U.S. FOOD & DRUG ADMINISTRATION

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

September 29, 2022

SUBSTANTIALLY EQUIVALENT

Fronto King LLC
Attention: Edmund Tucker, SR, Chief Executive Officer
22 Court Ave
Brockton, MA 02301

FDA Submission Tracking Number (STN): SE0023356.PD2**,** see Appendix A

Dear Edmund Tucker, SR:

We completed our review of your SE Report[1] 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 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 comply 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 Jill Grospierre, M.S., Regulatory Health Project Manager, at 301-796-1714 or Jill.Grospierre@fda.hhs.gov.

Sincerely,

Todd L. Cecil -S

Digitally signed by Todd L. Cecil -S
Date: 2022.09.29 11:21:47 -04'00'

Todd L. Cecil, Ph.D.
Acting 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[2]

New and Predicate Tobacco Products Subject of This Letter

Attributes of SE Report		
Submission date	September 9, 2020	
Receipt date	September 9, 2020	
Applicant	Fronto King LLC	
Product manufacturer	FK Global	
Product category	Cigars	
Product subcategory	Cigar Component	
Attributes	**New Product**	**Predicate Product**
STN	SE0023356.PD2	GF2012754
Product name	Fronto King Mini Leaf	Fronto King Original Whole Leaf
Eligibility status	Not applicable	Pre-Existing Tobacco Product
Package type	Foil Pouch	Foil Pouch
Package quantity	1 Wrapper	1 Wrapper
Characterizing flavor	None	None
Length[3]	416 millimeters (mm)	551 mm
Width[3]	188 mm	289 mm
Additional Properties[3]	Whole tobacco leaf; Mass: 6862 grams (g)	Whole tobacco leaf; Mass: 13,581 g

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

[3] Per the applicant, the new and predicate products consist of a single, whole tobacco leaf; as the tobacco leaf is an agricultural product, it naturally varies in size.

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.