



June 22, 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): SE0015386

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 Todd L. Cecil -S
Date: 2021.06.22 08:38:26 -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

Appendix A
New and Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
Submission date	August 6, 2019	
Receipt date	August 6, 2019	
Product manufacturer	BBK Tobacco & Foods LLP dba HBI International and Blaugrana Corporation	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0015386	N/A
Product name	CYCLONES HONEY 2FER ²	CYCLONES HONEY ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Tube	Plastic Tube
Package quantity	2 Cones	1 Cone
Characterizing flavor	Honey	Honey
Length	79 mm	105 mm
Diameter 1^{3,4}	10 mm	10 mm
Diameter 2^{3,3}	15 mm	16 mm
Additional property	Plastic Taper, Wooden Stick	Plastic Taper, Wooden Stick

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

³ Applicant provided radius which allowed for a calculation of diameter

⁴ Applicant provided two measurements, one for the widest end of the cone, and the second for the tapered end where the paper tip is set.

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: “[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