such statement is accurate: "BBK Tobacco & Foods LLP dba HBI International does not have or know of any research or data regarding any adverse health effects specifically related to Raw Classic Rolls Single Wide."

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: "BBK Tobacco & Foods LLP dba HBI International does not have or know of any research or data regarding any adverse health effects specifically related to Raw Classic Rolls Single Wide."

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.