



May 24, 2021

SUBSTANTIALLY EQUIVALENT

Commonwealth Brands, Inc.
ATTENTION: Carole Folmar, J.D., Director of Regulatory & Scientific Affairs
714 Green Valley Road
Greensboro, NC 27408

FDA Submission Tracking Number (STN): SE0002733, see Appendix A

Dear Ms. Folmar:

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. Under the provisions of sections 910 and 905(j) of the FD&C Act, you may continue to legally market 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).

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. It is your responsibility under section 910(a)(4) to make your health information summary available upon request by any person.

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 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 Megan Nguyen, Regulatory Health Project Manager, at (301) 796 - 7826 or Megan.Nguyen@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.05.24 09:56:42 -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		
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0002733	N/A
Product name	Montclair Blue King Box ²	Montclair Full Flavor Kings Box ²
Eligibility status	Not applicable	Grandfathered
Package type	Box	Box
Package quantity	20 cigarettes	20 cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter ³	7.85 mm	7.85 mm
Ventilation	14%	12%

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

³ The applicant submitted the circumference which allowed for a calculation of diameter.

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.