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

November 19, 2019

SUBSTANTIALLY EQUIVALENT

KT&G Corporation
Attention: Michael Hinckle, Esquire
430 Davis Drive, Suite 400
Morrisville, NC 27560

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Mr. Hinckle:

We completed our review of your SE Reports[1] and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A. Under the provisions of sections 910 and 905(j) of the FD&C Act, you may continue to legally market 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 publicly available our finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

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,

Digitally signed by Matthew R. Holman -S
Date: 2019.11.19 07:46:50 -05'00'

Matthew R. Holman, Ph.D.
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

Common Attributes of SE Reports		
Date of Submission:	March 10, 2011	
Date of Receipt:	March 21, 2011	
Product Manufacturer:	KT&G Corporation	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product Specific Attributes	**Predicate Tobacco Product Specific Attributes**
Submission Tracking Number:	SE0003493	N/A
Product Name:[2]	Carnival Blue 100's Soft Pack	Carnival Lights 100's Soft Pack
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Length:	100 mm	100 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	20%	29%
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered [3]
	New Tobacco Product Specific Attributes	**Predicate Tobacco Product Specific Attributes**
Submission Tracking Number:	SE0003494	N/A
Product Name:[2]	Carnival Silver 100's Soft Pack	Carnival Ultra Lights 100's Soft Pack
Package Type:	Soft Pack	Soft Pack
Package Quantity:	20 Cigarettes	20 Cigarettes
Length:	100 mm	100 mm
Diameter:	7.8 mm	7.8 mm
Ventilation:	36%	47%
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Grandfathered [3]

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

[3] Based on the information provided, OCE determined that the subject tobacco product qualifies for Grandfathered Status and Predicate Eligibility.

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.