



December 03, 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 Numbers (STNs):** Multiple STNs, see Appendix A

Dear Dr. Becker:

We completed our review of your SE Reports<sup>1</sup> and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A<sup>2</sup> 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.

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

<sup>2</sup> In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco product in SE0017543 to the grandfathered tobacco product in SE0015554. Although the new product has different characteristics than the grandfathered tobacco product in SE0015554, FDA found that those differences do not cause the new tobacco products to raise different questions of public health, and thus the new tobacco product is also substantially equivalent to the grandfathered product in SE0015554.

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 Todd L. Cecil -S

Date: 2020.12.03 13:45:24 -05'00'

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

<b>Common Attributes of SE Reports</b>		
Submission date	April 30, 2020 <sup>3</sup> or August 25, 2020 <sup>4</sup>	
Receipt date	April 30, 2020 <sup>3</sup> or August 25, 2020 <sup>4</sup>	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International	
Product category	Roll-Your-Own Tobacco Products	
Product subcategory	Paper Tip	
<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
<b>STN</b>	<b>SE0016550</b>	<b>N/A</b>
Product name	RAW ORGANIC HEMP CONNOISSEUR KSS (with tips) <sup>5</sup>	ELEMENTS KS SLIM with FILTER TIPS <sup>5</sup>
Eligibility status	Not applicable	Grandfathered
Package type	Book	Booklet
Package quantity	32 Tips	32 Tips
Characterizing flavor	None	None
Length	54 mm	54 mm
Width	19 mm	19 mm
Additional property	Tips only	The paper is off-white in color and has "ELEMENTS" watermark
<b>STN</b>	<b>SE0016572</b>	<b>N/A</b>
Product name	RAW ORGANIC HEMP ARTESANO KSS <sup>5</sup>	ELEMENTS KS SLIM with FILTER TIPS <sup>5</sup>
Eligibility status	Not applicable	Grandfathered
Package type	Book	Booklet
Package quantity	32 Tips	32 Tips
Characterizing flavor	None	None
Length	54 mm	54 mm
Width	19 mm	19 mm
Additional properties	5 perforations Tips only	The paper is off-white in color and has "ELEMENTS" watermark

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<sup>3</sup> SE0016550 and SE0016572

<sup>4</sup> SE0017543

<sup>5</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
<b>STN</b>	<b>SE0017543</b>	<b>SE0015554</b>
Product name	RAW PRE-ROLLED 100 TIP TIN <sup>5</sup>	ELEMENTS PRE-ROLLED TIPS <sup>5</sup>
Eligibility status	Not applicable	Previously Found SE
Package type	Tin	Tray Slider Box
Package quantity	100 Tips	21 Tips
Characterizing flavor	None	None
Length	58.5 mm	58.0 mm
Width	18 mm	18 mm
Additional properties	Beige Red "RAW" logo Perforations Pre-rolled	White Blue "ELEMENTS" logo Pre-rolled

## **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.